



# Standards of Medical Care in Diabetes—2020 Abridged for Primary Care Providers

American Diabetes Association

The American Diabetes Association's (ADA's) *Standards of Medical Care in Diabetes* is updated and published annually in a supplement to the January issue of *Diabetes Care*. The Standards are developed by the ADA's multidisciplinary Professional Practice Committee, which comprises physicians, diabetes educators, and other expert diabetes health care professionals. The Standards include the most current evidence-based recommendations for diagnosing and treating adults and children with all forms of diabetes. ADA's grading system uses **A**, **B**, **C**, or **E** to show the evidence level that supports each recommendation.

- **A**—Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered
- **B**—Supportive evidence from well-conducted cohort studies
- **C**—Supportive evidence from poorly controlled or uncontrolled studies
- **E**—Expert consensus or clinical experience

This is an abridged version of the current Standards containing the evidence-based recommendations most pertinent to primary care. The recommendations, tables, and figures included here retain the same numbering used in the complete 2020 Standards and so are not numbered sequentially in this abridged version. All of the recommendations included here are substantively the same as in the complete Standards. The abridged version does not include references. The complete 2020 Standards of Care, including all supporting references, is available at [professional.diabetes.org/standards](http://professional.diabetes.org/standards).

## 1. IMPROVING CARE AND PROMOTING HEALTH IN POPULATIONS

### Diabetes and Population Health

Population health is defined as “the health outcomes of a group of individuals, including the distribution of health

outcomes within the group”; these outcomes can be measured in terms of health outcomes (mortality, morbidity, health, and functional status), disease burden (incidence and prevalence), and behavioral and metabolic factors (exercise, diet, A1C, etc.).

### Recommendations

- 1.1 Ensure treatment decisions are timely, rely on evidence-based guidelines, and are made collaboratively with patients based on individual preferences, prognoses, and comorbidities. **B**
- 1.2 Align approaches to diabetes management with the Chronic Care Model (CCM). This model emphasizes person-centered team care, integrated long-term treatment approaches to diabetes and comorbidities, and ongoing collaborative communication and goal setting between all team members. **A**
- 1.3 Care systems should facilitate team-based care and utilization of patient registries, decision support tools, and community involvement to meet patient needs. **B**
- 1.4 Assess diabetes health care maintenance using reliable and relevant data metrics to improve processes of care and health outcomes, with simultaneous emphasis on care costs. **B**

### Six Core Elements

The CCM includes six core elements to optimize the care of patients with chronic disease:

1. Delivery system design (moving from a *reactive* to a *proactive* care delivery system where planned visits are coordinated through a team-based approach)
2. Self-management support
3. Decision support (basing care on evidence-based, effective care guidelines)
4. Clinical information systems (using registries that can provide patient-specific and population-based support to the care team)

This is an abridged version of the American Diabetes Association's *Standards of Medical Care in Diabetes—2020*. *Diabetes Care* 2020;43(Suppl. 1):S1–S212. The complete 2020 Standards supplement, including all supporting references, is available at [professional.diabetes.org/standards](http://professional.diabetes.org/standards).

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5. Community resources and policies (identifying or developing resources to support healthy lifestyles)
6. Health systems (to create a quality-oriented culture)

A 5-year effectiveness study of the CCM in 53,436 primary care patients with type 2 diabetes suggested that the use of this model of care delivery reduced the cumulative incidence of diabetes-related complications and all-cause mortality. Patients who were enrolled in the CCM experienced a reduction in cardiovascular disease (CVD) risk by 56.6%, microvascular complications by 11.9%, and mortality by 66.1%. The same study suggested that health care utilization was lower in the CCM group, resulting in health care savings of \$7,294 per individual over the study period.

### *Strategies for System-Level Improvement*

1. Care teams
2. Telemedicine
3. Behaviors and well-being
4. Cost considerations
5. Access to care and quality improvement

## **Tailoring Treatment for Social Context**

### *Recommendations*

- 1.5 Providers should assess social context, including potential food insecurity, housing stability, and financial barriers, and apply that information to treatment decisions. **A**
- 1.6 Refer patients to local community resources when available. **B**
- 1.7 Provide patients with self-management support from lay health coaches, navigators, or community health workers when available. **A**

Health inequities related to diabetes and its complications are well documented and are heavily influenced by social determinants of health (SDoH). SDoH are defined as the economic, environmental, political, and social conditions in which people live and are responsible for a major part of health inequality worldwide. The ADA recognizes the association between social and environmental factors and the prevention and treatment of diabetes and has issued a call for research that seeks to better understand how these SDoH influence behaviors and how the relationships between these variables might be modified for the prevention and management of diabetes.

The complete 2020 Standards of Care include a discussion of assessment and treatment considerations in the context

of food insecurity, homelessness, seasonal agricultural work, and language barriers.

## **2. CLASSIFICATION AND DIAGNOSIS OF DIABETES**

### **Classification**

Diabetes can be classified into the following general categories:

1. Type 1 diabetes (due to autoimmune  $\beta$ -cell destruction, usually leading to absolute insulin deficiency)
2. Type 2 diabetes (due to a progressive loss of  $\beta$ -cell insulin secretion frequently on the background of insulin resistance)
3. Gestational diabetes mellitus (GDM; diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation)
4. Specific types of diabetes due to other causes, e.g., monogenic diabetes syndromes (such as neonatal diabetes and maturity-onset diabetes of the young), diseases of the exocrine pancreas (such as cystic fibrosis and pancreatitis), and drug- or chemical-induced diabetes (such as with glucocorticoid use, in the treatment of HIV/AIDS, or after organ transplantation)

It is important for providers to realize that classification of diabetes type is not always straightforward at presentation, and misdiagnosis may occur. The diagnosis may become more obvious over time and should be reevaluated if there is concern.

### **Screening and Diagnostic Tests for Prediabetes and Type 2 Diabetes**

The diagnostic criteria for diabetes and prediabetes are shown in Table 2.2/2.5.

### *Recommendations*

- 2.6 Screening for prediabetes and type 2 diabetes with an informal assessment of risk factors or validated tools should be considered in asymptomatic adults. **B**
- 2.7 Testing for prediabetes and/or type 2 diabetes in asymptomatic people should be considered in adults of any age with overweight or obesity ( $\text{BMI} \geq 25 \text{ kg/m}^2$  or  $\geq 23 \text{ kg/m}^2$  in Asian Americans) and who have one or more additional risk factors for diabetes (Table 2.3). **B**
- 2.8 Testing for prediabetes and/or type 2 diabetes should be considered in women planning pregnancy

with overweight or obesity and/or who have one or more additional risk factor for diabetes (Table 2.3). **C**

- 2.9 For all people, testing should begin at age 45 years. **B**
- 2.10 If tests are normal, repeat testing carried out at a minimum of 3-year intervals is reasonable. **C**
- 2.12 In patients with prediabetes and type 2 diabetes, identify and treat other CVD risk factors. **B**
- 2.13 Risk-based screening for prediabetes and/or type 2 diabetes should be considered after the onset of puberty or after 10 years of age, whichever occurs earlier, in children and adolescents with overweight (BMI  $\geq$ 85th percentile) or obesity (BMI  $\geq$ 95th percentile) and who have additional risk factors for diabetes. (See Table 2.4 for evidence grading of risk factors.)

Marked discrepancies between measured A1C and plasma glucose levels should prompt consideration that the A1C assay may not be reliable for that individual, and

one should consider using an assay without interference or plasma blood glucose criteria for diagnosis. (See “6. Glycemic Targets” in the complete 2020 Standards of Care for conditions causing discrepancies.) Unless there is a clear clinical diagnosis based on overt signs of hyperglycemia, diagnosis requires two abnormal test results from the same sample or in two separate test samples. If using two separate test samples, it is recommended that the second test, which may either be a repeat of the initial test or a different test, be performed without delay. If the patient has a test result near the margins of the diagnostic threshold, the provider should follow the patient closely and repeat the test in 3–6 months.

### 3. PREVENTION OR DELAY OF TYPE 2 DIABETES

#### Recommendation

- 3.1 At least annual monitoring for the development of type 2 diabetes in those with prediabetes is suggested. **E**

**TABLE 2.2/2.5** Criteria for the screening and diagnosis of prediabetes and diabetes

	Prediabetes	Diabetes
A1C	5.7–6.4% (39–47 mmol/mol)*	$\geq$ 6.5% (48 mmol/mol)†
Fasting plasma glucose	100–125 mg/dL (5.6–6.9 mmol/L)*	$\geq$ 126 mg/dL (7.0 mmol/L)†
Oral glucose tolerance test	140–199 mg/dL (7.8–11.0 mmol/L)*	$\geq$ 200 mg/dL (11.1 mmol/L)†
Random plasma glucose		$\geq$ 200 mg/dL (11.1 mmol/L)‡

Adapted from Tables 2.2 and 2.5 in the complete Standards of Care. \*For all three tests, risk is continuous, extending below the lower limit of the range and becoming disproportionately greater at the higher end of the range. †In the absence of unequivocal hyperglycemia, diagnosis requires two abnormal test results from the same sample or in two separate samples. ‡Only diagnostic in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis.

**TABLE 2.3** Criteria for testing for diabetes or prediabetes in asymptomatic adults

1. Testing should be considered in adults with overweight or obesity (BMI  $\geq$ 25 kg/m<sup>2</sup> or  $\geq$ 23 kg/m<sup>2</sup> in Asian Americans) who have one or more of the following risk factors:
  - First-degree relative with diabetes
  - High-risk race/ethnicity (e.g., African American, Latino, Native American, Asian American, Pacific Islander)
  - History of CVD
  - Hypertension ( $\geq$ 140/90 mmHg or on therapy for hypertension)
  - HDL cholesterol level  $<$ 35 mg/dL (0.90 mmol/L) and/or a triglyceride level  $>$ 250 mg/dL (2.82 mmol/L)
  - Women with polycystic ovary syndrome
  - Physical inactivity
  - Other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans)
2. Patients with prediabetes (A1C  $\geq$ 5.7% [39 mmol/mol], impaired glucose tolerance, or impaired fasting glucose) should be tested yearly.
3. Women who were diagnosed with GDM should have lifelong testing at least every 3 years.
4. For all other patients, testing should begin at age 45 years.
5. If results are normal, testing should be repeated at a minimum of 3-year intervals, with consideration of more frequent testing depending on initial results and risk status.

Screening for prediabetes and type 2 diabetes risk through an informal assessment of risk factors (Table 2.3) or with an assessment tool such as the ADA risk test ([diabetes.org/socrisktest](https://diabetes.org/socrisktest)) is recommended to guide providers on whether performing a diagnostic test for prediabetes and previously undiagnosed type 2 diabetes (Table 2.2/2.5) is appropriate. Those who are determined to be at high risk for type 2 diabetes, including people with an A1C of 5.7–6.4% (39–47 mmol/mol), impaired glucose tolerance, or impaired fasting glucose, are ideal candidates for diabetes prevention efforts.

## Lifestyle Interventions

### Recommendations

- 3.2 Refer patients with prediabetes to an intensive behavioral lifestyle intervention program modeled on the Diabetes Prevention Program (DPP) to achieve and maintain 7% loss of initial body weight and increase moderate-intensity physical activity (such as brisk walking) to at least 150 min/week. **A**
- 3.3 A variety of eating patterns are acceptable for persons with prediabetes. **B**
- 3.4 Based on patient preference, technology-assisted diabetes prevention interventions may be effective in preventing type 2 diabetes and should be considered. **B**
- 3.5 Given the cost-effectiveness of diabetes prevention, such intervention programs should be covered by third-party payers. **B**

The DPP trial demonstrated that an intensive lifestyle intervention could reduce the incidence of type 2 diabetes by 58% over 3 years. Follow-up of three large studies of lifestyle intervention for diabetes prevention has shown sustained reduction in the rate of conversion to type 2 diabetes: 39% reduction at 30 years in the Da Qing Diabetes Prevention Study, 43% reduction at 7 years in the Finnish Diabetes Prevention

Study, and 34% reduction at 10 years and 27% reduction at 15 years in the U.S. Diabetes Prevention Program Outcomes Study.

## Pharmacologic Interventions

### Recommendation

- 3.6 Metformin therapy for prevention of type 2 diabetes should be considered in those with prediabetes, especially for those with BMI  $\geq 35$  kg/m<sup>2</sup>, those aged <60 years, and women with prior GDM. **A**

Although no drugs have been approved by the U.S. Food and Drug Administration (FDA) for diabetes prevention, several have shown promise in research studies. Metformin has the strongest evidence base and demonstrated long-term safety as pharmacologic therapy for diabetes prevention. Cost, side effects, and durable efficacy require consideration when using other pharmacologic agents for diabetes prevention in those with prediabetes.

## Prevention of CVD

### Recommendation

- 3.8 Prediabetes is associated with heightened cardiovascular (CV) risk; therefore, screening for and treatment of modifiable risk factors for CVD are suggested. **B**

## Diabetes Self-Management Education and Support

### Recommendation

- 3.9 Diabetes self-management education and support (DSMES) programs may be appropriate venues for people with prediabetes to receive education and support to develop and maintain behaviors that can prevent or delay the development of type 2 diabetes. **B**

**TABLE 2.4** Risk-based screening for type 2 diabetes or prediabetes in asymptomatic children and adolescents in a clinical setting

Testing should be considered in youth\* with overweight ( $\geq 85$ th percentile) or obesity ( $\geq 95$ th percentile) **A** who have one or more additional risk factors based on the strength of their association with diabetes:

- Maternal history of diabetes or GDM during the child's gestation **A**
- Family history of type 2 diabetes in first- or second-degree relative **A**
- Race/ethnicity (Native American, African American, Latino, Asian American, Pacific Islander) **A**
- Signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, polycystic ovary syndrome, or small-for-gestational-age birth weight) **B**

\*After the onset of puberty or after 10 years of age, whichever occurs earlier. If tests are normal, repeat testing at a minimum of 3-year intervals, or more frequently if BMI is increasing, is recommended. Reports of type 2 diabetes before age 10 years exist, and this can be considered with numerous risk factors.

