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Diabetes Care®

WWW.DIABETES.ORG/DIABETESCARE

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SUPPLEMENT
1

AMERICAN DIABETES ASSOCIATION

STANDARDS OF MEDICAL CARE IN DIABETES—2018

 American
Diabetes
Association.
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2019 Standards of Medical Care in Diabetes: What is New and Why

 American
Diabetes
Association®

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Disclosures

- Investigator Initiated Trial Support:
 - Merck: Sitaliptin impact on exercise capacity (T2D)
- Funding: NIH, VA
- Consultant:
 - Oramed
- Board of Directors
 - ADA

Standards of Care

- Funded out of the ADA's general revenues and *does not use* industry support.
- Slides correspond with sections within the Standards of Medical Care in Diabetes - 2018.
- Reviewed and approved by the Association's Board of Directors.

Process

- ADA's Professional Practice Committee (PPC) conducts annual review & revision.
- Searched Medline for human studies related to each subsection and published since January 1, 2017.
- Recommendations revised per new evidence, for clarity, or to better match text to strength of evidence.

[Professional.diabetes.org/SOC](https://professional.diabetes.org/SOC)

General Process Changes

- Standards will be ADA's sole source of Clinical Practice Recommendations
- The PPC will continue to update the Standards annually, but has the option to update more frequently online should the PPC determine that new evidence or regulatory changes merit immediate incorporation
- ADA will begin taking proposals from the community for statements, consensus reports, scientific reviews, and clinical/research conferences

[Professional.diabetes.org/SOC](https://professional.diabetes.org/SOC)

Evidence Grading System

A	• Clear evidence from well-conducted, generalizable RCTs, that are adequately powered, including: • Evidence from a well-conducted multicenter trial or meta-analysis that incorporated quality ratings in the analysis; • Compelling nonexperimental evidence; • Supportive evidence from well-conducted RCTs that are adequately powered
B	• Supportive evidence from a well-conducted cohort studies
	• Supportive evidence from a well-conducted case-control study
C	• Supportive evidence from poorly controlled or uncontrolled studies
	• Conflicting evidence with the weight of evidence supporting the recommendation
E	• Expert consensus or clinical experience

Hitting the highlights:

- New continuously updated SOC
- Open with pt centered care (population)
- Screening (DM and complications)
- Where is the Grade A evidence?
 - Pre-diabetes
 - Exercise
 - Nutrition
 - CV safety
- Controversies (pregnancy, blood pressure*)
- Mental health recognition AND tools
- Close with Pt centered care (individual)

1. Improving Care and Promoting Health in Populations

Care Delivery Systems

- 33-49% of patients still do not meet targets for A1C, blood pressure, or lipids.
- Only 14% of patients meet targets for all A1C, BP, lipids, and nonsmoking status.
- Progress in CVD risk factor control is slowing.
- Substantial system-level improvements are needed.
- Delivery system is fragmented, lacks clinical information capabilities, duplicates services & is poorly designed.

Diabetes is not a death sentence: *But it is usually for life*

\$1 in 4



30.3
Million

24/7/365



Chronic Care Model (CCM)

The CCM includes Six Core Elements to optimize the care of patients with chronic disease:

1. Delivery system design
2. Self-management support
3. Decision support
4. Clinical information systems
5. Community resources & policies
6. Health systems

Tailoring Treatment for Social Context

Key Recommendations:

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

Health Inequities

Social determinants of health are not always recognized and often go undiscussed in the clinical encounter

- Food Insecurity
- Homelessness
- Language Barriers
 - Non-English speaking/low literacy

Support Patient Self-Management

- Implement a systematic approach to support patient behavior change efforts, including:
 - High-quality diabetes self-management education and support (DSMES)
 - Clinical content & skills
 - Behavioral strategies (goal setting, problem solving, etc.)
 - Engagement with psychosocial concerns
 - Addressing barriers to medication taking

Screening: Awareness presents opportunity

TAKE THE DIABETES RISK TEST

Know your risk for type 2 diabetes. Share the test with everyone you know.

 American Diabetes Association.
ALERT!DAY

Support people



Raise voice



diabetes.org/risktest

ARE YOU AT RISK FOR

TYPE 2 DIABETES?



Diabetes Risk Test

- How old are you?**
Less than 40 years (0 points)
40–49 years (1 point)
50–59 years (2 points)
60 years or older (3 points)
- Are you a man or a woman?**
Man (1 point) Woman (0 points)
- If you are a woman, have you ever been diagnosed with gestational diabetes?**
Yes (1 point) No (0 points)
- Do you have a mother, father, sister, or brother with diabetes?**
Yes (1 point) No (0 points)
- Have you ever been diagnosed with high blood pressure?**
Yes (1 point) No (0 points)
- Are you physically active?**
Yes (0 points) No (1 point)
- What is your weight status?**
(see chart at right)

Write your score in the box.

Add up your score.

If you scored 5 or higher:
You are at increased risk for having type 2 diabetes. However, only your doctor can tell for sure if you do have type 2 diabetes or prediabetes (a condition that precedes type 2 diabetes in which blood glucose levels are higher than normal). Talk to your doctor to see if additional testing is needed.

Type 2 diabetes is more common in African Americans, Hispanics/Latinos, American Indians, and Asian Americans and Pacific Islanders.

Higher body weights increase diabetes risk for everyone. Asian Americans are at increased diabetes risk at lower body weights than the rest of the general public (about 15 pounds lower).

For more information, visit us at diabetes.org or call 1-800-DIABETES (1-800-342-2383)

Height	Weight (lbs.)		
4' 10"	119-142	143-190	191+
4' 11"	124-147	148-197	198+
5' 0"	128-152	153-203	204+
5' 1"	132-157	158-210	211+
5' 2"	136-163	164-217	218+
5' 3"	141-168	169-224	225+
5' 4"	145-173	174-231	232+
5' 5"	150-179	180-239	240+
5' 6"	155-185	186-246	247+
5' 7"	159-190	191-254	255+
5' 8"	164-196	197-261	262+
5' 9"	169-202	203-269	270+
5' 10"	174-208	209-277	278+
5' 11"	179-214	215-285	286+
6' 0"	184-220	221-293	294+
6' 1"	189-226	227-301	302+
6' 2"	194-232	233-310	311+
6' 3"	200-239	240-318	319+
6' 4"	205-245	246-327	328+

(1 Point) (2 Points) (3 Points)

You weigh less than the amount in the left column (0 points)

Adapted from Bang et al., Ann Intern Med 151:775-783, 2009.
Original algorithm was validated without gestational diabetes as part of the model.

Lower Your Risk

The good news is that you can manage your risk for type 2 diabetes. Small steps make a big difference and can help you live a longer, healthier life.

If you are at high risk, your first step is to see your doctor to see if additional testing is needed.

Visit diabetes.org or call 1-800-DIABETES (1-800-342-2383) for information, tips on getting started, and ideas for simple, small steps you can take to help lower your risk.



Visit us on Facebook
[Facebook.com/AmericanDiabetesAssociation](https://www.facebook.com/AmericanDiabetesAssociation)

A1C: New Recommendations

- To avoid misdiagnosis or missed diagnosis, the A1C test should be performed using a method that is certified by the NGSP and standardized to the Diabetes Control and Complications Trial (DCCT) assay. **B**
- Marked discordance between measured A1C and plasma glucose levels should raise the possibility of A1C assay interference due to hemoglobin variants (i.e., hemoglobinopathies) and consideration of using an assay without interference or plasma blood glucose criteria to diagnose diabetes. **B**
- In conditions associated with increased red blood cell turnover, such as sickle cell disease, pregnancy (second and third trimesters), hemodialysis, recent blood loss or transfusion, or erythropoietin therapy, only plasma blood glucose criteria should be used to diagnose diabetes. **B**

Prediabetes: Recommendations

- Screening for prediabetes and risk for future diabetes with an informal assessment of risk factors or validated tools should be considered in asymptomatic adults. **B**
- Testing for prediabetes and risk for future diabetes in asymptomatic people should be considered in adults of any age who are overweight or obese (BMI ≥ 25 kg/m² or ≥ 23 kg/m² in Asian Americans) and who have one or more risk factors for diabetes (**Table 2.3**). **B**
- For all people, testing should begin at age 45 years. **B**

Risk-Based Screening in Asymptomatic Children and Adolescents

Table 2.5—Risk-based screening for type 2 diabetes or prediabetes in asymptomatic children and adolescents in a clinical setting*

Criteria

- Overweight (BMI >85th percentile for age and sex, weight for height >85th percentile, or weight >120% of ideal for height) **A**

Plus one or more additional risk factors based on the strength of their association with diabetes as indicated by evidence grades:

- 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**
-

*Persons aged <18 years.

Type 2 Diabetes: Recommendations

- Screening for type 2 diabetes with an informal assessment of risk factors or validated tools should be considered in asymptomatic adults. **B**
- Testing for type 2 diabetes in asymptomatic people should be considered in adults of any age who are overweight or obese ($\text{BMI} \geq 25 \text{ kg/m}^2$ or $\geq 23 \text{ kg/m}^2$ in Asian Americans) and who have 1 or more additional risk factors for diabetes (**Table 2.3**). **B**
- **For all patients, testing should begin at age 45 years.** **B**
- If tests are normal, repeat testing carried out at a minimum of 3-year intervals is reasonable. **C**

Monogenic Diabetes Syndromes: Recommendations

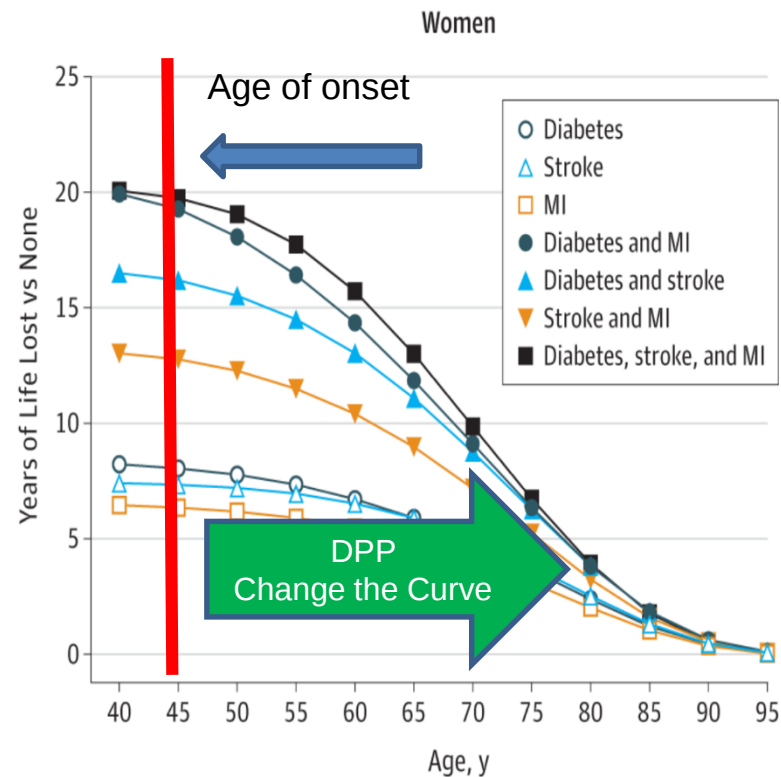
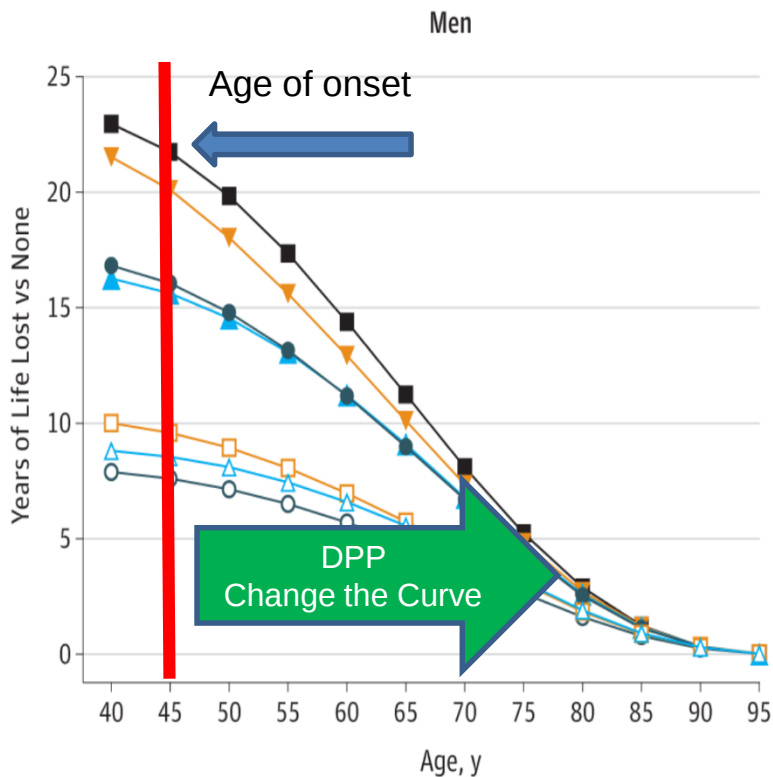
- All children diagnosed with diabetes in the first 6 months of life should have immediate genetic testing for neonatal diabetes. **A**
- Children and adults, diagnosed in early adulthood, who have diabetes not characteristic of T1DM or T2DM that occurs in successive generations (suggestive of an autosomal dominant pattern of inheritance) should have genetic testing for MODY. **A**
- In both instances, consultation with a center specializing in diabetes genetics is recommended to understand the significance of these mutations and how best to approach further evaluation, treatment, and genetic counseling. **E**

Patient-Centered Collaborative Care

- A patient-centered communication style that uses person-centered and strength-based language, 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**

Medical Evaluation: Diabetes Shortens Life Span

Screening and complication prevention



Comprehensive Medical Evaluation

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. **E**
- Review previous treatment & risk factor control in patients with established diabetes. **E**
- Begin patient engagement in the formulation of a care management plan. **B**
- Develop a plan for continuing care. **B**

Referrals for Initial Care Management

- | |
|--|
| • Eye care professional for annual dilated eye exam |
| • Family planning for women of reproductive age |
| • Registered dietitian for MNT |
| • DSMES |
| • Dentist for comprehensive dental and periodontal examination |
| • Mental health professional, if indicated |

Cognitive Impairment/Dementia: Recommendation

- In people with a history of cognitive impairment/dementia, intensive glucose control cannot be expected to remediate deficits. Treatment should be tailored to avoid significant hypoglycemia. **B**

Anxiety Disorders: Recommendations

- Consider screening for anxiety in people exhibiting anxiety or worries regarding diabetes complications, insulin injections or infusion, taking medications, and/or hypoglycemia that interfere with self-management behaviors and 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**
- People with hypoglycemic unawareness, which can co-occur with fear of hypoglycemia, should be treated using blood glucose awareness training (or other evidence-based intervention) to help reestablish awareness of hypoglycemia and reduce fear of hypoglycemia. **A**

Depression: Recommendations

- Providers should consider annual screening of all patients with diabetes, especially those with a self-reported history of depression, for depressive symptoms with age-appropriate depression screening measures, recognizing that further evaluation will be necessary for individuals who have a positive screen. **B**
- Beginning at diagnosis of complications or when there are significant changes in medical status, consider assessment for depression. **B**

Depression: Recommendations

- Referrals for treatment of depression should be made to mental health providers with experience using cognitive behavioral therapy, interpersonal therapy, or other evidence-based treatment approaches in conjunction with collaborative care with the patient's diabetes treatment team. **A**

Disordered Eating Behavior: Recommendations

- Providers should consider reevaluating the treatment regimen of people with diabetes who present with symptoms of disordered eating behavior, an eating disorder, or disrupted patterns of eating. **B**
- Consider screening for disordered or disrupted eating using validated screening measures when hyperglycemia and weight loss are unexplained based on self-reported behaviors related to medication dosing, meal plan, and physical activity. In addition, a review of the medical regimen is recommended to identify potential treatment-related effects on hunger/caloric intake. **B**