## 4. COMPREHENSIVE MEDICAL EVALUATION AND ASSESSMENT OF COMORBIDITIES

### Patient-Centered Collaborative Care

#### Recommendations

- 4.1 A patient-centered communication style that uses person-centered and strength-based language and active listening; elicits patient preferences and beliefs; and assesses literacy, numeracy, and potential barriers to care should be used to optimize patient health outcomes and health-related quality of life. **B**
- 4.2 Diabetes care should be managed by a multidisciplinary team that may draw from primary care physicians, subspecialty physicians, nurse practitioners, physician assistants, nurses, dietitians, exercise specialists, pharmacists, dentists, podiatrists, and mental health professionals. **E**

Individuals with diabetes must assume an active role in their care. The goals of treatment for diabetes are to prevent or delay complications and maintain

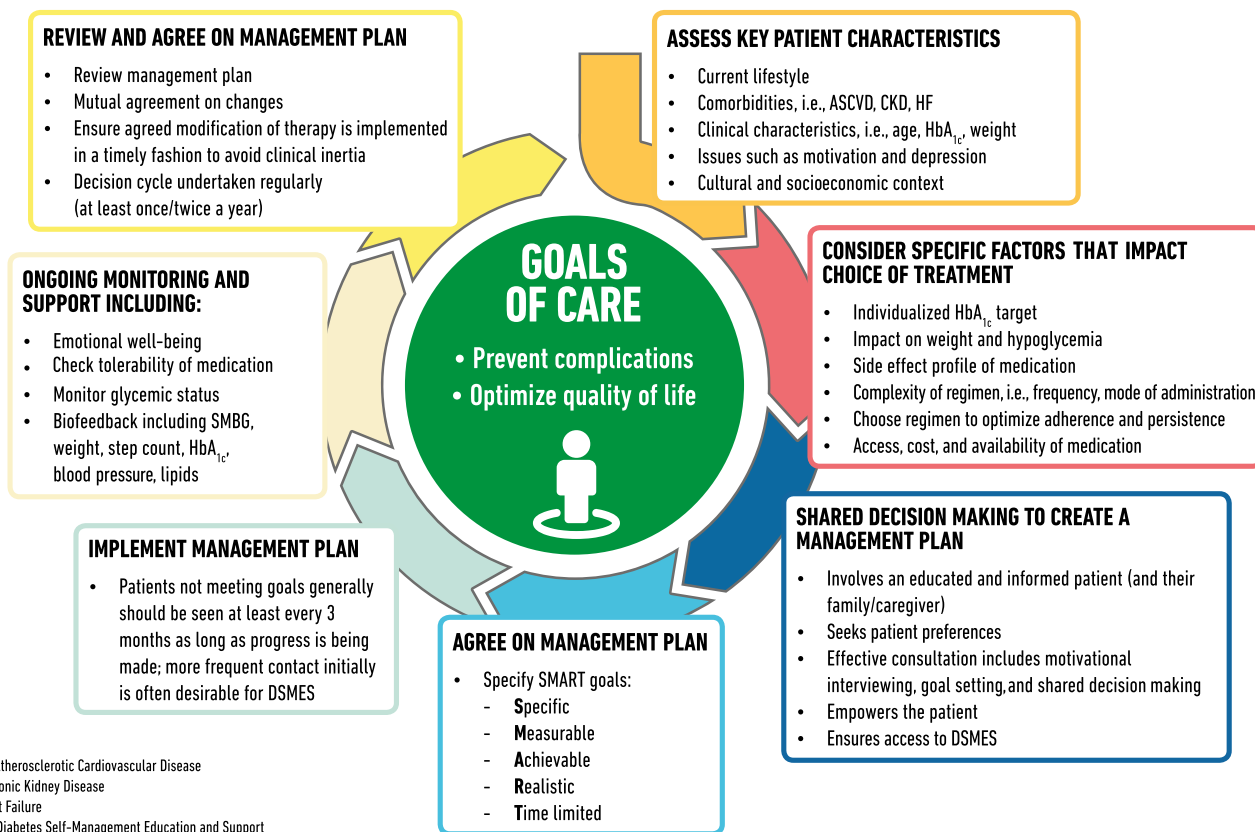
quality of life. Treatment goals and plans for meeting them should be created collaboratively with patients (Figure 4.1).

### Comprehensive Medical Evaluation

#### Recommendations

- 4.3 A complete medical evaluation should be performed at the initial visit to:
- Confirm the diagnosis and classify diabetes. **B**
  - Evaluate for diabetes complications and potential comorbid conditions. **B**
  - Review previous treatment and risk factor control in patients with established diabetes. **B**
  - Begin patient engagement in the formulation of a care management plan. **B**
  - Develop a plan for continuing care. **B**
- 4.4 A follow-up visit should include most components of the initial comprehensive medical evaluation, including interval medical history, assessment of medication-taking behavior and intolerance/side effects, physical examination, laboratory evaluation

## DECISION CYCLE FOR PATIENT-CENTERED GLYCEMIC MANAGEMENT IN TYPE 2 DIABETES



**FIGURE 4.1** Decision cycle for patient-centered glycemic management in type 2 diabetes. HbA<sub>1c</sub>, glycated hemoglobin. Reprinted from Davies MJ, D'Alessio DA, Fradkin J, et al. Diabetes Care 2018;41:2669–2701.



as appropriate to assess attainment of A1C and metabolic targets, and assessment of risk for complications, diabetes self-management behaviors, nutrition, psychosocial health, and the need for referrals, immunizations, or other routine health maintenance screening. **B**

- 4.5 Ongoing management should be guided by the assessment of diabetes complications and shared decision-making to set therapeutic goals. **B**
- 4.6 The 10-year risk of a first atherosclerotic cardiovascular disease (ASCVD) event should be assessed using the race- and sex-specific Pooled Cohort Equations to better stratify ASCVD risk. **B**

### Immunizations

Children and adults with diabetes should receive vaccinations according to age-specific recommendations. The Centers for Disease Control and Prevention provides vaccination schedules at [www.cdc.gov/vaccines/schedules](http://www.cdc.gov/vaccines/schedules).

### Assessment of Comorbidities

Besides assessing diabetes-related complications, clinicians and their patients need to be aware of common comorbidities that may complicate diabetes management.

### Autoimmune Diseases

#### Recommendations

- 4.12 Patients with type 1 diabetes should be screened for autoimmune thyroid disease soon after diagnosis and periodically thereafter. **B**
- 4.13 Adult patients with type 1 diabetes should be screened for celiac disease in the presence of gastrointestinal symptoms, signs, or laboratory manifestations suggestive of celiac disease. **B**

### Cancer

Patients with diabetes should be encouraged to undergo recommended age- and sex-appropriate cancer screenings and to reduce their modifiable cancer risk factors (obesity, physical inactivity, and smoking).

### Other Conditions

Nonalcoholic fatty liver disease, hepatitis C infection, pancreatitis, hearing impairment, HIV, cognitive impairment/dementia, hip fractures, low testosterone in men, obstructive sleep apnea, and periodontal disease are all more common in people with diabetes. See “4.

Comprehensive Medical Evaluation and Assessment of Comorbidities” in the complete 2020 Standards of Care for discussion on these topics.

## 5. FACILITATING BEHAVIOR CHANGE AND WELL-BEING TO IMPROVE HEALTH OUTCOMES

Effective behavior management and psychological well-being are foundational to achieving treatment goals for people with diabetes. Essential to achieving these goals are DSMES, medical nutrition therapy (MNT), routine physical activity, smoking cessation counseling when needed, and psychosocial care.

### DSMES

#### Recommendations

- 5.1 In accordance with the national standards for DSMES, all people with diabetes should participate in diabetes self-management education (DSME) and receive the support needed to facilitate the knowledge, decision-making, and skills mastery necessary for diabetes self-care. **A**
- 5.2 There are four critical times to evaluate the need for DSME to promote skills acquisition in support of regimen implementation, MNT, and well-being: at diagnosis, annually, when complicating factors arise, and when transitions in care occur. **E**
- 5.3 Clinical outcomes, health status, and well-being are key goals of DSMES that should be measured as part of routine care. **C**
- 5.4 DSMES should be patient centered, may be given in group or individual settings and/or use technology, and should be communicated with the entire diabetes care team. **A**

### Medical Nutrition Therapy

Evidence suggests that there is not an ideal percentage of calories from carbohydrate, protein, and fat for all people with diabetes. Therefore, macronutrient distribution should be based on an individualized assessment of current eating patterns, preferences, and metabolic goals. Consider personal preferences (e.g., tradition, culture, religion, health beliefs, and economics) as well as metabolic goals when working with individuals to determine the best eating pattern for them. An individualized eating pattern considers the individual's health status, skills, resources, food preferences, and health goals. Referral to a registered dietitian nutritionist (RD/RDN) is essential to assess the overall nutrition status of, and to work collaboratively with, the patient to create a personalized meal plan that coordinates and aligns with the overall treatment plan, including physical activity and medication use.

## Physical Activity

### Recommendations

- 5.24 Children and adolescents with type 1 or type 2 diabetes or prediabetes should engage in 60 min/day or more of moderate- or vigorous-intensity aerobic activity, with vigorous muscle-strengthening and bone-strengthening activities at least 3 days/week. **C**
- 5.25 Most adults with type 1 **C** and type 2 **B** diabetes should engage in 150 min or more of moderate- to vigorous-intensity aerobic activity per week, spread over at least 3 days/week, with no more than 2 consecutive days without activity. Shorter durations (minimum 75 min/week) of vigorous-intensity or interval training may be sufficient for younger and more physically fit individuals.
- 5.26 Adults with type 1 **C** and type 2 **B** diabetes should engage in 2–3 sessions/week of resistance exercise on nonconsecutive days.
- 5.27 All adults, and particularly those with type 2 diabetes, should decrease the amount of time spent in daily sedentary behavior. **B** Prolonged sitting should be interrupted every 30 min for blood glucose benefits. **C**
- 5.28 Flexibility training and balance training are recommended 2–3 times/week for older adults with diabetes. Yoga and tai chi may be included based on individual preferences to increase flexibility, muscular strength, and balance. **C**

The ADA position statement “Physical Activity/Exercise and Diabetes” offers specific recommendations and precautions related to type of diabetes, age, activity done, and presence of diabetes-related health complications including retinopathy, peripheral neuropathy, autonomic neuropathy, and diabetic kidney disease (DKD).

## Smoking Cessation: Tobacco and E-Cigarettes

### Recommendations

- 5.29 Advise all patients not to use cigarettes and other tobacco products **A** or e-cigarettes. **A**
- 5.30 After identification of tobacco or e-cigarette use, include smoking cessation counseling and other forms of treatment as a routine component of diabetes care. **A**

## Psychosocial Issues

### Recommendations

- 5.32 Psychosocial screening and follow-up may include, but are not limited to, attitudes about diabetes, expectations for medical management and outcomes, affect or mood, general and diabetes-related

quality of life, available resources (financial, social, and emotional), and psychiatric history. **E**

- 5.33 Providers should consider assessment for symptoms of diabetes distress, depression, anxiety, disordered eating, and cognitive capacities using appropriate standardized and validated tools at the initial visit, at periodic intervals, and when there is a change in disease, treatment, or life circumstance. Including caregivers and family members in this assessment is recommended. **B**
- 5.34 Consider screening older adults (aged  $\geq 65$  years) with diabetes for cognitive impairment and depression. **B**
- 5.36 Consider screening for anxiety in people exhibiting anxiety or worries regarding diabetes complications, insulin administration, and taking medications, as well as fear of hypoglycemia and/or hypoglycemia unawareness that interferes with self-management behaviors, and in those who express fear, dread, or irrational thoughts and/or show anxiety symptoms such as avoidance behaviors, excessive repetitive behaviors, or social withdrawal. Refer for treatment if anxiety is present. **B**
- 5.44 Annually screen people who are prescribed atypical antipsychotic medications for prediabetes or diabetes. **B**

Diabetes distress refers to significant negative psychological reactions to emotional burdens and worries specific to an individual’s experience in having to manage a severe, complicated, and demanding chronic disease such as diabetes. Validated tools are available to measure the level of distress and identify issues that care team members may address. The ADA position statement “Psychosocial Care for People With Diabetes” provides a list of assessment tools and additional details.

## 6. GLYCEMIC TARGETS

### Assessment of Glycemic Control

Glycemic management is primarily assessed with the A1C test, the primary measure studied in clinical trials demonstrating the benefits of improved glycemic control. Self-monitoring of blood glucose (SMBG) may help with self-management and medication adjustment, particularly in individuals taking insulin. Continuous glucose monitoring (CGM) also has an important role in assessing the effectiveness and safety of treatment in many patients with type 1 diabetes, and limited data suggest it may also be helpful in selected patients with type 2 diabetes, such as those on intensive insulin regimens.

## A1C Testing

### Recommendations

- 6.1 Perform the A1C test *at least* two times a year in patients who are meeting treatment goals (and who have stable glycemic control). **E**
- 6.2 Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals. **E**
- 6.3 Point-of-care testing for A1C provides the opportunity for more timely treatment changes. **E**

## Glucose Assessment

### Recommendations

- 6.4 Standardized, single-page glucose reports with visual cues such as the Ambulatory Glucose Profile (AGP) should be considered as a standard printout for all CGM devices. **E**
- 6.5 Time in range is associated with the risk of microvascular complications and should be an acceptable end point for clinical trials and can be used for assessment of glycemic control. Additionally, time below target (<70 and <54 mg/dL [3.9 and 3.0 mmol/L]) and time above target (>180 mg/dL [10.0 mmol/L]) are useful parameters for reevaluation of the treatment regimen. **E**

Glucose monitoring is key for the achievement of glycemic targets for many people with diabetes. SMBG is an integral component of effective therapy for patients taking

insulin. CGM has emerged as a complementary method for the assessment of glucose levels. The patient's specific needs and goals should dictate SMBG frequency and timing or the consideration of CGM use.

## Glucose Assessment Using CGM

CGM has evolved rapidly in both accuracy and affordability. To make CGM metrics more actionable, standardized reports with visual cues such as the AGP (Figure 6.1) are recommended and may help patients and providers interpret the data and use it to guide treatment decisions.