Serious Mental Illness

- Annually screen people who are prescribed atypical antipsychotic medications for prediabetes or diabetes. **B**
- If a second-generation antipsychotic medication is prescribed for adolescents or adults with diabetes, changes in weight, glycemic control, and cholesterol levels should be carefully monitored and the treatment regimen should be reassessed. **C**
- Incorporate monitoring of diabetes self-care activities into treatment goals in people with diabetes and serious mental illness. **B**

4. Lifestyle Management

DSMES Delivery

Four critical time points for DSMES delivery:

1. At diagnosis
2. Annually for assessment of education, nutrition, and emotional needs
3. When new complicating factors (health conditions, physical limitations, emotional factors, or basic living needs) arise that influence self-management; and
4. When transitions in care occur

Goals of Nutrition Therapy

1. To promote and support healthful eating patterns, emphasizing a variety of nutrient-dense foods in appropriate portion sizes, to improve overall health and to:
 - Achieve and maintain body weight goals
 - Attain individualized glycemic, blood pressure, and lipid goals
 - Delay or prevent the complications of diabetes
2. To address individual nutrition needs based on personal & cultural preferences, health literacy & numeracy, access to healthful foods, willingness and ability to make behavioral changes, & barriers to change

Goals of Nutrition Therapy (2)

3. To maintain the pleasure of eating by providing non-judgmental messages about food choices
4. To provide an individual with diabetes the practical tools for developing healthful eating patterns rather than focusing on individual macronutrients, micronutrients, or single foods

Physical Activity: Recommendations

- Children and adolescents with 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**
- 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.

Recommendations: Physical Activity (2)

- Adults with type 1 **C** and type 2 **B** diabetes should engage in 2-3 sessions/week of resistance exercise on nonconsecutive days.
- 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, particularly in adults with type 2 diabetes. **C**
- 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**

Psychosocial Issues: Recommendations

- Psychosocial care should be integrated with a collaborative, patient-centered approach and provided to all people with diabetes, with the goals of optimizing health outcomes and health-related quality of life (QOL). **A**
- 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 QOL, available resources (financial, social, and emotional), and psychiatric history. **E**

Psychosocial issues

Diabetes Distress



**Mental Health Provider
Diabetes Education Program**



Psychosocial Issues: Recommendations (2)

- Providers should consider assessment for symptoms of diabetes distress, depression, anxiety, disordered eating, and cognitive capacities using patient-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**
- Consider screening older adults (aged ≥ 65 years) with diabetes for cognitive impairment and depression. **B**

Diabetes Distress

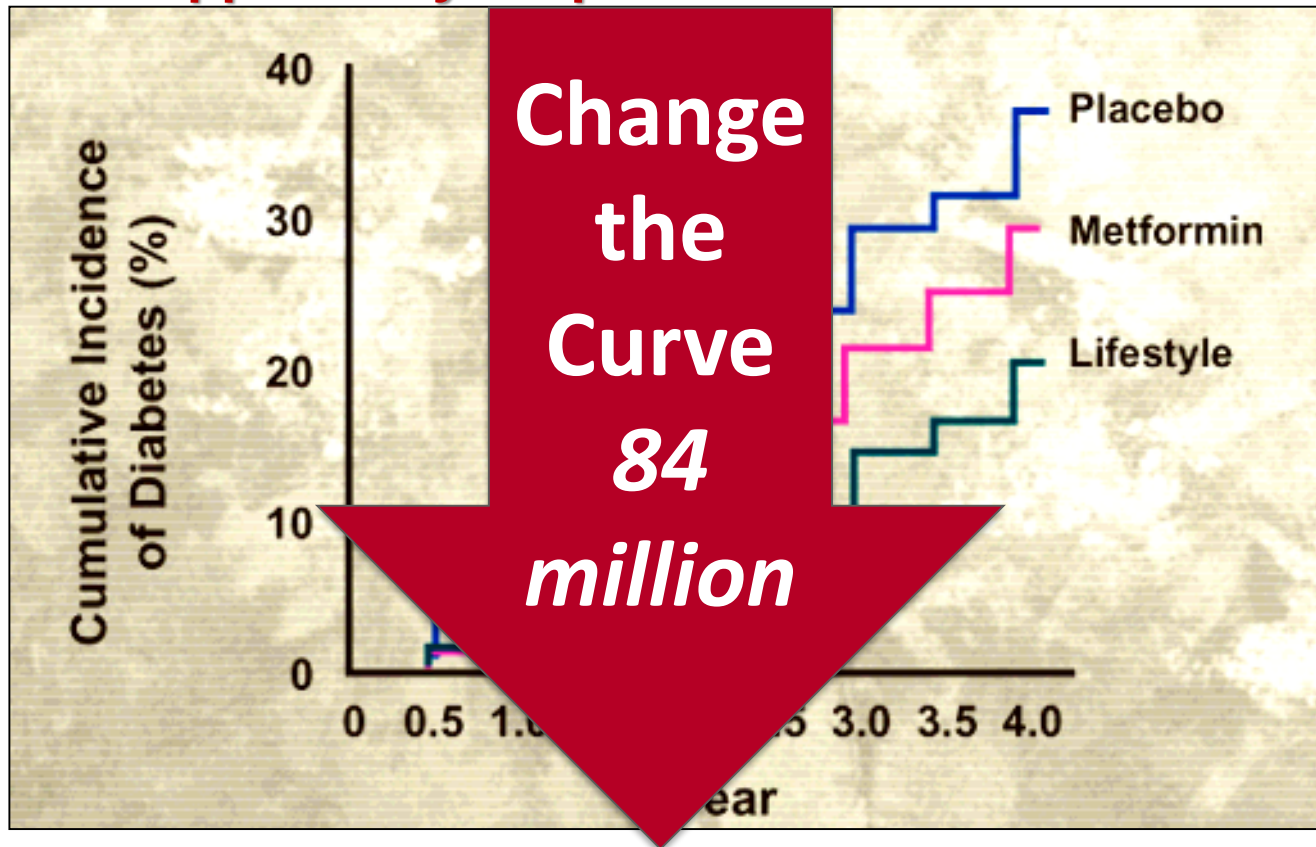
- Diabetes distress
 - Very common and distinct from other psychological disorders
 - Negative psychological reactions related to emotional burdens of managing a demanding chronic disease
- Recommendation:
 - Routinely monitor people with diabetes for diabetes distress, particularly when treatment targets are not met and/or at the onset of diabetes complications. **B**

Referral for Psychosocial Care

Table 4.2—Situations that warrant referral of a person with diabetes to a mental health provider for evaluation and treatment

- If self-care remains impaired in a person with DD after tailored diabetes education
- If a person has a positive screen on a validated screening tool for depressive symptoms
- In the presence of symptoms or suspicions of disordered eating behavior, an eating disorder, or disrupted patterns of eating
- If intentional omission of insulin or oral medication to cause weight loss is identified
- If a person has a positive screen for anxiety or fear of hypoglycemia
- If a serious mental illness is suspected
- In youth and families with behavioral self-care difficulties, repeated hospitalizations for diabetic ketoacidosis, or significant distress
- If a person screens positive for cognitive impairment
- Declining or impaired ability to perform diabetes self-care behaviors
- Before undergoing bariatric or metabolic surgery and after surgery if assessment reveals an ongoing need for adjustment support

Diabetes Prevention Program: An opportunity for prevention



Targets and Tools



CASE 2-Channel 9 Health Fair

Lack of harmonization of
guidelines impacts PCPs
who deliver the majority
of diabetes care

TZ

SU

DPP4i

Assessment of Glycemic Control

- Two primary techniques are available for health providers and patients to assess the effectiveness of a management plan on glycemic control:
 1. Patient self-monitoring of blood glucose (SMBG)
 2. A1C
- Continuous glucose monitoring (CGM) also has an important role in assessing the efficacy and safety of treatment in subgroups of patients with T1DM and in selected patients with T2DM.
 - Data indicate similar A1C and safety with the use of CGM compared with SMBG.

Approach to the Management of Hyperglycemia

Patient/Disease Features

Risk of hypoglycemia/drug adverse effects

Disease Duration

Life expectancy

Important comorbidities

Established vascular complications

Patient attitude & expected treatment efforts

Resources & support system

more stringent ← A1C 7% → less stringent

low

high

newly diagnosed

long-standing

long

short

absent

Few/mild

severe

absent

Few/mild

severe

Usually not modifiable

highly motivated, adherent, excellent self-care capabilities

less motivated, nonadherent, poor self-care capabilities

readily available

limited

Potentially modifiable

Glycemic Targets:

Standards of Medical Care in Diabetes - 2018. *Diabetes Care* 2018; 41 (Suppl. 1): S55-S64

Summary of Glycemic Recommendations

Table 6.2—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.

Hypoglycemia: Recommendations

- Individuals at risk for hypoglycemia should be asked about symptomatic and asymptomatic hypoglycemia at each encounter. **C**
- Glucose (15–20 g) is the preferred treatment for the conscious individual with blood glucose ≤ 70 mg/dL, 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. **E**

Classification of Hypoglycemia

Table 6.3—Classification of hypoglycemia*

Level	Glycemic criteria	Description
Hypoglycemia alert value (level 1)	≤ 70 mg/dL (3.9 mmol/L)	Sufficiently low for treatment with fast-acting carbohydrate and dose adjustment of glucose-lowering therapy
Clinically significant hypoglycemia (level 2)	< 54 mg/dL (3.0 mmol/L)	Sufficiently low to indicate serious, clinically important hypoglycemia
Severe hypoglycemia (level 3)	No specific glucose threshold	Hypoglycemia associated with severe cognitive impairment requiring external assistance for recovery

*Adapted from ref. 75.

Hypoglycemia: Recommendations (2)

- Glucagon should be prescribed for all individuals at increased risk of clinically significant hypoglycemia, defined as blood glucose < 54 mg/dL, so it is available if 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. **E**
- Hypoglycemia unawareness or one or more episodes of severe hypoglycemia should trigger reevaluation of the treatment regimen. **E**

Hypoglycemia: Recommendations (3)

- Insulin-treated patients with hypoglycemia unawareness or an episode of clinically significant 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**
- 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. Obesity Management for the Treatment of Type 2 Diabetes

Recommendations: Assessment

- At each patient encounter, BMI should be calculated and documented in the medical record. **B**
 - BMI should be:
 - Classified to determine the presence of overweight or obesity
 - Discussed with the patient
 - Documented in the patient record
 - Remember that BMI cutpoints for Asian Americans are lower than in other populations

Overweight/Obesity Treatment Options in T2DM

Treatment	Body Mass Index (BMI) Category (kg/m ²)				
	25.0-26.9 (or 23.0-26.9*)	27.0-29.9	30.0-34.9 (or 27.5-32.4*)	35.0-39.9 (or 32.5-37.4*)	≥40 (or ≥37.5*)
Diet, physical activity & behavioral therapy	+	+	+	+	+
Pharmacotherapy		+	+	+	+
Metabolic surgery			+	+	+

* Cutoff points for Asian-American individuals.

+ Treatment may be indicated for selected, motivated patients.

Pharmacotherapy: Recommendations

- When choosing glucose-lowering medications for overweight or obese patients with T2DM, consider their effect on weight. **E**
- Whenever possible, minimize the medications for comorbid conditions that are associated with weight gain. **E**

Pharmacotherapy: Recommendations (2)

- Weight loss meds may be effective as adjuncts to diet, physical activity & behavioral counseling for selected patients with T2DM and BMI ≥ 27 kg/m². Potential benefits must be weighed against the potential risks of the medications. **A**
- If patient's response to weight loss medications is <5% weight loss after 3 months or if there are any safety or tolerability issues at any time, the medication should be discontinued and alternative medications or treatment approaches should be considered. **A**

Medications Approved by the FDA for the Treatment of Obesity

Generic drug name (proprietary name(s)), dosage, strength, and form	Usual adult dosing frequency	Average wholesale price (per month) ¹³	Adverse effects ^{1,5-12}	
			Common ⁶	Serious ⁶
Short-term treatment (a few weeks)				
Phentermine (Lomaira)	37.5mg q.d. or 8mg t.i.d.	\$5-\$76 (37.5 mg); \$52 (8 mg)	Headache, elevated blood pressure, elevated heart rate, insomnia, dry mouth, constipation, anxiety, palpitations	Dyspnea, angina pectoris, syncope, severe hypertension
Long-term treatment (more than a few weeks)				
Lipase inhibitor				
Orlistat (Alli) 60 mg caps or orlistat (Xenical) 120 mg caps	60 mg or 120 mg t.i.d. (during or up to 1 h after a low-fat meal)	\$41-82 (60 mg); \$703 (120 mg)	Abdominal pain/ discomfort, oily spotting/ stool, fecal urgency, flatulence, malabsorption of fat soluble vitamins (A, D, E, K) and medications (e.g., cyclosporine, thyroid hormone replacement, or anticonvulsants), potentiation of the effects of warfarin	Liver failure and oxalate nephropathy
Selective serotonin (5-HT) _{2C} receptor agonist				
Lorcaserin (Belviq) 10 mg tabs	10 mg b.i.d.	\$289	Hypoglycemia, headache, fatigue	Serotonin syndrome or NMS-like reactions, suicidal ideation, heart valve disorder (<2.4%), bradycardia
Lorcaserin (Belviq XR) 20 mg extended-release tabs	20 mg q.d.	\$289	Hypoglycemia, headache, fatigue	Serotonin syndrome or NMS-like reactions, suicidal ideation, heart valve disorder (<2.4%), bradycardia

Medications Approved by the FDA for the Treatment of Obesity (2)

Generic drug name (proprietary name(s)), dosage, strength, and form	Usual adult dosing frequency	Average wholesale price (per month) ¹³	Adverse effects ^{1,5-12}	
			Common ⁶	Serious ⁶
Sympathomimetic amine anorectic/antiepileptic combination				
Phentermine/topiramate ER (Qsymia) 3.75 mg/ 23 mg caps, 7.5 mg/ 46 mg caps, 11.25 mg/ 69 mg caps, 15 mg/ 92 mg caps	Recommended dose: 3.75 mg/23 mg q.d. for 14 days, then increase to 7.5 mg/ 46 mg q.d. Maximum dose: 15 mg/92 mg q.d.	\$239 (maximum dose using the highest strength)	Paresthesia, xerostomia, constipation, headache	Topiramate is teratogenic and has been associated with cleft lip/palate
Opioid antagonist/aminoketone antidepressant combination				
Naltrexone/bupropion (Contrave) 8 mg/90 mg tabs	Maximum dose: two tablets of Contrave b.i.d. for a total daily dosage of naltrexone 32 mg/bupropion 360 mg	\$290 (maximum dose)	Nausea, constipation, headache, vomiting	Depression, precipitation of mania, contraindicated in patients with a seizure disorder
Glucagon-like peptide 1 receptor agonist				
Liraglutide (Saxenda) 6 mg/mL prefilled pen	Maintenance dose: 3 mg s.c. q.d.	\$1,385	Hypoglycemia, nausea, vomiting, diarrhea, constipation, headache	Pancreatitis, thyroid C-cell tumors in rodents, contraindicated in patients with personal/ family history of MTC or MEN2, acute renal failure

Metabolic Surgery

- Evidence supports gastrointestinal (GI) operations as effective treatments for overweight T2DM patients.
- Randomized controlled trials with postoperative follow-up ranging from 1 to 5 years have documented sustained diabetes remission in 30–63% of patients, though erosion of remission occurs in 35-50% or more.
- With or without diabetes relapse, the majority of patients who undergo surgery maintain substantial improvement of glycemic control for at least 5 to 15 years.