## A1C Goals

### Recommendations

- 6.6 An A1C goal for many nonpregnant adults of <7% (53 mmol/mol) is appropriate. **A**
- 6.7 On the basis of provider judgment and patient preference, achievement of lower A1C levels (such as <6.5%) may be acceptable if this can be achieved safely without significant hypoglycemia or other adverse effects of treatment. **C**
- 6.8 Less stringent A1C goals (such as <8% [64 mmol/mol]) may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions, or long-standing diabetes in whom the goal is difficult to achieve despite DSME, appropriate glucose

## AGP Report

### GLUCOSE STATISTICS AND TARGETS

**26 Feb 2019–10 Mar 2019**  
**% Time CGM is Active**

**13 days**  
**99.9%**

Glucose Ranges	Targets [% of Readings (Time/Day)]
Target Range 70–180 mg/dL .....	Greater than 70% (16h 48min)
Below 70 mg/dL .....	Less than 4% (58min)
Below 54 mg/dL .....	Less than 1% (14min)
Above 180 mg/dL .....	Less than 25% (6h)
Above 250 mg/dL .....	Less than 5% (1h 12min)

Each 5% increase in time in range (70–180 mg/dL) is clinically beneficial.

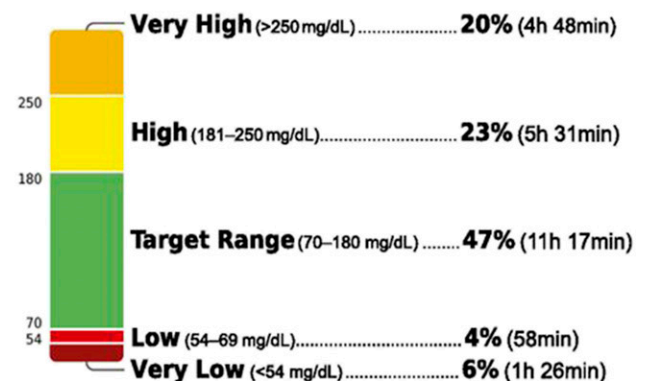
<b>Average Glucose</b>	<b>173 mg/dL</b>
<b>Glucose Management Indicator (GMI)</b>	<b>7.6%</b>
<b>Glucose Variability</b>	<b>49.5%</b>

Defined as percent coefficient of variation (%CV); target ≤36%

Name \_\_\_\_\_

MRN \_\_\_\_\_

### TIME IN RANGES



**FIGURE 6.1** Sample AGP report. Adapted from Battelino T, Danne T, Bergenstal RM, et al. Diabetes Care 2019;42:1593–1603.



**TABLE 6.3** Summary of glycemic recommendations for many nonpregnant adults with diabetes

A1C	<7.0% (53 mmol/mol)*
Preprandial capillary plasma glucose	80–130 mg/dL* (4.4–7.2 mmol/L)
Peak postprandial capillary plasma glucose†	<180 mg/dL* (10.0 mmol/L)

\*More or less stringent glycemic goals may be appropriate for individual patients. Goals should be individualized based on duration of diabetes, age/life expectancy, comorbid conditions, known CVD or advanced microvascular complications, hypoglycemia unawareness, and individual patient considerations. †Postprandial glucose may be targeted if A1C goals are not met despite reaching preprandial glucose goals. Postprandial glucose measurements should be made 1–2 h after the beginning of the meal, generally peak levels in patients with diabetes.

monitoring, and effective doses of multiple glucose-lowering agents including insulin. **B**

- 6.9 Reassess glycemic targets over time based on the criteria in Figure 6.2. **E**

See “6. Glycemic Targets,” “13. Children and Adolescents,” and “14. Management of Diabetes in Pregnancy” in the complete 2020 Standards of Care. Table 6.3 summarizes glycemic recommendations for many nonpregnant adults.

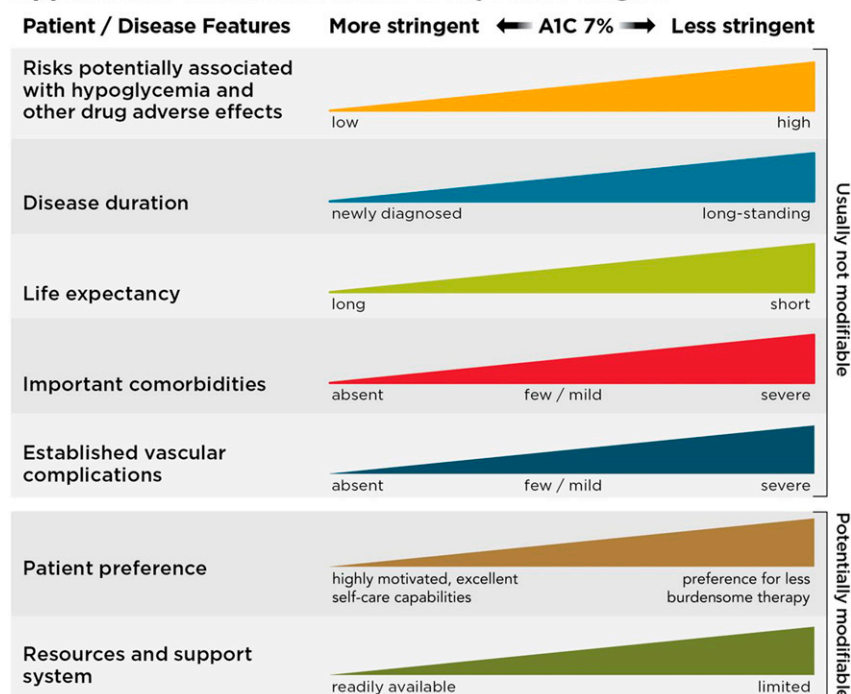
## Hypoglycemia

Table 6.4 summarizes the classification of hypoglycemia levels.

### Recommendations

- 6.10 Individuals at risk for hypoglycemia should be asked about symptomatic and asymptomatic hypoglycemia at each encounter. **C**
- 6.11 In patients taking medication that can lead to hypoglycemia, investigate, screen, and assess risk for or occurrence of unrecognized hypoglycemia, considering that patients may have hypoglycemia unawareness. **C**
- 6.12 Glucose (15–20 g) is the preferred treatment for the conscious individual with blood glucose <70 mg/dL [3.9 mmol/L]), although any form of carbohydrate that contains glucose may be used. Fifteen minutes after treatment, if SMBG shows continued hypoglycemia, the treatment should be repeated. Once SMBG returns to normal, the individual should consume a meal or snack to prevent recurrence of hypoglycemia. **B**
- 6.13 Glucagon should be prescribed for all individuals at increased risk of level 2 hypoglycemia, defined as blood glucose <54 mg/dL (3.0 mmol/L), so it

### Approach to Individualization of Glycemic Targets



**FIGURE 6.2** Depicted are patient and disease factors used to determine optimal A1C targets. Characteristics and predicaments toward the left justify more stringent efforts to lower A1C; those toward the right suggest less stringent efforts. A1C 7% = 53 mmol/mol. Adapted with permission from Inzucchi SE, Bergenstal RM, Buse JB, et al. Diabetes Care 2015;38:140–149.

is available should it be needed. Caregivers, school personnel, or family members of these individuals should know where it is and when and how to administer it. Glucagon administration is not limited to health care professionals, particularly with the availability of intranasal and stable soluble glucagon available in autoinjector pens. **E**

- 6.14 Hypoglycemia unawareness or one or more episodes of level 3 hypoglycemia should trigger hypoglycemia avoidance education and reevaluation of the treatment regimen. **E**
- 6.15 Insulin-treated patients with hypoglycemia unawareness, one level 3 hypoglycemic event, or a pattern of unexplained level 2 hypoglycemia should be advised to raise their glycemic targets to strictly avoid hypoglycemia for at least several weeks in order to partially reverse hypoglycemia unawareness and reduce risk of future episodes. **A**
- 6.16 Ongoing assessment of cognitive function is suggested with increased vigilance for hypoglycemia by the clinician, patient, and caregivers if low cognition or declining cognition is found. **B**

## 7. DIABETES TECHNOLOGY

Diabetes technology describes the devices, software, and hardware used to manage diabetes. It includes delivery systems such as insulin pumps, pens, and syringes as well as CGM devices and glucose meters. Newer forms of diabetes technology include hybrid devices that both deliver insulin and monitor glucose levels and software that provides diabetes self-management support. Increased patient interest has increased the use of diabetes technology in the primary care setting.

### Recommendation

- 7.1 Use of technology should be individualized based on a patient's needs, desires, skill level, and availability of devices. Nonprofit websites can offer advice for providers and patients to determine the suitability of various options. **E**

## SMBG

### Recommendations

- 7.2 Most patients using intensive insulin regimens (multiple daily injection [MDI] or continuous subcutaneous insulin infusion [CSII; insulin pump therapy]) should be encouraged to assess glucose levels using SMBG (and/or CGM) prior to meals and snacks, at bedtime, prior to exercise, when they

**TABLE 6.4** Classification of hypoglycemia

Glycemic criteria/description	
Level 1	Glucose <70 mg/dL (3.9 mmol/L) and $\geq$ 54 mg/dL (3.0 mmol/L)
Level 2	Glucose <54 mg/dL (3.0 mmol/L)
Level 3	A severe event characterized by altered mental and/or physical status requiring assistance for treatment of hypoglycemia

Reprinted from Agiostratidou G, Anhalt H, Ball D, et al. Diabetes Care 2017;40:1622–1630.

**TABLE 7.3** CGM devices

Real-time CGM	CGM systems that measure glucose levels continuously and provide the user automated alarms and alerts at specific glucose levels and/or for changing glucose levels.
Intermittently scanned CGM	CGM systems that measure glucose levels continuously but only display glucose values when swiped by a reader or a smart phone that reveals the glucose levels.
Blinded (professional) CGM	CGM devices that measure glucose levels that are not displayed to the patient in real time. These devices are generally initiated in a clinic, using a reader that is owned by the clinic. They are removed after a period of time (generally 10–14 days) and analyzed by the patient and provider to assess glycemic patterns and trends.
Unblinded CGM	CGM devices that measure glucose levels that are displayed to the patient.

suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to and while performing critical tasks such as driving. **B**

- 7.3 When prescribed as part of a DSMES program, SMBG may help to guide treatment decisions and/or self-management for patients taking less frequent insulin injections. **B**

## CGM

Table 7.3 defines the types of available CGM devices.

### Recommendations

- 7.11 When used properly, real-time and intermittently scanned CGM in conjunction with insulin therapy are useful tools to lower A1C and/or reduce hypoglycemia in adults with type 2 diabetes who are not meeting glycemic targets. **B**

The use of real-time CGM in adults with type 1 diabetes on either CSII or MDI is supported by data showing reduction

in both hypoglycemia and A1C. People with type 2 diabetes on CSII or MDI have shown significant reduction in A1C in multiple studies of real-time or intermittently scanned CGM but did not show a reduction in hypoglycemia.

## 8. OBESITY MANAGEMENT FOR THE TREATMENT OF TYPE 2 DIABETES

There is strong evidence that treating obesity can delay the progression from prediabetes to type 2 diabetes. It also has been shown to be beneficial in the treatment of type 2 diabetes. Modest and sustained weight loss has been shown to improve glycemic control and reduce the need for glucose-lowering medications. Clinical benefits can be seen with a minimum of 3–5% weight loss.

### Assessment

#### Recommendations

- 8.1 Measure height and weight and calculate BMI at annual visits or more frequently. **E**
- 8.2 Based on clinical considerations, such as the presence of comorbid heart failure (HF) or significant unexplained weight gain or loss, weight may need to be monitored and evaluated more frequently. **B** If deterioration of medical status is associated with significant weight gain or loss, inpatient evaluation should be considered, specifically focused on the association between medication use, food intake, and glycemic status. **E**
- 8.3 For patients with a high level of weight-related distress, special accommodations should be made to ensure privacy during weighing. **E**
- 8.7 As all energy-deficit food intake will result in weight loss, eating plans should be individualized to meet the patient's protein, fat, and carbohydrate needs while still promoting weight loss. **A**
- 8.8 Food availability should be queried, as well as other cultural circumstances that could affect dietary patterns. **C**
- 8.9 For patients who achieve short-term weight-loss goals, long-term ( $\geq 1$  year) weight maintenance programs are recommended when available. Such programs should at minimum provide monthly contact, as well as encourage ongoing monitoring of body weight (weekly or more frequently) and other self-monitoring strategies, including participation in high levels of physical activity (200–300 min/week). **A**
- 8.10 To achieve weight loss of  $>5\%$ , short-term (3-month) interventions that use very low-calorie diets ( $\leq 800$  kcal/day) and meal replacements may be prescribed for carefully selected patients by trained practitioners in medical care settings with close medical monitoring. To maintain weight loss, such programs must incorporate long-term comprehensive weight-maintenance counseling. **B**

### Diet, Physical Activity, and Behavioral Therapy

#### Recommendations

- 8.4 Diet, physical activity, and behavioral therapy designed to achieve and maintain  $\geq 5\%$  weight loss is recommended for patients with type 2 diabetes who have overweight or obesity and are ready to achieve weight loss. Greater benefits in control of diabetes and CV factors may be gained from even greater weight loss. **B**
- 8.5 Such interventions should be high intensity ( $\geq 16$  sessions in 6 months) and focus on dietary changes, physical activity, and behavioral strategies to achieve a 500–750 kcal/day energy deficit. **A**
- 8.6 Individual's motivation, life circumstances, and willingness to make lifestyle changes to achieve weight loss should be assessed along with medical status when weight loss interventions are undertaken. **C**
- 8.11 When choosing glucose-lowering medications for patients with type 2 diabetes and overweight or obesity, consider a medication's effect on weight. **B**
- 8.12 Whenever possible, minimize medications for comorbid conditions that are associated with weight gain. **E**
- 8.13 Weight-loss medications are effective as adjuncts to diet, physical activity, and behavioral counseling for selected patients with type 2 diabetes and  $\text{BMI} \geq 27 \text{ kg/m}^2$ . Potential benefits must be weighed against potential risks of medications. **A**
- 8.14 If a patient's response to weight-loss medications is  $<5\%$  weight loss after 3 months or if there are significant safety or tolerability issues at any time, the medication should be discontinued and alternative medications or treatment approaches should be considered. **A**

### Pharmacotherapy

#### Recommendations

- 8.11 When choosing glucose-lowering medications for patients with type 2 diabetes and overweight or obesity, consider a medication's effect on weight. **B**
- 8.12 Whenever possible, minimize medications for comorbid conditions that are associated with weight gain. **E**
- 8.13 Weight-loss medications are effective as adjuncts to diet, physical activity, and behavioral counseling for selected patients with type 2 diabetes and  $\text{BMI} \geq 27 \text{ kg/m}^2$ . Potential benefits must be weighed against potential risks of medications. **A**
- 8.14 If a patient's response to weight-loss medications is  $<5\%$  weight loss after 3 months or if there are significant safety or tolerability issues at any time, the medication should be discontinued and alternative medications or treatment approaches should be considered. **A**

The FDA has approved medications for both short- and long-term weight management along with diet, exercise, and behavioral therapy. Nearly all of these FDA-approved medications have been found to improve glycemic control in patients with type 2 diabetes and delay progression to type 2 diabetes in patients at risk. Table 8.2 in the complete 2020 Standards of Care provides a list of

FDA-approved medications for the treatment of obesity, along with their advantages and disadvantages. The efficacy and safety of these medications should be assessed at least monthly for the first 3 months.