Metabolic Surgery: Recommendations

- Metabolic surgery *should be recommended* as an option to treat T2DM in appropriate surgical candidates with BMI ≥ 40 kg/m² (37.5*), regardless of the level of glycemic control or complexity of glucose-lowering regimens, and in adults with BMIs 35.0-39.9 kg/m² (32.5-37.4*) when hyperglycemia is inadequately controlled despite lifestyle and optimal medical therapy. **A**
- Metabolic surgery *should be considered* as an option for adults with T2DM and BMI 30-34.9 kg/m² (27.5-32.4*) if hyperglycemia is inadequately controlled despite optimal medical control by either oral or injectable medications (including insulin). **B**
- Metabolic surgery should be performed in high-volume centers with multidisciplinary teams that understand and are experienced in the management of diabetes and gastrointestinal surgery. **C**

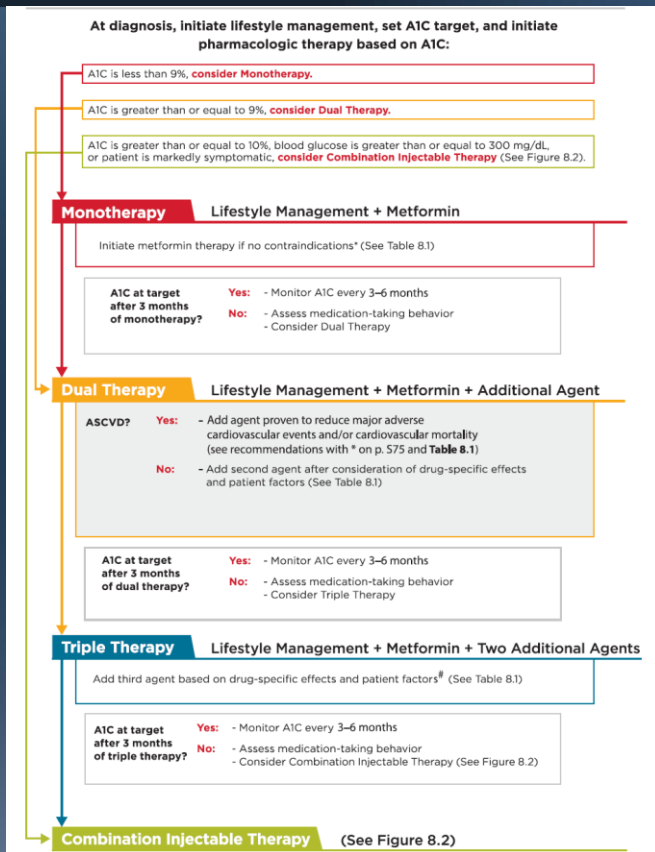
Metabolic Surgery: Recommendations (2)

- Long-term lifestyle support and routine monitoring of micronutrient and nutritional status must be provided after surgery, according to guidelines for postoperative management of metabolic surgery by national and international professional societies. **C**
- People presenting for metabolic surgery should receive a comprehensive mental health assessment. **B** Surgery should be postponed in patients with histories of alcohol or substance abuse, significant depression, suicidal ideation, or other mental health conditions until these conditions have been fully addressed. **E**
- People who undergo metabolic surgery should be evaluated to assess the need for ongoing mental health services to help them adjust to medical and psychosocial changes after surgery. **C**

Metabolic Surgery: Adverse Effects

- Costly
- Some associated risks
- Outcomes vary
- Patients undergoing metabolic surgery may be at higher risk for depression, substance abuse, and other psychosocial issues

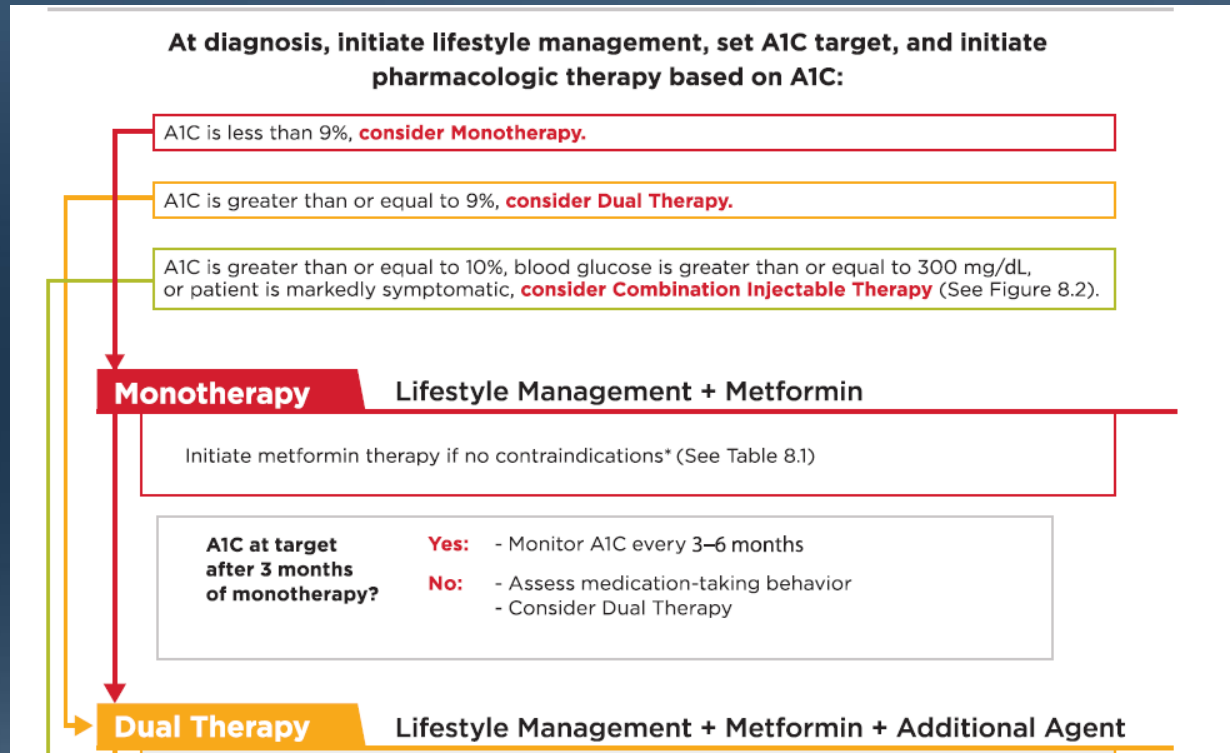
Antihyperglycemic Therapy in Adults with T2DM



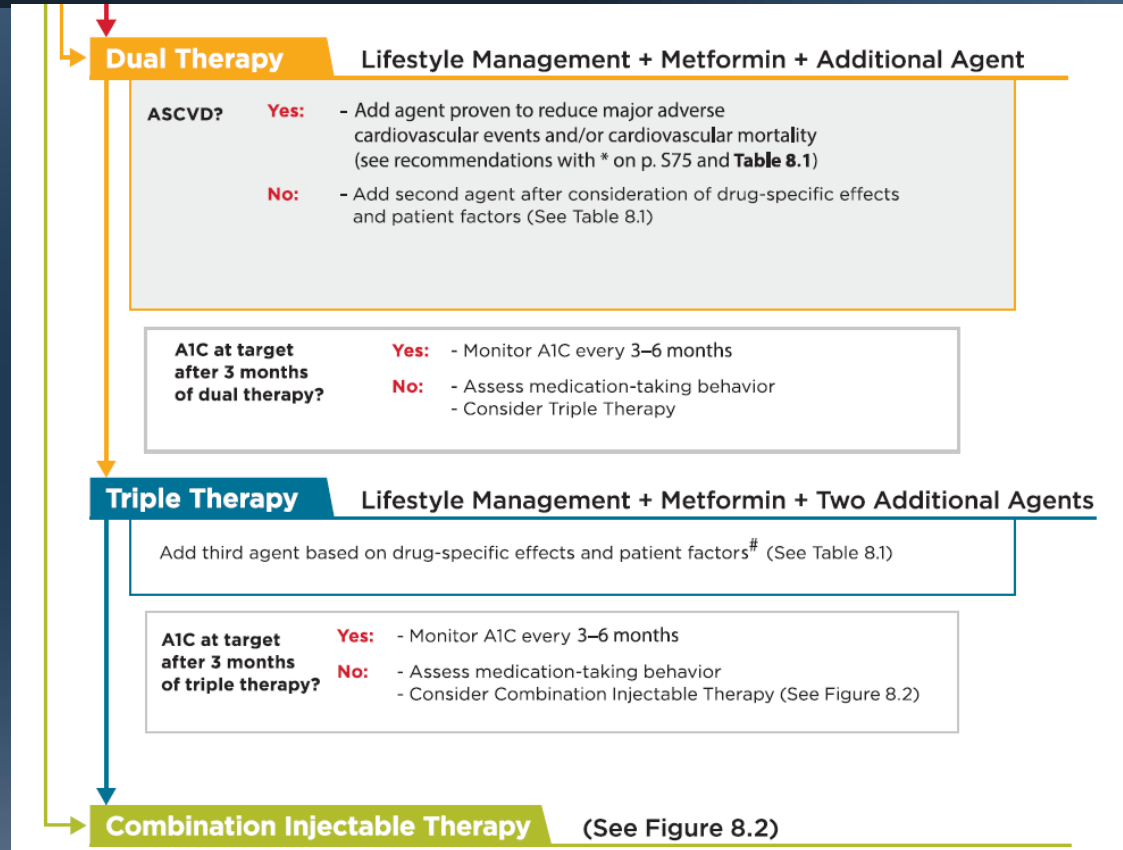
Pharmacologic Approaches to Glycemic Treatment:

Standards of Medical Care in Diabetes - 2018. Diabetes Care 2018; 41 (Suppl. 1): S73-S85

Antihyperglycemic Therapy in Adults with T2DM



Antihyperglycemic Therapy in Adults with T2DM



Pharmacologic Approaches to Glycemic Treatment:

Standards of Medical Care in Diabetes - 2018. Diabetes Care 2018; 41 (Suppl. 1): S73-S85

Table 8.1—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	CHF			Progression of DKD	Dosing/Use considerations	
Metformin		High	No	Neutral (Potential for Modest Loss)	Potential Benefit	Neutral	Low	Oral	Neutral	Contraindicated with eGFR <30	- Gastrointestinal side effects common (diarrhea, nausea) - Potential for B12 deficiency
SGLT-2 Inhibitors		Intermediate	No	Loss	Benefit: canagliflozin, empagliflozin†	Benefit: canagliflozin, empagliflozin	High	Oral	Benefit: canagliflozin, empagliflozin	- Canagliflozin: not recommended with eGFR <45 - Dapagliflozin: not recommended with eGFR <60; contraindicated with eGFR <30 - Empagliflozin: contraindicated with eGFR <30	FDA Black Box: Risk of amputation (canagliflozin) - Risk of bone fractures (canagliflozin) - DKA risk (all agents, rare in T2DM) - Genitourinary infections - Risk of volume depletion, hypotension ↑LDL cholesterol
GLP-1 RAs		High	No	Loss	Neutral Exenatide, exenatide extended release Benefit: liraglutide†	Neutral	High	SQ	Benefit: liraglutide	- Exenatide: not indicated with eGFR <30 - Lixisenatide: caution with eGFR <30 - Increased risk of side effects in patients with renal impairment	FDA Black Box: Risk of thyroid C-cell tumors (liraglutide, albiglutide, dulaglutide, exenatide extended release) - Gastrointestinal side effects common (nausea, vomiting, diarrhea) - Injection site reactions ?Acute pancreatitis risk
DPP-4 Inhibitors		Intermediate	No	Neutral	Neutral	Potential Risk: saxagliptin, alogliptin	High	Oral	Neutral	Renal dose adjustment required; can be used in renal impairment	- Potential risk of acute pancreatitis - Joint pain
Thiazolidinediones		High	No	Gain	Potential Benefit: pioglitazone	Increased Risk	Low	Oral	Neutral	- No dose adjustment required - Generally not recommended in renal impairment due to potential for fluid retention	FDA Black Box: Congestive heart failure (pioglitazone, rosiglitazone) - Fluid retention (edema; heart failure) - Benefit in NASH - Risk of bone fractures - Bladder cancer (pioglitazone) ↑LDL cholesterol (rosiglitazone)
Sulfonylureas (2nd Generation)		High	Yes	Gain	Neutral	Neutral	Low	Oral	Neutral	- Gliburide: not recommended - Glipizide & glimepiride: initiate conservatively to avoid hypoglycemia	FDA Special Warning on increased risk of cardiovascular mortality based on studies of an older sulfonylurea (tolbutamide)
Insulin	Human Insulin	Highest	Yes	Gain	Neutral	Neutral	Low	SQ	Neutral	Lower insulin doses required with a decrease in eGFR; titrate per clinical response	- Injection site reactions - Higher risk of hypoglycemia with human insulin (NPH or premixed formulations) vs. analogs
	Analog						High	SQ			

*See ref. 31 for description of efficacy. †FDA approved for CVD benefit. CVD, cardiovascular disease; DKA, diabetic ketoacidosis; DKD, diabetic kidney disease; NASH, nonalcoholic steatohepatitis; RAs, receptor agonists; SQ, subcutaneous; T2DM, type 2 diabetes.

Combination Injectable Therapy in T2DM

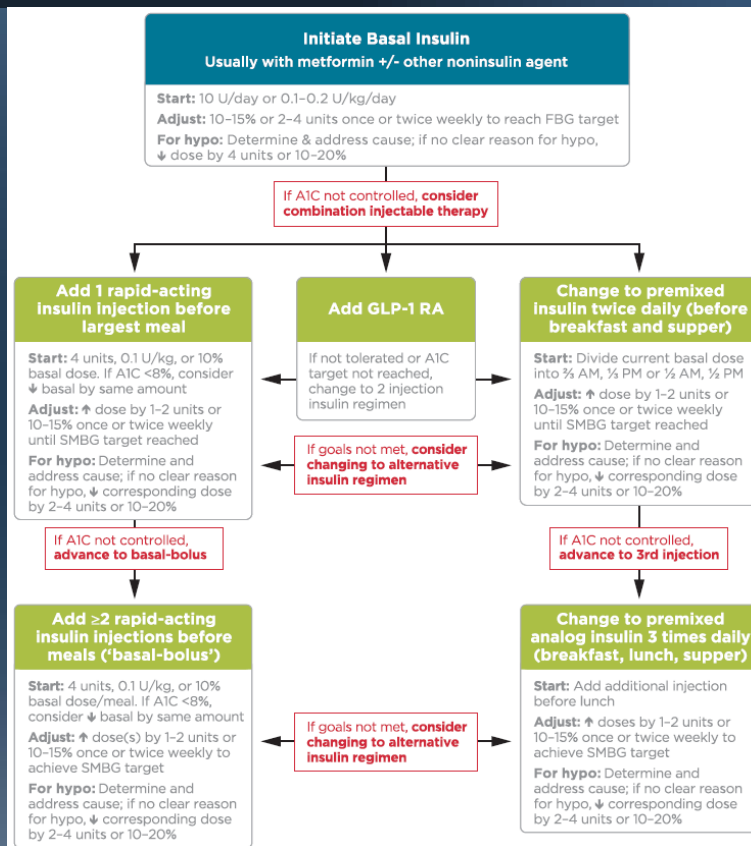


Table 8.3—Median monthly cost of maximum approved daily dose of noninsulin glucose-lowering agents in the U.S.