## Metabolic Surgery

### Recommendations

- 8.15 Metabolic surgery should be recommended as an option to treat type 2 diabetes in screened surgical candidates with BMI  $\geq 40$  kg/m<sup>2</sup> (BMI  $\geq 37.5$  kg/m<sup>2</sup> in Asian Americans) and in adults with BMI 35.0–39.9 kg/m<sup>2</sup> (32.5–37.4 kg/m<sup>2</sup> in Asian Americans) who do not achieve durable weight loss and improvement in comorbidities (including hyperglycemia) with nonsurgical methods. **A**
- 8.16 Metabolic surgery may be considered as an option for adults with type 2 diabetes and BMI 30.0–34.9 kg/m<sup>2</sup> (27.5–32.4 kg/m<sup>2</sup> in Asian Americans) who do not achieve durable weight loss and improvement in comorbidities (including hyperglycemia) with tested efficacious nonsurgical methods. **A**
- 8.17 Metabolic surgery should be performed in high-volume centers with multidisciplinary teams knowledgeable about and experienced in the management of diabetes and gastrointestinal surgery. **E**
- 8.18 Long-term lifestyle support and routine monitoring of micronutrient and nutritional status must be provided to patients after surgery, according to guidelines for postoperative management of metabolic surgery by national and international professional societies. **C**
- 8.19 People being considered for metabolic surgery should be evaluated for comorbid psychological conditions and social and situational circumstances that have the potential to interfere with surgery outcomes. **B**
- 8.20 People who undergo metabolic surgery should routinely be evaluated to assess the need for ongoing mental health services to help with the adjustment to medical and psychosocial changes after surgery. **C**

## 9. PHARMACOLOGIC APPROACHES TO GLYCEMIC TREATMENT

### Pharmacologic Therapy for Type 1 Diabetes

#### Recommendations

- 9.1 Most people with type 1 diabetes should be treated with MDI of prandial and basal insulin or CSII. **A**

- 9.2 Most individuals with type 1 diabetes should use rapid-acting insulin analogs to reduce hypoglycemia risk. **A**
- 9.3 Patients with type 1 diabetes should be trained to match prandial insulin doses to carbohydrate intake, premeal blood glucose, and anticipated physical activity. **C**

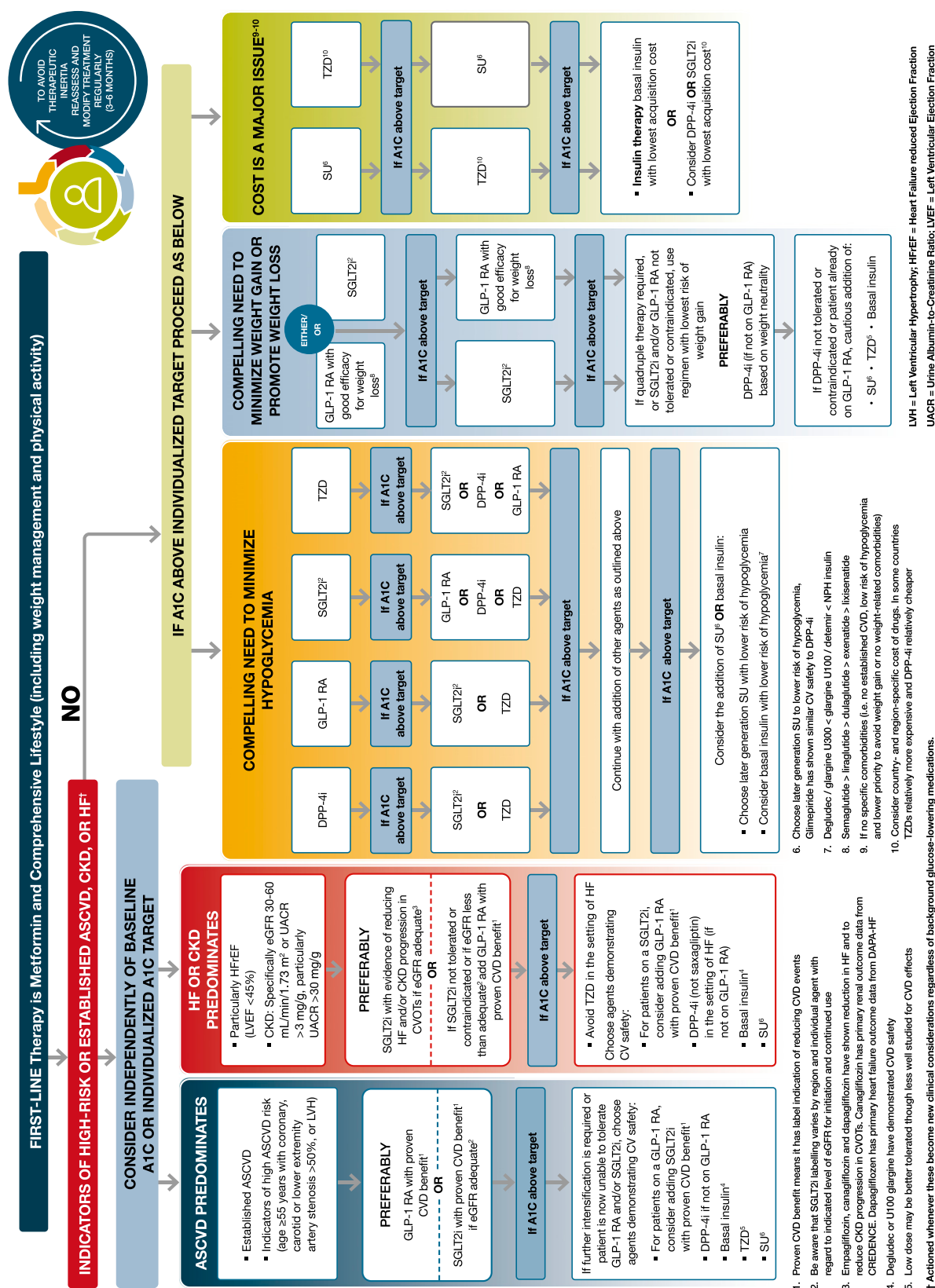
See “9. Pharmacologic Approaches to Glycemic Treatment” in the complete 2020 Standards of Care for more detailed information on pharmacologic approaches to type 1 diabetes management.

### Pharmacologic Therapy for Type 2 Diabetes

Figure 9.1, Figure 9.2, and Table 9.1 provide details for informed decision-making on pharmacologic agents for type 2 diabetes.

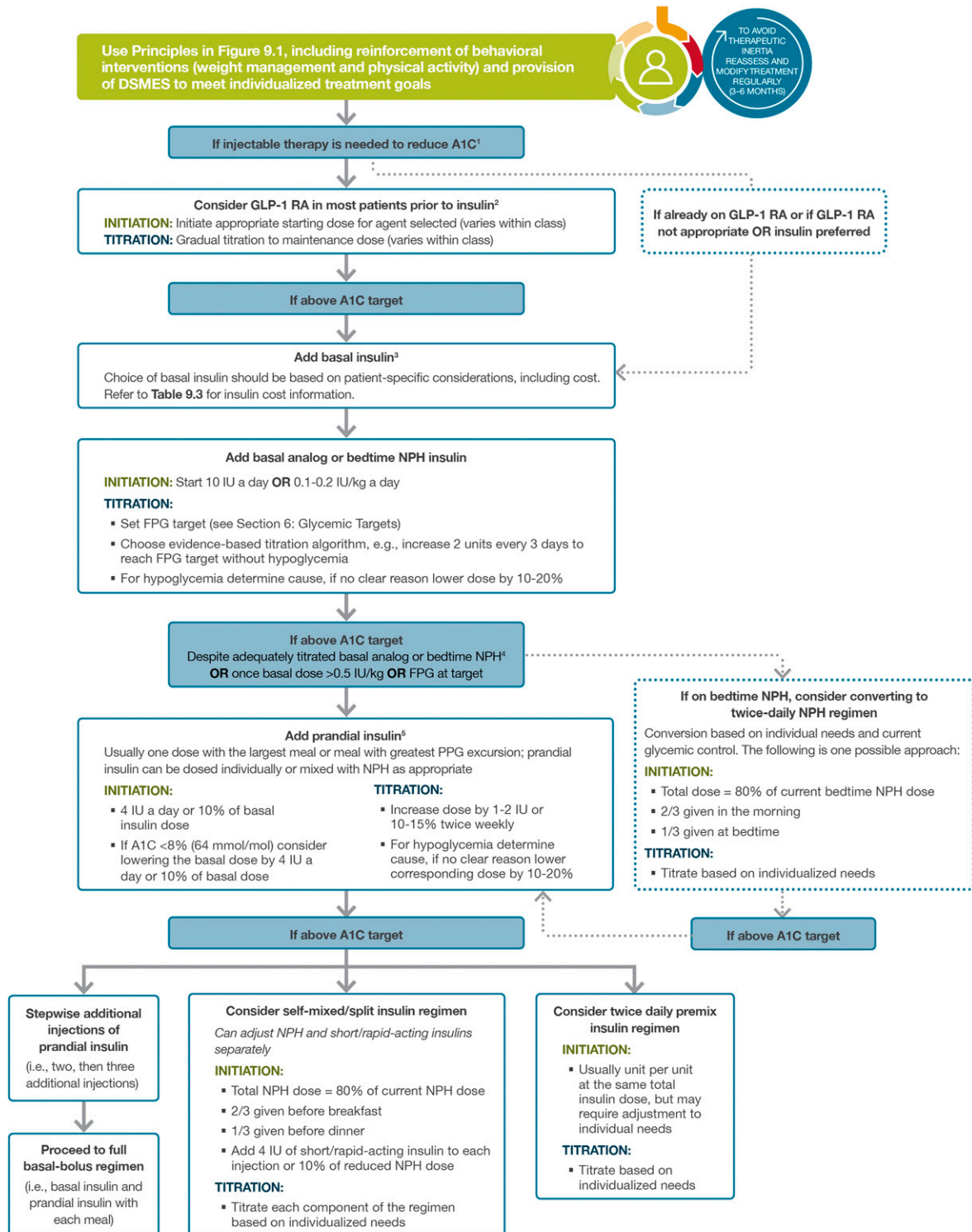
#### Recommendations

- 9.4 Metformin is the preferred initial pharmacologic agent for the treatment of type 2 diabetes. **A**
- 9.5 Once initiated, metformin should be continued as long as it is tolerated and not contraindicated; other agents, including insulin, should be added to metformin. **A**
- 9.6 Early combination therapy can be considered in some patients at treatment initiation to extend the time to treatment failure. **A**
- 9.7 The early introduction of insulin should be considered if there is evidence of ongoing catabolism (weight loss), if symptoms of hyperglycemia are present, or when A1C levels ( $>10\%$  [86 mmol/mol]) or blood glucose levels ( $\geq 300$  mg/dL [16.7 mmol/L]) are very high. **E**
- 9.8 A patient-centered approach should be used to guide the choice of pharmacologic agents. Considerations include CV comorbidities, hypoglycemia risk, impact on weight, cost, risk for side effects, and patient preferences (Figure 9.1). **E**
- 9.9 Among patients with type 2 diabetes who have established ASCVD or indicators of high-risk, established kidney disease, or HF, a sodium–glucose cotransporter 2 (SGLT2) inhibitor or glucagon-like peptide 1 (GLP-1) receptor agonist with demonstrated CVD benefit (Table 9.1) is recommended as part of the glucose-lowering regimen independent of A1C and in consideration of patient-specific factors (Figure 9.1). **A**
- 9.10 In patients with type 2 diabetes who need greater glucose lowering than can be obtained with oral agents, GLP-1 receptor agonists are preferred to insulin when possible. **B**



**FIGURE 9.1** Glucose-lowering medication in type 2 diabetes: overall approach. For appropriate context, see Figure 4.1. CREDENCE. Evaluation of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Participants With Diabetic Nephropathy. CVOTs, CV outcomes trials; DPP-4i, dipeptidyl peptidase 4 inhibitor; GLP-1 RA, GLP-1 receptor agonist; SGLT2i, SGLT2 inhibitor; SU, sulfonylurea; TZD, thiazolidinedione. Adapted from Davies MJ, D'Alessio DA, Fradkin J, et al. Diabetes Care 2018;41:2669–2701 and Buse JB, Wexler DJ, Tsapas A, et al. Diabetes Care 19 December 2019 [Epub ahead of print]. DOI: 10.2337/dci19-0066.





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

**FIGURE 9.2** Intensifying to injectable therapies. FPG, fasting plasma glucose; FRC, fixed-ratio combination; GLP-1 RA, GLP-1 receptor agonist; iDegLira, insulin degludec/liraglutide; iGlarLixi, insulin glargine/lixisenatide; max, maximum; PPG, postprandial glucose; Table 9.3 appears in the complete 2020 Standards of Care. Adapted from Davies MJ, D'Alessio DA, Fradkin J, et al. Diabetes Care 2018;41: 2669–2701.

**TABLE 9.1** Drug-specific and patient factors to consider when selecting antihyperglycemic treatment in adults with type 2 diabetes

	Efficacy	Hypoglycemia	Weight change	CV effects		Cost	Oral/SQ	Renal effects		Additional considerations
				ASCVD	HF			Progression of DKD	Dosing/use considerations*	
<b>Metformin</b>	High	No	Neutral (potential for modest loss)	Potential benefit	Neutral	Low	Oral	Neutral	<ul style="list-style-type: none"> <li>Contraindicated with eGFR &lt;30 mL/min/1.73 m<sup>2</sup></li> </ul>	<ul style="list-style-type: none"> <li>Gastrointestinal side effects common (diarrhea, nausea)</li> <li>Potential for B12 deficiency</li> </ul>
<b>SGLT-2 Inhibitors</b>	Intermediate	No	Loss	Benefit: empagliflozin <sup>†</sup> , canagliflozin	Benefit: empagliflozin <sup>†</sup> , canagliflozin, dapagliflozin <sup>‡</sup>	High	Oral	Benefit: canagliflozin <sup>§</sup> , empagliflozin, dapagliflozin	<ul style="list-style-type: none"> <li>Renal dose adjustment required (canagliflozin, dapagliflozin, empagliflozin, ertugliflozin)</li> </ul>	<ul style="list-style-type: none"> <li><b>FDA Black Box:</b> Risk of amputation (<b>canagliflozin</b>)</li> <li>Risk of bone fractures (canagliflozin)</li> <li>DKA risk (all agents, rare in T2DM)</li> <li>Genitourinary infections</li> <li>Risk of volume depletion, hypotension</li> <li>↑LDL cholesterol</li> <li>Risk of Fournier's gangrene</li> </ul>
<b>GLP-1 RAs</b>	High	No	Loss	Neutral: lixisenatide	Neutral	High	SQ; oral (semaglutide)	Benefit: lixisenatide	<ul style="list-style-type: none"> <li>Renal dose adjustment required (exenatide, lixisenatide)</li> <li>Caution when initiating or increasing dose due to potential risk of acute kidney injury</li> </ul>	<ul style="list-style-type: none"> <li><b>FDA Black Box:</b> Risk of thyroid C-cell tumors (<b>liraglutide, exenatide extended release</b>)</li> <li>Gastrointestinal side effects common (nausea, vomiting, diarrhea)</li> <li>Injection site reactions</li> <li>?Acute pancreatitis risk</li> </ul>
<b>DPP-4 Inhibitors</b>	Intermediate	No	Neutral	Neutral	Potential risk: saxagliptin	High	Oral	Neutral	<ul style="list-style-type: none"> <li>Renal dose adjustment required (saxagliptin, saxagliptin, alogliptin); can be used in renal impairment</li> <li>No dose adjustment required for linagliptin</li> </ul>	<ul style="list-style-type: none"> <li>Potential risk of acute pancreatitis</li> <li>Joint pain</li> </ul>
<b>Thiazolidinediones</b>	High	No	Gain	Potential benefit: pioglitazone	Increased risk	Low	Oral	Neutral	<ul style="list-style-type: none"> <li>No dose adjustment required</li> <li>Generally not recommended in renal impairment due to potential for fluid retention</li> </ul>	<ul style="list-style-type: none"> <li><b>FDA Black Box:</b> Congestive heart failure (<b>pioglitazone, rosiglitazone</b>)</li> <li>Fluid retention (edema); heart failure</li> <li>Benefit in NASH</li> <li>Risk of bone fractures</li> <li>Bladder cancer (pioglitazone)</li> <li>↑LDL cholesterol (rosiglitazone)</li> </ul>
<b>Sulfonylureas (2nd generation)</b>	High	Yes	Gain	Neutral	Neutral	Low	Oral	Neutral	<ul style="list-style-type: none"> <li>Glyburide: not recommended</li> <li>Glipizide and glimepiride: initiate conservatively to avoid hypoglycemia</li> </ul>	<ul style="list-style-type: none"> <li>FDA Special Warning on increased risk of cardiovascular mortality based on studies of an older sulfonylurea (tolbutamide)</li> </ul>
<b>Insulin</b>	Highest	Yes	Gain	Neutral	Neutral	Low	SQ; inhaled	Neutral	<ul style="list-style-type: none"> <li>Lower insulin doses required with a decrease in eGFR; titrate per clinical response</li> </ul>	<ul style="list-style-type: none"> <li>Injection site reactions</li> <li>Higher risk of hypoglycemia with human insulin (NPH or premixed formulations) vs. analogs</li> </ul>
<b>Analog</b>						High	SQ			

\*For agent-specific dosing recommendations, please refer to the manufacturers' prescribing information. <sup>†</sup>FDA-approved for CVD benefit. <sup>‡</sup>FDA-approved for HF indication. <sup>§</sup>FDA-approved for CKD indication. DPP-4, dipeptidyl peptidase 4; DKA, diabetic ketoacidosis; GLP-1 RAs, GLP-1 receptor agonists; NASH, nonalcoholic steatohepatitis; SQ, subcutaneous; T2DM, type 2 diabetes.

- 9.11 Intensification of treatment for patients with type 2 diabetes not meeting treatment goals should not be delayed. **B**
- 9.12 The medication regimen and medication-taking behavior should be reevaluated at regular intervals (every 3–6 months) and adjusted as needed to incorporate specific factors that impact choice of treatment (Figure 4.1 and Table 9.1). **E**

### CV Outcomes Trials

See “10. CVD and Risk Management” below for details.

## 10. CVD AND RISK MANAGEMENT

*This section has received endorsement from the American College of Cardiology.*

ASCVD—defined as coronary heart disease, cerebrovascular disease, or peripheral arterial disease (PAD) presumed to be of atherosclerotic origin—is the leading cause of morbidity and mortality for individuals with diabetes. HF is another major cause of morbidity and mortality from CVD. For prevention and management of both ASCVD and HF, CV risk factors should be systematically assessed at least annually in all patients with diabetes. These risk factors include obesity/overweight, hypertension, dyslipidemia, smoking, a family history of premature coronary disease, chronic kidney disease (CKD), and the presence of albuminuria.

### The Risk Calculator

The American College of Cardiology/American Heart Association ASCVD risk calculator (Risk Estimator Plus) is a useful tool to estimate 10-year ASCVD risk (<http://tools.acc.org/ASCVD-Risk-Estimator-Plus>). This calculator includes diabetes as a risk factor because diabetes itself confers increased risk for ASCVD. It should be acknowledged that this risk calculator does not account for duration of diabetes or the presence of diabetes complications such as albuminuria.

## Hypertension/Blood Pressure Control

### Screening and Diagnosis

#### Recommendations

- 10.1 Blood pressure should be measured at every routine clinical visit. Patients found to have elevated blood pressure ( $\geq 140/90$  mmHg) should have blood pressure confirmed using multiple readings, including measurements on a separate day, to diagnose hypertension. **B**
- 10.2 All hypertensive patients with diabetes should monitor their blood pressure at home. **B**

### Treatment Goals

#### Recommendations

- 10.3 For patients with diabetes and hypertension, blood pressure targets should be individualized through a shared decision-making process that addresses CV risk, potential adverse effects of antihypertensive medications, and patient preferences. **C**
- 10.4 For individuals with diabetes and hypertension at higher CV risk (existing ASCVD or 10-year ASCVD risk  $\geq 15\%$ ), a blood pressure target of  $<130/80$  mmHg may be appropriate, if it can be safely attained. **C**
- 10.5 For individuals with diabetes and hypertension at lower risk for CVD (10-year ASCVD risk  $<15\%$ ), treat to a blood pressure target of  $<140/90$  mmHg. **A**
- 10.6 In pregnant patients with diabetes and preexisting hypertension, a blood pressure target of  $\leq 135/85$  mmHg is suggested in the interest of reducing the risk for accelerated maternal hypertension **A** and minimizing impaired fetal growth. **E**

### Individualization of Treatment Targets

Patients and clinicians should engage in a shared decision-making process to determine individual blood pressure targets. Potential adverse effects of antihypertensive therapy (e.g., hypotension, syncope, falls, acute kidney injury, and electrolyte abnormalities) should also be taken into account. Patients with older age, CKD, and frailty have been shown to be at higher risk of adverse effects of intensive blood pressure control.

### Treatment Strategies

Figure 10.1 provides an algorithm for the treatment of confirmed hypertension in people with diabetes.

### Lifestyle Intervention

#### Recommendation

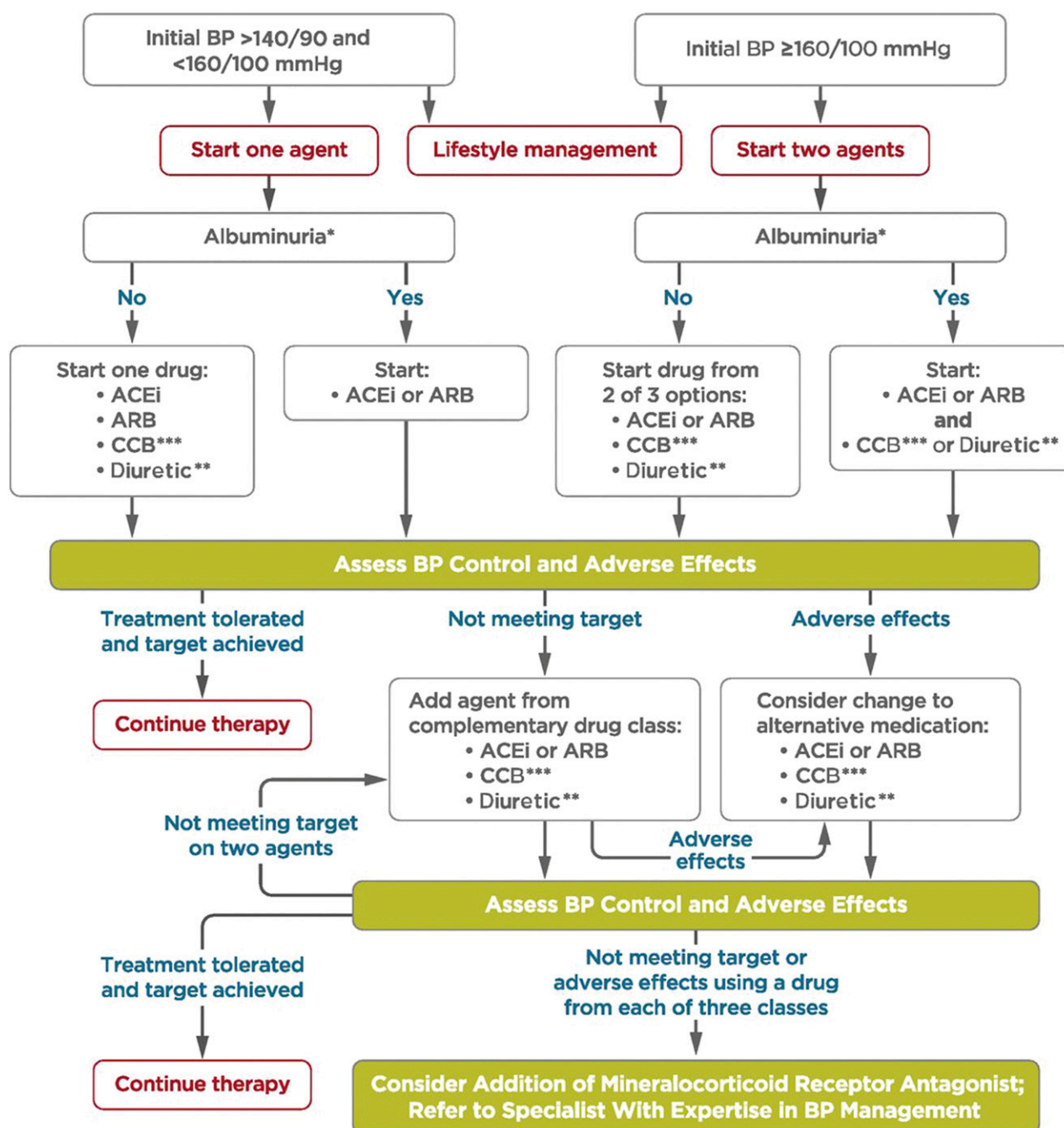
- 10.7 For patients with blood pressure  $>120/80$  mmHg, lifestyle intervention consists of weight loss if they have overweight or obesity, a Dietary Approaches to Stop Hypertension (DASH)-style eating pattern including reducing sodium and increasing potassium intake, moderation of alcohol intake, and increased physical activity. **A**

### Pharmacologic Interventions

#### Recommendations

- 10.8 Patients with confirmed office-based blood pressure  $\geq 140/90$  mmHg should, in addition to lifestyle therapy, have prompt initiation and timely

## Recommendations for the Treatment of Confirmed Hypertension in People With Diabetes



**FIGURE 10.1** Recommendations for the treatment of confirmed hypertension in people with diabetes. \*An ACE inhibitor (ACEi) or ARB is suggested to treat hypertension for patients with a UACR 30–299 mg/g Cr and strongly recommended for patients with a UACR  $\geq 300$  mg/g Cr. \*\*Thiazide-like diuretic; long-acting agents shown to reduce CV events, such as chlorthalidone and indapamide, are preferred. \*\*\*Dihydropyridine CCB. BP, blood pressure. Adapted from de Boer IH, Bangalore S, Benetos A, et al. Diabetes Care 2017;40:1273–1284.

titration of pharmacologic therapy to achieve blood pressure goals. [A](#)

10.9 Patients with confirmed office-based blood pressure  $\geq 160/100$  mmHg should, in addition to

lifestyle therapy, have prompt initiation and timely titration of two drugs or a single-pill combination of drugs demonstrated to reduce CV events in patients with diabetes. [A](#)



- 10.10 Treatment for hypertension should include drug classes demonstrated to reduce CV events in patients with diabetes (ACE inhibitors, angiotensin receptor blockers [ARBs], thiazide-like diuretics, or dihydropyridine calcium channel blockers [CCBs]). **A**
- 10.11 Multiple-drug therapy is generally required to achieve blood pressure targets. However, combinations of ACE inhibitors and ARBs and combinations of ACE inhibitors or ARBs with direct renin inhibitors should not be used. **A**
- 10.12 An ACE inhibitor or ARB, at the maximum tolerated dose indicated for blood pressure treatment, is the recommended first-line treatment for hypertension in patients with diabetes and urinary albumin-to-creatinine ratio (UACR)  $\geq 300$  mg/g creatinine (Cr) **A** or 30–299 mg/g Cr. **B** If one class is not tolerated, the other should be substituted. **B**
- 10.13 For patients treated with an ACE inhibitor, ARB, or diuretic, serum Cr/estimated glomerular filtration rate (eGFR) and serum potassium levels should be monitored at least annually. **B**

## Resistant Hypertension

### Recommendation

- 10.14 Patients with hypertension who are not meeting blood pressure targets on three classes of antihypertensive medications (including a diuretic) should be considered for mineralocorticoid receptor antagonist therapy. **B**

Prior to diagnosing resistant hypertension, a number of other conditions should be excluded, including medication nonadherence, white coat hypertension, and secondary hypertension. Mineralocorticoid receptor antagonists are effective for management of resistant hypertension in patients with type 2 diabetes when added to existing treatment with an ACE inhibitor or ARB, thiazide-like diuretic, or dihydropyridine CCB.