Class	Compound(s)	Dosage strength/product (if applicable)	Median AWP (min, max)†	Median NADAC (min, max)†	Maximum approved daily dose*
Biguanides	• Metformin	500 mg (IR)	\$84 (\$4, \$93)	\$2	2,000 mg
		850 mg (IR)	\$108 (\$6, \$109)	\$3	2,550 mg
		1,000 mg (IR)	\$87 (\$4, \$88)	\$2	2,000 mg
		500 mg (ER)	\$89 (\$82, \$6,671)	\$5 (\$5, \$3,630)	2,000 mg
		750 mg (ER)	\$72 (\$65, \$92)	\$5	1,500 mg
		1,000 mg (ER)	\$1,028 (\$1,028, \$7,214)	\$539 (\$539, \$5,189)	2,000 mg
Sulfonylureas (2nd generation)	• Glyburide	5 mg	\$93 (\$63, \$103)	\$17	20 mg
		6 mg (micronized)	\$50 (\$48, \$71)	\$12	12 mg (micronized)
	• Glipizide	10 mg (IR)	\$75 (\$67, \$97)	\$4	40 mg (IR)
		10 mg (XL)	\$48	\$16	20 mg (XL)
	• Glimepiride	4 mg	\$71 (\$71, \$198)	\$7	8 mg
Meglitinides (glinides)	• Repaglinide	2 mg	\$659 (\$122, \$673)	\$40	16 mg
	• Nateglinide	120 mg	\$155	\$56	360 mg
Thiazolidinediones	• Pioglitazone	45 mg	\$348 (\$283, \$349)	\$5	45 mg
	• Rosiglitazone	4 mg	\$387	\$314	8 mg
α-Glucosidase inhibitors	• Acarbose	100 mg	\$104 (\$104, \$106)	\$25	300 mg
	• Miglitol	100 mg	\$241	N/A††	300 mg
DPP-4 inhibitors	• Sitagliptin	100 mg	\$477	\$382	100 mg
	• Saxagliptin	5 mg	\$462	\$370	5 mg
	• Linagliptin	5 mg	\$457	\$367	5 mg
	• Alogliptin	25 mg	\$449	\$357	25 mg
Bile acid sequestrants	• Colesevelam	625 mg tabs	\$713	\$570	3.75 g
		1.875 g suspension	\$1,426	\$572	3.75 g
Dopamine-2 agonists	• Bromocriptine	0.8 mg	\$784	\$629	4.8 mg
SGLT2 inhibitors	• Canagliflozin	300 mg	\$512	\$411	300 mg
	• Dapagliflozin	10 mg	\$517	\$413	10 mg
	• Empagliflozin	25 mg	\$517	\$415	25 mg
GLP-1 receptor agonists	• Exenatide	10 µg pen	\$802	\$642	20 µg
	• Lixisenatide	20 µg pen	\$669	N/A††	20 µg
	• Liraglutide	18 mg/3 mL pen	\$968	\$775	1.8 mg
	• Exenatide (extended release)	2 mg powder for suspension or pen	\$747	\$600	2 mg**
	• Albiglutide	50 mg pen	\$626	\$500	50 mg**
	• Dulaglutide	1.5/0.5 mL pen	\$811	\$648	1.5 mg**
Amylin mimetics	• Pramlintide	120 µg pen	\$2,336	N/A††	120 µg/injection†††

ER and XL, extended release; IR, immediate release. †Calculated for 30-day supply (AWP or NADAC unit price × number of doses required to provide maximum approved daily dose × 30 days); median AWP or NADAC listed alone when only one product and/or price. *Utilized to calculate median AWP and NADAC (min, max); generic prices used, if available commercially. ††Not applicable; data not available. **Administered once weekly. †††AWP and NADAC calculated based on 120 µg three times daily.

Average wholesale price (AWP) and National Average Drug Acquisition Costs (NADAC) do not account for discounts, rebates, or other price adjustments that may affect the actual cost incurred by the patient, but highlight the importance of cost considerations.

Table 8.4—Median cost of insulin products in the U.S. calculated as AWP (39) and NADAC (40) per 1,000 units of specified dosage form/product

Insulins	Compounds	Dosage form/product	Median AWP (min, max)*	Median NADAC (min, max)*
Rapid-acting analogs	• Lispro	U-100 vial;	\$330	\$264
		U-100 3 mL cartridges;	\$408	\$326
		U-100 prefilled pen; U-200 prefilled pen	\$424	\$339
	• Aspart	U-100 vial;	\$331	\$265
		U-100 3 mL cartridges;	\$410	\$330
		U-100 prefilled pen	\$426	\$341
	• Glulisine	U-100 vial;	\$306	\$245
		U-100 prefilled pen	\$394	\$315
	• Inhaled insulin	Inhalation cartridges	\$725 (\$544, \$911)	N/A†
Short-acting analogs	• Human Regular	U-100 vial	\$165 (\$165, \$178)	\$135 (\$135, \$145)
Intermediate-acting analogs	• Human NPH	U-100 vial;	\$165 (\$165, \$178)	\$135 (\$135, \$145)
		U-100 prefilled pen	\$377	\$305
Concentrated Human Regular insulin	• U-500 Human Regular insulin	U-500 vial;	\$178	\$143
		U-500 prefilled pen	\$230	\$184
Basal analogs	• Glargine	U-100 vial; U-100 prefilled pen; U-300 prefilled pen	\$298	\$239 (\$239, \$241)
	• Glargine biosimilar	U-100 prefilled pen	\$253	\$203
	• Detemir	U-100 vial; U-100 prefilled pen	\$323	\$259
	• Degludec	U-100 prefilled pen; U-200 prefilled pen	\$355	\$285
Premixed insulin products	• NPH/Regular 70/30	U-100 vial;	\$165 (\$165, \$178)	\$134 (\$134, \$146)
		U-100 prefilled pen	\$377	\$305
	• Lispro 50/50	U-100 vial;	\$342	\$278
		U-100 prefilled pen	\$424	\$339
	• Lispro 75/25	U-100 vial;	\$342	\$273
		U-100 prefilled pen	\$424	\$340
	• Aspart 70/30	U-100 vial;	\$343	\$275
		U-100 prefilled pen	\$426	\$341
Premixed insulin/GLP-1 receptor agonist products	• Degludec/Liraglutide	100/3.6 prefilled pen	\$763	N/A†
	• Glargine/Lixisenatide	100/33 prefilled pen	\$508	\$404

*AWP or NADAC calculated as in Table 8.3; median listed alone when only one product and/or price. †Not applicable; data not available.

There have been substantial increases in the price of insulin in the past decade, and cost-effectiveness is an important consideration.

Table 9.2—Recommendations for statin and combination treatment in adults with diabetes

Age	ASCVD	Recommended statin intensity [^] and combination treatment*
<40 years	No	None [†]
	Yes	High • If LDL cholesterol ≥ 70 mg/dL despite maximally tolerated statin dose, consider adding additional LDL-lowering therapy (such as ezetimibe or PCSK9 inhibitor)[#]
≥ 40 years	No	Moderate [‡]
	Yes	High • If LDL cholesterol ≥ 70 mg/dL despite maximally tolerated statin dose, consider adding additional LDL-lowering therapy (such as ezetimibe or PCSK9 inhibitor)

*In addition to lifestyle therapy. [^]For patients who do not tolerate the intended intensity of statin, the maximally tolerated statin dose should be used. [†]Moderate-intensity statin may be considered based on risk-benefit profile and presence of ASCVD risk factors. ASCVD risk factors include LDL cholesterol ≥ 100 mg/dL (2.6 mmol/L), high blood pressure, smoking, chronic kidney disease, albuminuria, and family history of premature ASCVD. [‡]High-intensity statin may be considered based on risk-benefit profile and presence of ASCVD risk factors. [#]Adults aged <40 years with prevalent ASCVD were not well represented in clinical trials of non-statin-based LDL reduction. Before initiating combination lipid-lowering therapy, consider the potential for further ASCVD risk reduction, drug-specific adverse effects, and patient preferences.

High- and Moderate-Intensity Statin Therapy

Table 9.3—High-intensity and moderate-intensity statin therapy*

High-intensity statin therapy (lowers LDL cholesterol by $\geq 50\%$)	Moderate-intensity statin therapy (lowers LDL cholesterol by 30% to 50%)
Atorvastatin 40–80 mg	Atorvastatin 10–20 mg
Rosuvastatin 20–40 mg	Rosuvastatin 5–10 mg
	Simvastatin 20–40 mg
	Pravastatin 40–80 mg
	Lovastatin 40 mg
	Fluvastatin XL 80 mg
	Pitavastatin 2–4 mg

*Once-daily dosing. XL, extended release.