## Lipid Management

### Lifestyle Intervention

#### Recommendations

- 10.15 Lifestyle modification focusing on weight loss (if indicated); application of a Mediterranean-style or DASH eating pattern; reduction of saturated fat and *trans* fat; increase of dietary n-3 fatty acids, viscous fiber, and plant stanols/sterols intake; and increased

physical activity should be recommended to improve the lipid profile and reduce the risk of developing ASCVD in patients with diabetes. **A**

- 10.16 Intensify lifestyle therapy and optimize glycemic control for patients with elevated triglyceride levels ( $\geq 150$  mg/dL [1.7 mmol/L]) and/or low HDL cholesterol ( $< 40$  mg/dL [1.0 mmol/L] for men,  $< 50$  mg/dL [1.3 mmol/L] for women). **C**

## Ongoing Therapy and Monitoring With Lipid Panel

### Recommendations

- 10.17 In adults not taking statins or other lipid-lowering therapy, it is reasonable to obtain a lipid profile at the time of diabetes diagnosis, at an initial medical evaluation, and every 5 years thereafter if under the age of 40 years, or more frequently if indicated. **E**
- 10.18 Obtain a lipid profile at initiation of statins or other lipid-lowering therapy, 4–12 weeks after initiation or a change in dose, and annually thereafter as it may help to monitor the response to therapy and inform medication adherence. **E**

## Statin Treatment

### Recommendations

- 10.19 For patients with diabetes aged 40–75 years without ASCVD, use moderate-intensity statin therapy in addition to lifestyle therapy. **A**
- 10.20 For patients with diabetes aged 20–39 years with additional ASCVD risk factors, it may be reasonable to initiate statin therapy in addition to lifestyle therapy. **C**
- 10.21 In patients with diabetes at higher risk, especially those with multiple ASCVD risk factors or aged 50–70 years, it is reasonable to use high-intensity statin therapy. **B**
- 10.22 In adults with diabetes and 10-year ASCVD risk of 20% or higher, it may be reasonable to add ezetimibe to maximally tolerated statin therapy to reduce LDL cholesterol levels by 50% or more. **C**

## Secondary Prevention

- 10.23 For patients of all ages with diabetes and ASCVD, high-intensity statin therapy should be added to lifestyle therapy. **A**
- 10.24 For patients with diabetes and ASCVD considered very high risk using specific criteria, if LDL cholesterol is  $\geq 70$  mg/dL on maximally tolerated statin dose, consider adding additional LDL-lowering therapy (such as ezetimibe or PCSK9



inhibitor). **A** Ezetimibe may be preferred due to lower cost.

- 10.25 For patients who do not tolerate the intended intensity, the maximally tolerated statin dose should be used. **E**
- 10.26 In adults with diabetes aged >75 years already on statin therapy, it is reasonable to continue statin treatment. **B**
- 10.27 In adults with diabetes aged >75 years, it may be reasonable to initiate statin therapy after discussion of potential benefits and risks. **C**
- 10.28 Statin therapy is contraindicated in pregnancy. **B**

### *Treatment of Other Lipoprotein Fractions or Targets* *Recommendations*

- 10.29 For patients with fasting triglyceride levels  $\geq 500$  mg/dL, evaluate for secondary causes of hypertriglyceridemia and consider medical therapy to reduce the risk of pancreatitis. **C**
- 10.30 In adults with moderate hypertriglyceridemia (fasting or nonfasting triglycerides 175–499 mg/dL), clinicians should address and treat lifestyle factors (obesity and metabolic syndrome), secondary factors (diabetes, chronic liver or kidney disease and/or nephrotic syndrome, hypothyroidism), and medications that raise triglycerides. **C**
- 10.31 In patients with ASCVD or other CV risk factors on a statin with controlled LDL cholesterol but elevated triglycerides (135–499 mg/dL), the addition of icosapent ethyl can be considered to reduce CV risk. **A**

### *Other Combination Therapy* *Recommendations*

- 10.32 Statin plus fibrate combination therapy has not been shown to improve ASCVD outcomes and is generally not recommended. **A**
- 10.33 Statin plus niacin combination therapy has not been shown to provide additional CV benefit above statin therapy alone, may increase the risk of stroke with additional side effects, and is generally not recommended. **A**

### *Diabetes Risk With Statin Use*

Several studies have reported a modestly increased risk of incident diabetes with statin use, which may be limited to those with diabetes risk factors. A meta-analysis of 13 randomized statin trials showed an odds ratio of 1.09 for a new diagnosis of diabetes, so that (on average) treatment of 255 patients with statins for 4 years resulted in one

additional case of diabetes while simultaneously preventing 5.4 vascular events among those 255 patients.

### *Lipid-Lowering Agents and Cognitive Function*

A concern that statins or other lipid-lowering agents might cause cognitive dysfunction or dementia is not currently supported by evidence and should not deter their use in individuals with diabetes at high risk for ASCVD.

### **Antiplatelet Agents**

#### *Recommendations*

- 10.34 Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes and a history of ASCVD. **A**
- 10.35 For patients with ASCVD and documented aspirin allergy, clopidogrel (75 mg/day) should be used. **B**
- 10.36 Dual antiplatelet therapy (with low-dose aspirin and a P2Y<sub>12</sub> inhibitor) is reasonable for a year after an acute coronary syndrome **A** and may have benefits beyond this period. **B**
- 10.37 Aspirin therapy (75–162 mg/day) may be considered as a primary prevention strategy in those with diabetes who are at increased CV risk, after a comprehensive discussion with the patient on the benefits versus the comparable increased risk of bleeding. **A**

### *Risk Reduction*

Aspirin has been shown to be effective in reducing CV morbidity and mortality in high-risk patients with previous myocardial infarction or stroke (secondary prevention) and is strongly recommended. In primary prevention, however, among patients with no previous CV events, its net benefit is more controversial. Recommendations for using aspirin as primary prevention include both men and women aged  $\geq 50$  years with diabetes and at least one additional major risk factor (family history of premature ASCVD, hypertension, dyslipidemia, smoking, or CKD/albuminuria) who are not at increased risk of bleeding (e.g., older age, anemia, renal disease). The main adverse effect is an increased risk of gastrointestinal bleeding.

### **CVD**

#### *Recommendations*

##### **Screening**

- 10.38 In asymptomatic patients, routine screening for coronary artery disease is not recommended as it does not improve outcomes as long as ASCVD risk factors are treated. **A**

- 10.39 Consider investigations for coronary artery disease in the presence of any of the following: atypical cardiac symptoms (e.g., unexplained dyspnea, chest discomfort); signs or symptoms of associated vascular disease including carotid bruits, transient ischemic attack, stroke, claudication, or PAD; or electrocardiogram abnormalities (e.g., Q waves). **E**

### Treatment

- 10.40 In patients with known ASCVD, consider ACE inhibitor or ARB therapy to reduce the risk of CV events. **B**
- 10.41 In patients with prior myocardial infarction,  $\beta$ -blockers should be continued for at least 2 years after the event. **B**
- 10.42 In patients with type 2 diabetes with stable HF, metformin may be continued for glucose lowering if eGFR remains  $>30$  mL/min but should be avoided in unstable or hospitalized patients with HF. **B**
- 10.43 Among patients with type 2 diabetes who have established ASCVD or established kidney disease, an SGLT2 inhibitor or GLP-1 receptor agonist with demonstrated CVD benefit is recommended as part of the glucose-lowering regimen. **A**
- 10.43a In patients with type 2 diabetes and established ASCVD, multiple ASCVD risk factors, or DKD, an SGLT2 inhibitor with demonstrated CV benefit is recommended to reduce the risk of major adverse CV events and HF hospitalization. **A**
- 10.43b In patients with type 2 diabetes and established ASCVD or multiple risk factors for ASCVD, a GLP-1 receptor agonist with demonstrated CV benefit is recommended to reduce the risk of major adverse CV events. **A**
- 10.43c In patients with type 2 diabetes and established HF, an SGLT2 inhibitor may be considered to reduce risk of HF hospitalization. **C**

Numerous large, randomized controlled trials have reported statistically significant reductions in CV events for three of the FDA-approved SGLT2 inhibitors (empagliflozin, canagliflozin, and dapagliflozin) and four FDA-approved GLP-1 receptor agonists (liraglutide, albiglutide [although that agent was removed from the market for business reasons], semaglutide [lower risk of CV events in a moderate-sized clinical trial but one not powered as a CV outcomes trial], and dulaglutide). SGLT2 inhibitors also appear to reduce risk of HF hospitalization and progression of kidney disease in

patients with established ASCVD, multiple risk factors for ASCVD, or DKD.

## 11. MICROVASCULAR COMPLICATIONS AND FOOT CARE

### CKD

#### Recommendations

#### Screening

- 11.1 At least once a year, assess urinary albumin (e.g., spot UACR) and eGFR in patients with type 1 diabetes with duration of  $\geq 5$  years and in all patients with type 2 diabetes regardless of treatment. **B** Patients with urinary albumin  $>30$  mg/g Cr and/or an eGFR  $<60$  mL/min/1.73 m<sup>2</sup> should be monitored twice annually to guide therapy. **C**

#### Treatment

- 11.2 Optimize glucose control to reduce the risk or slow the progression of CKD. **A**
- 11.3 For patients with type 2 diabetes and DKD, consider use of an SGLT2 inhibitor in patients with an eGFR  $\geq 30$  mL/min/1.73 m<sup>2</sup> and urinary albumin  $>30$  mg/g Cr, particularly in those with urinary albumin  $>300$  mg/g Cr, to reduce risk of CKD progression, CV events, or both. **A** In patients with CKD who are at increased risk for CV events, use of a GLP-1 receptor agonist may reduce risk of progression of albuminuria, CV events, or both (Table 9.1). **C**
- 11.4 Optimize blood pressure control to reduce the risk or slow the progression of CKD. **A**
- 11.5 Do not discontinue renin-angiotensin system blockade for minor increases in serum Cr ( $<30\%$ ) in the absence of volume depletion. **B**
- 11.6 For people with nondialysis-dependent CKD, dietary protein intake should be approximately 0.8 g/kg body weight per day (the recommended daily allowance). **A** For patients on dialysis, higher levels of dietary protein intake should be considered, since malnutrition is a major problem in some dialysis patients. **B**
- 11.7 In nonpregnant patients with diabetes and hypertension, either an ACE inhibitor or an ARB is recommended for those with modestly elevated UACR (30–299 mg/g Cr) **B** and is strongly recommended for those with UACR  $\geq 300$  mg/g Cr and/or eGFR  $<60$  mL/min/1.73 m<sup>2</sup>. **A**
- 11.8 Periodically monitor serum Cr and potassium levels for the development of increased Cr or changes in

CKD is classified based on: • Cause (C) • GFR (G) • Albuminuria (A)				Albuminuria categories Description and range		
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				<30 mg/g <3 mg/mmol	30-299 mg/g 3-29 mg/mmol	≥300 mg/g ≥30 mg/mmol
GFR categories (mL/min/1.73 m <sup>2</sup> ) Description and range	G1	Normal or high	≥90	1 if CKD	Treat 1	Refer* 2
	G2	Mildly decreased	60-89	1 if CKD	Treat 1	Refer* 2
	G3a	Mildly to moderately decreased	45-59	Treat 1	Treat 2	Refer 3
	G3b	Moderately to severely decreased	30-44	Treat 2	Treat 3	Refer 3
	G4	Severely decreased	15-29	Refer* 3	Refer* 3	Refer 4+
	G5	Kidney failure	<15	Refer 4+	Refer 4+	Refer 4+

**FIGURE 11.1** Risk of CKD progression, frequency of visits, and referral to nephrology according to GFR and albuminuria. The GFR and albuminuria grid depicts the risk of progression, morbidity, and mortality by color, from best to worst (green, yellow, orange, red, dark red). The numbers in the boxes are a guide to the frequency of visits (number of times per year). Green can reflect CKD with normal eGFR and UACR only in the presence of other markers of kidney damage, such as imaging showing polycystic kidney disease or kidney biopsy abnormalities, with follow-up measurements annually; yellow requires caution and measurements at least once per year; orange requires measurements twice per year; red requires measurements three times per year; and dark red requires measurements four times per year. These are general

parameters only, based on expert opinion, and underlying comorbid conditions and disease state as well as the likelihood of impacting a change in management for any individual patient must be taken into account. "Refer" indicates that nephrology services are recommended. \*Referring clinicians may wish to discuss with their nephrology service, depending on local arrangements regarding treating or referring. Reprinted with permission from Vassalotti JA, Centor R, Turner BJ, Greer RC, Choi M, Sequist TD; National Kidney Foundation Kidney Disease Outcomes Quality Initiative. Am J Med 2016;129:153-162.e7.

potassium when ACE inhibitors, ARBs, or diuretics are used. **B**

- 11.9 An ACE inhibitor or ARB is not recommended for the primary prevention of CKD in patients with diabetes who have normal blood pressure, normal UACR (<30 mg/g Cr), and normal eGFR. **A**
- 11.10 Patients should be referred for evaluation by a nephrologist if they have an eGFR <30 mL/min/1.73 m<sup>2</sup>. **A**
- 11.11 Promptly refer to a physician experienced in the care of kidney disease for uncertainty about the etiology of kidney disease, difficult management issues, and rapidly progressing kidney disease. **A**

### Epidemiology and Staging of CKD

CKD is characterized by persistent albuminuria, low eGFR, and other manifestations of kidney damage (Figure 11.1). The degree of albuminuria is associated with CKD progression, CVD, and mortality. CKD among people with diabetes markedly increases CVD risk and health care costs.

### Selection of Glucose-Lowering Medications for People With CKD

Metformin is contraindicated for use in patients with an eGFR <30 mL/min/1.73 m<sup>2</sup>. Treatment

with metformin should be reassessed for patients with an eGFR <45 mL/min/1.73 m<sup>2</sup> and should be temporarily discontinued at the time of or before iodinated contrast imaging procedures in patients with eGFR 30–60 mL/min/1.73 m<sup>2</sup>. SGLT2 inhibitors and GLP-1 receptor agonists should be considered for patients with type 2 diabetes and CKD who require another drug added to metformin to attain target A1C or cannot use or tolerate metformin. Agents from these drug classes are suggested because they appear to reduce risks of CKD progression, CVD events, and hypoglycemia. Several large clinical trials have proven the effectiveness of both SGLT2 and GLP-1 receptor agonists in reducing the progression of albuminuria and the risk of developing or worsening nephropathy. A detailed summary of the clinical trials data can be found in "11. Microvascular Complications and Foot Care" in the complete 2020 Standards of Care.

Two clinical trials studied the combinations of ACE inhibitors and ARBs and found no benefits on CVD or CKD and a higher rate of adverse events (hyperkalemia and/or acute kidney injury) with the combination. Therefore, the combined use of an ACE inhibitor and an ARB should be avoided.

## Diabetic Retinopathy

### Recommendations

- 11.12 Optimize glycemic control to reduce the risk or slow the progression of diabetic retinopathy. **A**
- 11.13 Optimize blood pressure and serum lipid control to reduce the risk or slow the progression of diabetic retinopathy. **A**

### Screening

- 11.14 Adults with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 years after the onset of diabetes. **B**
- 11.15 Patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist at the time of the diabetes diagnosis. **B**
- 11.16 If there is no evidence of retinopathy for one or more annual eye exams and glycemia is well controlled, then screening every 1–2 years may be considered. If any level of diabetic retinopathy is present, subsequent dilated retinal examinations should be repeated at least annually by an ophthalmologist or optometrist. If retinopathy is progressing or sight-threatening, then examinations will be required more frequently. **B**
- 11.17 Programs that use retinal photography (with remote reading or use of a validated assessment tool) to improve access to diabetic retinopathy screening can be appropriate screening strategies for diabetic retinopathy. Such programs need to provide pathways for timely referral for a comprehensive eye examination when indicated. **B**
- 11.18 Women with preexisting type 1 or type 2 diabetes who are planning pregnancy or who are pregnant should be counseled on the risk of development and/or progression of diabetic retinopathy. **B**
- 11.19 Eye examinations should occur before pregnancy or in the first trimester in patients with preexisting type 1 or type 2 diabetes, and then patients should be monitored every trimester and for 1 year postpartum as indicated by the degree of retinopathy. **B**

### Treatment

- 11.20 Promptly refer patients with any level of macular edema, severe nonproliferative diabetic retinopathy (a precursor of proliferative diabetic retinopathy), or any proliferative diabetic retinopathy

to an ophthalmologist who is knowledgeable and experienced in the management of diabetic retinopathy. **A**

- 11.21 The traditional standard treatment, panretinal laser photocoagulation therapy, is indicated to reduce the risk of vision loss in patients with high-risk proliferative diabetic retinopathy and, in some cases, severe nonproliferative diabetic retinopathy. **A**
- 11.24 The presence of retinopathy is not a contraindication to aspirin therapy for cardioprotection, as aspirin does not increase the risk of retinal hemorrhage. **A**

## Neuropathy

### Recommendations

### Screening

- 11.25 All patients should be assessed for diabetic peripheral neuropathy starting at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes and at least annually thereafter. **B**
- 11.26 Assessment for distal symmetric polyneuropathy should include a careful history and assessment of either temperature or pinprick sensation (small fiber function) and vibration sensation using a 128-Hz tuning fork (for large-fiber function). All patients should have annual 10-g monofilament testing to identify feet at risk for ulceration and amputation. **B**
- 11.27 Symptoms and signs of autonomic neuropathy should be assessed in patients with microvascular complications. **E**

### Treatment

- 11.28 Optimize glucose control to prevent or delay the development of neuropathy in patients with type 1 diabetes **A** and to slow the progression of neuropathy in patients with type 2 diabetes. **B**
- 11.29 Assess and treat patients to reduce pain related to diabetic peripheral neuropathy **B** and symptoms of autonomic neuropathy and to improve quality of life. **E**

### Neuropathic Pain

Pregabalin and duloxetine have received regulatory approval by the FDA in treating diabetic neuropathic pain. Pregabalin is the most extensively studied drug for this purpose, and duloxetine has also shown efficacy.

Tapentadol, an opioid analgesic, also has FDA approval for use in the treatment of diabetic neuropathic pain, but is not recommended as a first- or second-line agent due to safety concerns surrounding the risk of addiction.

## Foot Care

### Recommendations

- 11.31 Perform a comprehensive foot evaluation at least annually to identify risk factors for ulcers and amputations. **B**
- 11.32 Patients with evidence of sensory loss or prior ulceration or amputation should have their feet inspected at every visit. **B**
- 11.33 Obtain a prior history of ulceration, amputation, Charcot foot, angioplasty or vascular surgery, cigarette smoking, retinopathy, and renal disease and assess current symptoms of neuropathy (pain, burning, numbness) and vascular disease (leg fatigue, claudication). **B**
- 11.34 The examination should include inspection of the skin, assessment of foot deformities, neurological assessment (10-g monofilament testing with at least one other assessment: pinprick, temperature, vibration), and vascular assessment including pulses in the legs and feet. **B**
- 11.35 Patients with symptoms of claudication or decreased or absent pedal pulses should be referred for ankle-brachial index and for further vascular assessment as appropriate. **C**
- 11.36 A multidisciplinary approach is recommended for individuals with foot ulcers and high-risk feet (e.g., dialysis patients and those with Charcot foot or prior ulcers or amputation). **B**
- 11.37 Refer patients who smoke or who have histories of prior lower-extremity complications, loss of protective sensation, structural abnormalities, or PAD to foot care specialists for ongoing preventive care and lifelong surveillance. **C**
- 11.38 Provide general preventive foot self-care education to all patients with diabetes. **B**
- 11.39 The use of specialized therapeutic footwear is recommended for high-risk patients with diabetes including those with severe neuropathy, foot deformities, ulcers, callous formation, poor peripheral circulation, or history of amputation. **B**

Foot ulcers and amputation, which are consequences of diabetic neuropathy and PAD, are common and represent major causes of morbidity and mortality in people with diabetes. Early recognition and treatment of patients with

diabetes and feet at risk for ulcers and amputations can delay or prevent adverse outcomes.

“11. Microvascular Complications and Foot Care” in the complete 2020 Standards of Care provides further details on appropriate screening.

## Treatment

People with neuropathy or evidence of increased plantar pressures (e.g., erythema, warmth, or calluses) may be adequately managed with well-fitted walking shoes or athletic shoes that cushion the feet and redistribute pressure. People with bony deformities (e.g., hammer-toes, prominent metatarsal heads, bunions) may need extra-wide or deep shoes, and some will require custom-molded shoes. Use of custom therapeutic footwear can help reduce the risk of future foot ulcers in high-risk patients.

## 12. OLDER ADULTS

### Recommendations

- 12.1 Consider the assessment of medical, psychological, functional (self-management abilities), and social geriatric domains in older adults to provide a framework to determine targets and therapeutic approaches for diabetes management. **B**
- 12.2 Screen for geriatric syndromes (i.e., polypharmacy, cognitive impairment, depression, urinary incontinence, falls, and persistent pain) in older adults as they may affect diabetes self-management and diminish quality of life. **B**

Diabetes is an important health condition for the aging population. Approximately one-quarter of people over the age of 65 years have diabetes and one-half of older adults have prediabetes. Older adults with diabetes have higher rates of premature death, functional disability, accelerated muscle loss, and coexisting illnesses, such as hypertension, coronary heart disease, and stroke, than those without diabetes. Screening for diabetes complications in older adults should be individualized and periodically revisited, as the results of screening tests may impact targets and therapeutic approaches. At the same time, older adults with diabetes also are at greater risk than other older adults for several common geriatric syndromes, such as polypharmacy, cognitive impairment, depression, urinary incontinence, injurious falls, and persistent pain. If left unaddressed, these conditions may affect the diabetes self-management abilities and quality of life of older adults with diabetes.



## Neurocognitive Function

### Recommendation

- 12.3 Screening for early detection of mild cognitive impairment or dementia should be performed for adults 65 years of age or older at the initial visit and annually as appropriate. **B**

## Hypoglycemia

### Recommendation

- 12.4 Hypoglycemia should be avoided in older adults with diabetes. It should be assessed and managed by adjusting glycemic targets and pharmacologic regimens. **B**

Older adults are at higher risk of hypoglycemia for many reasons, including insulin deficiency necessitating insulin therapy and progressive renal insufficiency. It is important to prevent hypoglycemia to reduce the risk of cognitive decline and other major adverse outcomes.

## Treatment Goals

### Recommendations

- 12.5 Older adults who are otherwise healthy with few coexisting chronic illnesses and intact cognitive function and functional status should have lower glycemic goals (such as A1C <7.5% [58 mmol/mol]), while those with multiple coexisting chronic illnesses, cognitive impairment, or functional dependence should have less stringent glycemic goals (such as A1C <8.0–8.5% [64–69 mmol/mol]). **C**
- 12.6 Glycemic goals for some older adults might reasonably be relaxed as part of individualized care, but hyperglycemia leading to symptoms or risk of acute hyperglycemia complications should be avoided in all patients. **C**
- 12.7 Screening for diabetes complications should be individualized in older adults. Particular attention should be paid to complications that would lead to functional impairment. **C**
- 12.8 Treatment of hypertension to individualized target levels is indicated in most older adults. **C**
- 12.9 Treatment of other CV risk factors should be individualized in older adults considering the time frame of benefit. Lipid-lowering therapy and aspirin therapy may benefit those with life expectancies at least equal to the time frame of primary prevention or secondary intervention trials. **E**

The care of older adults with diabetes is complicated by their clinical, cognitive, and functional heterogeneity. Providers caring for older adults with diabetes must take

this heterogeneity into consideration when setting and prioritizing treatment goals. For patients with complications and reduced functionality, it is reasonable to set less intensive glycemic goals. Patients with good cognitive and physical function may benefit from interventions and goals similar to those of younger adults.

Patients with type 1 diabetes are living longer, and the population of these patients >65 years of age is growing. This population has unique challenges and requires distinct treatment considerations. DSME and ongoing support are vital components of diabetes care for older adults and their caregivers.

Older adults with diabetes are likely to benefit from control of other CV risk factors, with treatment of hypertension to individualized target levels indicated in most. There is less evidence for lipid-lowering and aspirin therapy, although the benefits of these interventions are likely to apply to older adults whose life expectancies equal or exceed the time frames of clinical prevention trials.

## Lifestyle Management

### Recommendation

- 12.10 Optimal nutrition and protein intake is recommended for older adults; regular exercise, including aerobic activity and resistance training, should be encouraged in all older adults who can safely engage in such activities. **B**

## Pharmacologic Therapy

### Recommendations

- 12.11 In older adults with type 2 diabetes at increased risk of hypoglycemia, medication classes with low risk of hypoglycemia are preferred. **B**
- 12.12 Overtreatment of diabetes is common in older adults and should be avoided. **B**
- 12.13 Deintensification (or simplification) of complex regimens is recommended to reduce the risk of hypoglycemia and polypharmacy, if it can be achieved within the individualized A1C target. **B**
- 12.14 Consider costs of care and insurance coverage rules when developing treatment plans in order to reduce risk of cost-related nonadherence. **B**

Special care is required in prescribing and monitoring pharmacologic therapies in older adults. See Figure 9.1 for general recommendations regarding glucose-lowering treatment for adults with type 2 diabetes and Table 9.1 for patient- and drug-specific factors to

consider when selecting glucose-lowering agents. Metformin is the first-line agent for older adults with type 2 diabetes.

Tight glycemic control in older adults with multiple medical conditions is considered overtreatment and is associated with an increased risk of hypoglycemia; unfortunately, overtreatment is common in clinical practice. Deintensification of regimens in patients taking non-insulin glucose-lowering medications can be achieved by either lowering the dose or discontinuing some medications, so long as the individualized glycemic target is maintained. Simplification of insulin regimens may also be appropriate. The needs of older adults with diabetes and their caregivers should be evaluated to construct a tailored care plan.

## Treatment in Skilled Nursing Facilities and Nursing Homes

### Recommendations

- 12.15 Consider diabetes education for the staff of long-term care (LTC) and rehabilitation facilities to improve the management of older adults with diabetes. **E**
- 12.16 Patients with diabetes residing in long-term care facilities need careful assessment to establish individualized glycemic goals and to make appropriate choices of glucose-lowering agents based on their clinical and functional status. **E**

Management of diabetes is unique in the LTC setting. Practical guidance is needed for medical providers as well as LTC staff and caregivers. Treatments for each patient should be individualized. Special management considerations include the need to avoid both hypoglycemia and the complications of hyperglycemia. The ADA position statement “Management of Diabetes in Long-term Care and Skilled Nursing Facilities” provide more information on this topic.

## End-of-Life Care

### Recommendations

- 12.17 When palliative care is needed in older adults with diabetes, providers should initiate conversations regarding the goals and intensity of care. Strict glucose and blood pressure control may not be necessary **E**, and reduction of therapy may be appropriate. Similarly, the intensity of lipid management can be relaxed, and withdrawal of lipid-lowering therapy may be appropriate. **A**

Overall, palliative medicine promotes comfort, symptom control and prevention (pain, hypoglycemia, hyperglycemia, and dehydration), and preservation of dignity and quality of life in patients with limited life expectancy. Different patient categories have been proposed for diabetes management in those with advanced disease. These include stable patients, patients with organ failure, and dying patients.

## 13. CHILDREN AND ADOLESCENTS

The management of diabetes in children and adolescents cannot simply be derived from care routinely provided to adults with diabetes. The epidemiology, pathophysiology, developmental considerations, and response to therapy in pediatric-onset diabetes are different from adult diabetes.

### Type 1 Diabetes

Type 1 diabetes is the most common form of diabetes in youth. A multidisciplinary team of specialists trained in pediatric diabetes management and sensitive to the challenges of children and adolescents with type 1 diabetes and their families should provide care for this population.

See “13. Children and Adolescents” in the complete 2020 Standards of Care for specific recommendations. The ADA position statements “Type 1 Diabetes in Children and Adolescents” and “Evaluation and Management of Youth-Onset Type 2 Diabetes” offer additional information.

### Type 2 Diabetes

#### Management

#### Recommendations

#### Glycemic Targets

- 13.59 A reasonable A1C target for most children and adolescents with type 2 diabetes treated with oral agents alone is <7% (53 mmol/mol). More stringent A1C targets (such as <6.5% [48 mmol/mol]) may be appropriate for selected individual patients if they can be achieved without significant hypoglycemia or other adverse effects of treatment. Appropriate patients might include those with short duration of diabetes and lesser degrees of  $\beta$ -cell dysfunction and patients treated with lifestyle or metformin only who achieve significant weight improvement. **E**

## Pharmacologic Management

- 13.60 Less-stringent A1C goals (such as 7.5% [58 mmol/mol]) may be appropriate if there is increased risk of hypoglycemia. **E**
- 13.62 Initiate pharmacologic therapy, in addition to lifestyle therapy, at diagnosis of type 2 diabetes. **A**
- 13.63 In incidentally diagnosed or metabolically stable patients (A1C <8.5% [69 mmol/mol] and asymptomatic), metformin is the initial pharmacologic treatment of choice if renal function is normal. **A**
- 13.64 Youth with marked hyperglycemia (blood glucose  $\geq 250$  mg/dL [13.9 mmol/L], A1C  $\geq 8.5\%$  [69 mmol/mol]) without acidosis at diagnosis who are symptomatic with polyuria, polydipsia, nocturia, and/or weight loss should be treated initially with basal insulin while metformin is initiated and titrated. **B**
- 13.67 If glycemic targets are no longer met with metformin (with or without basal insulin), liraglutide (a GLP-1 receptor agonist) therapy should be considered in children 10 years of age or older if they have no past medical history or family history of medullary thyroid carcinoma or multiple endocrine neoplasia type 2. **A**
- 13.70 Use of medications not approved by the FDA for youth with type 2 diabetes is not recommended outside of research trials. **B**

## Transition From Pediatric to Adult Care

### Recommendation

- 13.107 Pediatric diabetes providers should begin to prepare youth for transition to adult health care in early adolescence and, at the latest, at least 1 year before the transition. **E**

“13. Children and Adolescents” in the complete 2020 Standards of Care describes the comprehensive treatment of children with type 2 diabetes.

## 14. MANAGEMENT OF DIABETES IN PREGNANCY

The prevalence of diabetes in pregnancy is increasing in the U.S. along with the epidemic in obesity seen worldwide. Type 1 and type 2 diabetes are increasing in women of reproductive age, and there also has been a dramatic increase in rates of GDM. Diabetes confers an increase maternal and fetal risk. Specific risks of diabetes in pregnancy include spontaneous abortion, fetal anomalies, preeclampsia, fetal demise, macrosomia, neonatal hypoglycemia, hyperbilirubinemia, and neonatal respiratory distress syndrome, among others. In addition, diabetes in pregnancy may increase the risk of

obesity, hypertension, and type 2 diabetes in offspring later in life.

## Preconception Counseling

### Recommendations

- 14.1 Starting at puberty and continuing in all women with diabetes and reproductive potential, preconception counseling should be incorporated into routine diabetes care. **A**
- 14.2 Family planning should be discussed, and effective contraception (with consideration of long-acting, reversible contraception) should be prescribed and used until a woman's treatment regimen and A1C are optimized for pregnancy. **A**
- 14.3 Preconception counseling should address the importance of achieving glucose levels as close to normal as is safely possible, ideally A1C <6.5% (48 mmol/mol), to reduce the risk of congenital anomalies, preeclampsia, macrosomia, and other complications. **B**

## Preconception Care

### Recommendations

- 14.4 Women with preexisting diabetes who are planning a pregnancy should ideally be managed beginning in preconception in a multidisciplinary clinic including an endocrinologist, maternal-fetal medicine specialist, dietitian, and diabetes educator, when available. **B**
- 14.5 In addition to focused attention on achieving glycemic targets **A**, standard preconception care should be augmented with extra focus on nutrition, diabetes education, and screening for diabetes comorbidities and complications. **E**
- 14.6 Women with preexisting type 1 or type 2 diabetes who are planning pregnancy or who have become pregnant should be counseled on the risk of development and/or progression of diabetic retinopathy. Dilated eye examinations should occur ideally before pregnancy or in the first trimester, and then patients should be monitored every trimester and for 1 year postpartum as indicated by the degree of retinopathy and as recommended by the eye care provider. **B**

Table 14.1 in the complete 2020 Standards of Care provides details on preconception care. Diabetes-specific testing should be performed such as A1C, Cr, and UACR. “14. Management of Diabetes in Pregnancy” in the complete 2020 Standards of Care provides details on the management of preexisting diabetes in pregnancy.

## Management of GDM

### Recommendations

- 14.13 Lifestyle behavior change is an essential component of management of GDM and may suffice for the treatment of many women. Insulin should be added if needed to achieve glycemic targets. **A**
- 14.14 Insulin is the preferred medication for treating hyperglycemia in GDM. Metformin and glyburide should not be used as first-line agents, as both cross the placenta to the fetus. **A** Other oral and noninsulin injectable glucose-lowering medications lack long-term safety data.
- 14.15 Metformin, when used to treat polycystic ovary syndrome and induce ovulation, should be discontinued by the end of the first trimester. **A**

Studies have shown that at least 70–85% of women with GDM can control it with lifestyle modification alone. The Dietary Reference Intake for all pregnant women recommends a minimum of 175 g carbohydrate, a minimum of 71 g protein, and 28 g fiber. The diet should not be high in saturated fat.

## Pregnancy and Drug Considerations

### Recommendations

- 14.19 In pregnant patients with diabetes and hypertension or significant proteinuria, a consistent blood pressure >135/85 mmHg should be treated in the interest of optimizing long-term maternal health. Blood pressure targets should range no lower than 120/80 mmHg, as lower blood pressure targets may impair fetal growth. **C**
- 14.20 Potentially harmful medications in pregnancy (i.e., ACE inhibitors, ARBs, statins) should be stopped at conception and avoided in sexually active women of childbearing age who are not using reliable contraception. **B**

## Postpartum Care

### Recommendations

- 14.21 Insulin resistance decreases dramatically immediately postpartum, and insulin requirements need to be evaluated and adjusted as they are often roughly half the prepregnancy requirements for the initial few days postpartum. **C**
- 14.22 A contraceptive plan should be discussed and implemented with all women with diabetes of reproductive potential. **C**

- 14.23 Screen women with a recent history of GDM at 4–12 weeks postpartum, using the 75-g oral glucose tolerance test and clinically appropriate nonpregnancy diagnostic criteria. **B**
- 14.24 Women with a history of GDM found to have prediabetes should receive intensive lifestyle interventions and/or metformin to prevent diabetes. **A**
- 14.25 Women with a history of GDM should have lifelong screening for the development of type 2 diabetes or prediabetes at least every 3 years. **B**
- 14.26 Women with a history of GDM should seek preconception screening for diabetes and preconception care to identify and treat hyperglycemia and prevent congenital malformations. **E**
- 14.27 Postpartum care should include psychosocial assessment and support for self-care. **E**

## 15. DIABETES CARE IN THE HOSPITAL

Among hospitalized patients, both hyperglycemia and hypoglycemia are associated with adverse outcomes, including death. Therefore, careful management of inpatients with diabetes has direct and immediate benefits. When caring for hospitalized patients with diabetes, consult with a specialized diabetes or glucose management team when possible.

### Hospital Care Delivery Standards

#### Recommendations

- 15.1 Perform an A1C on all patients with diabetes or hyperglycemia (blood glucose >140 mg/dL [7.8 mmol/L]) admitted to the hospital if not performed in the prior 3 months. **B**
- 15.2 Insulin should be administered using validated written or computerized protocols that allow for predefined adjustments in the insulin dosage based on glycemic fluctuations. **C**

#### Considerations on Admission

Initial orders should state the type of diabetes. Because inpatient treatment and discharge planning are more effective if based on preadmission glycemia, an A1C should be measured on all patients with diabetes or hyperglycemia.

### Glycemic Targets in Hospitalized Patients

#### Recommendations

- 15.4 Insulin therapy should be initiated for treatment of persistent hyperglycemia starting at a threshold  $\geq 180$  mg/dL (10.0 mmol/L). Once insulin therapy is started, a target glucose range of 140–180 mg/dL

(7.8–10.0 mmol/L) is recommended for the majority of critically ill patients and noncritically ill patients. **A**

- 15.5 More stringent goals, such as 110–140 mg/dL (6.1–7.8 mmol/L), may be appropriate for selected patients if they can be achieved without significant hypoglycemia. **C**

Hyperglycemia in hospitalized patients is defined as blood glucose levels >140 mg/dL (7.8 mmol/L). An admission A1C value  $\geq 6.5\%$  (48 mmol/mol) suggests that diabetes preceded hospitalization. Hypoglycemia in the hospital is classified the same as in any setting. (See “6. Glycemic Targets” above.)

### Bedside Blood Glucose Monitoring

In patients who are eating, glucose monitoring should be performed before meals; in those not eating, glucose monitoring is advised every 4–6 h. Testing every 30 min to every 2 h is required for intravenous insulin infusion.

Several inpatient studies have shown that CGM use did not improve glucose control but detected a greater number of hypoglycemic events than point-of-care glucose testing. However, there are insufficient data on clinical outcomes, safety, and cost-effectiveness to recommend using CGM in hospitalized patients.

### Glucose-Lowering Treatment in Hospitalized Patients

#### Recommendations

- 15.6 Basal insulin or a basal plus bolus correction insulin regimen is the preferred treatment for noncritically ill hospitalized patients with poor oral intake or those who are taking nothing by mouth. **A** An insulin regimen with basal, prandial, and correction components is the preferred treatment for noncritically ill hospitalized patients with good nutritional intake. **A**
- 15.7 Use of only a sliding scale insulin regimen in the inpatient hospital setting is strongly discouraged. **A**

In most instances in the hospital setting, insulin is the preferred treatment for glycemic control. In certain circumstances, it may be appropriate to continue home regimens including oral glucose-lowering medications. If oral medications are held in the hospital, there should be a protocol for resuming them 1–2 days before discharge.

#### Insulin Therapy

In the critical care setting, continuous intravenous insulin infusion is the best method for achieving glycemic targets. Outside of critical care units, scheduled insulin regimens as described above are recommended.

For patients who are eating, insulin injections should align with meals. In such instances, point-of-care glucose testing should be performed immediately before meals. An insulin regimen with basal and correction components is necessary for all hospitalized patients with type 1 diabetes, with the addition of prandial insulin if patients are eating. A transition protocol from insulin infusion to subcutaneous insulin is recommended.

#### Noninsulin Therapies

The safety and efficacy of noninsulin glucose-lowering therapies in the hospital setting is an area of active research. See “15. Diabetes Care in the Hospital” in the complete 2020 Standards of Care for a comprehensive review of the inpatient use of these medications.

### Hypoglycemia

#### Recommendations

- 15.8 A hypoglycemia management protocol should be adopted and implemented by each hospital or hospital system. A plan for preventing and treating hypoglycemia should be established for each patient. Episodes of hypoglycemia in the hospital should be documented in the medical record and tracked. **E**
- 15.9 The treatment regimen should be reviewed and changed as necessary to prevent further hypoglycemia when a blood glucose value of <70 mg/dL (3.9 mmol/L) is documented. **C**

Patients with or without diabetes may experience hypoglycemia in the hospital setting. While hypoglycemia is associated with increased mortality, it may be a marker of underlying disease rather than the cause of fatality. Recently, several groups have developed algorithms to predict episodes of hypoglycemia among inpatients. Models such as these are potentially important and, once validated for general use, could provide a valuable tool to reduce rates of hypoglycemia in hospitalized patients.

### MNT in the Hospital

The goals of MNT in the hospital are to provide adequate calories to meet metabolic demands, optimize glycemic control, and address personal food preferences, and facilitate creation of a discharge plan. The ADA does not endorse any single meal plan. When nutritional issues in the hospital are complex, the involvement of an RD/RDN can contribute to patient care.

### Self-Management in the Hospital

Diabetes self-management in the hospital may be appropriate for selected patients. Sufficient cognitive and



physical skills, adequate oral intake, proficiency in carbohydrate estimation, and knowledge of sick-day management are some of the requirements. Self-administered insulin with a stable MDI regimen or insulin pump therapy may be considered. A protocol should exist for these situations.

### Standards for Special Situations

See “15. Diabetes Care in the Hospital” in the complete 2020 Standards of Care for guidance on enteral/parenteral feedings, glucocorticoid therapy, perioperative care, and diabetic ketoacidosis and hyperosmolar hyperglycemic state.

### Transition From the Acute Care Setting

#### Recommendation

- 15.10 There should be a structured discharge plan tailored to the individual patient with diabetes. **B**

Transition from the acute care setting presents risk for all patients. A structured discharge plan may reduce length of hospital stay and readmission rates and increase patient satisfaction.

#### Medication Reconciliation

- The patient’s medications must be cross-checked to ensure that no chronic medications were stopped and to ensure the safety of new prescriptions.
- Prescriptions for new or changed medication should be filled and reviewed with the patient and family at or before discharge.

Discharge planning should begin at admission and be updated as patient needs change. An outpatient follow-up visit 1 month after discharge is recommended. An earlier appointment (in 1–2 weeks) is preferred, and frequent contact may be needed.

## 16. DIABETES ADVOCACY

For a list of ADA advocacy position statements, including “Diabetes and Driving” and “Diabetes and Employment,” see “16. Diabetes Advocacy” in the complete 2020 Standards of Care.

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