Antiplatelet Agents: Recommendations

- Use aspirin therapy (75-162 mg/day) as a secondary prevention strategy in those with diabetes and a history of ASCVD. **A**
- For patients with ASCVD and documented aspirin allergy, clopidogrel (75 mg/day) should be used. **B**
- Dual antiplatelet therapy (with low-dose aspirin and a P2Y12 inhibitor) is reasonable for a year after an acute coronary syndrome **A** and may have benefits beyond this period. **B**

Coronary Heart Disease: Recommendations

Screening

- In asymptomatic patients, routine screening for CAD is not recommended as it does not improve outcomes as long as ASCVD risk factors are treated. **A**
- Consider investigations for CAD in the presence of:
 - 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
 - EKG abnormalities (e.g. Q waves). **E**

Older Adults

- 26% of patients >65 years of age have diabetes.
- Older adults have higher rates of premature death, functional disability & coexisting illnesses.
- At greater risk for polypharmacy, cognitive impairment, urinary incontinence, injurious falls & persistent pain.
- Screening for complications should be individualized and periodically revisited.
- At higher risk for depression.

Older Adults: Recommendations

- Consider the assessment of medical, psychological, functional, and social geriatric domains in older adults to provide a framework to determine targets and therapeutic approaches for diabetes management. C
- Screening for geriatric syndromes may be appropriate in older adults experiencing limitations in their basic and instrumental activities of daily living as they may affect diabetes self-management and be related to health-related quality of life. C

Older Adults: Recommendations (2)

Neurocognitive Function:

- Screening for early detection of mild cognitive impairment of dementia and depression is indicated for adults 65 years of age or older at the initial visit and annually as appropriate. **B**

Older Adults: Recommendations (3)

Hypoglycemia:

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

Older Adults: Recommendations (4)

Treatment Goals:

- Older adults who are otherwise healthy with few coexisting chronic illnesses and intact cognitive function and functional status should have lower glycemic goals (A1C <7.5%), while those with multiple coexisting chronic illnesses, cognitive impairment, or functional dependence should have less stringent glycemic goals (A1C <8.0-8.5%). **C**
- Glycemic goals for some older adults might reasonably be relaxed as part of individualized care, but hyperglycemia leading to symptoms or risk of acute hyperglycemic complications should be avoided in all patients. **C**

Older Adults: Recommendations (8)

Treatment in Skilled Nursing Facilities and Nursing Homes:

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

Older Adults: Recommendations (9)

End-Of-Life Care:

- When palliative care is needed in older adults with diabetes, strict blood pressure control may not be necessary, and withdrawal of therapy may be appropriate. Similarly, the intensity of lipid management can be relaxed, and withdrawal of lipid-lowering therapy may be appropriate. E
- Overall comfort, prevention of distressing symptoms, and preservation of quality of life and dignity are primary goals for diabetes management at end of life. E

Framework for Considering Treatment Goals in Older Adults with Diabetes

Table 11.1—Framework for considering treatment goals for glycemia, blood pressure, and dyslipidemia in older adults with diabetes (2)

Patient characteristics/health status	Rationale	Reasonable A1C goal [‡]	Fasting or preprandial glucose	Bedtime glucose	Blood pressure	Lipids
Healthy (few coexisting chronic illnesses, intact cognitive and functional status)	Longer remaining life expectancy	<7.5% (58 mmol/mol)	90–130 mg/dL (5.0–7.2 mmol/L)	90–150 mg/dL (5.0–8.3 mmol/L)	<140/90 mmHg	Statin unless contraindicated or not tolerated
Complex/intermediate (multiple coexisting chronic illnesses* or 2+ instrumental ADL impairments or mild-to-moderate cognitive impairment)	Intermediate remaining life expectancy, high treatment burden, hypoglycemia vulnerability, fall risk	<8.0% (64 mmol/mol)	90–150 mg/dL (5.0–8.3 mmol/L)	100–180 mg/dL (5.6–10.0 mmol/L)	<140/90 mmHg	Statin unless contraindicated or not tolerated
Very complex/poor health (LTC or end-stage chronic illnesses** or moderate-to-severe cognitive impairment or 2+ ADL dependencies)	Limited remaining life expectancy makes benefit uncertain	<8.5% [†] (69 mmol/mol)	100–180 mg/dL (5.6–10.0 mmol/L)	110–200 mg/dL (6.1–11.1 mmol/L)	<150/90 mmHg	Consider likelihood of benefit with statin (secondary prevention more so than primary)

This represents a consensus framework for considering treatment goals for glycemia, blood pressure, and dyslipidemia in older adults with diabetes. The patient characteristic categories are general concepts. Not every patient will clearly fall into a particular category. Consideration of patient and caregiver preferences is an important aspect of treatment individualization. Additionally, a patient's health status and preferences may change over time. ADL, activities of daily living. [‡]A lower A1C goal may be set for an individual if achievable without recurrent or severe hypoglycemia or undue treatment burden. *Coexisting chronic illnesses are conditions serious enough to require medications or lifestyle management and may include arthritis, cancer, congestive heart failure, depression, emphysema, falls, hypertension, incontinence, stage 3 or worse chronic kidney disease, myocardial infarction, and stroke. By "multiple," we mean at least three, but many patients may have five or more (47). **The presence of a single end-stage chronic illness, such as stage 3–4 congestive heart failure or oxygen-dependent lung disease, chronic kidney disease requiring dialysis, or uncontrolled metastatic cancer, may cause significant symptoms or impairment of functional status and significantly reduce life expectancy. [†]A1C of 8.5% (69 mmol/mol) equates to an estimated average glucose of ~200 mg/dL (11.1 mmol/L). Looser A1C targets above 8.5% (69 mmol/mol) are not recommended as they may expose patients to more frequent higher glucose values and the acute risks from glycosuria, dehydration, hyperglycemic hyperosmolar syndrome, and poor wound healing.

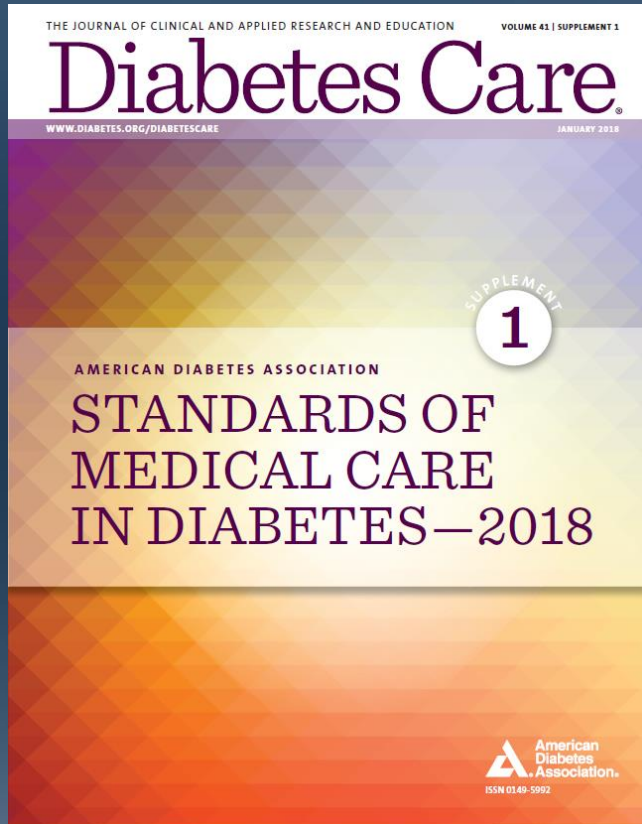
15. Diabetes Advocacy

Advocacy Position Statements

- ADA publishes evidence-based advocacy statements on issues including:
 - Diabetes and employment
 - Diabetes and driving
 - Diabetes management in schools, child care programs, and correctional institutions.
- These are important tools in educating:
 - Schools
 - Employers
 - Licensing agencies
 - Policy makers

Helpful Resources

2018 Standards of Care - Resources



- Full version available
- Abridged version for PCPs
- Free app (February 2018)
- Pocket cards with key figures
- Free webcast for continuing education credit

Professional.Diabetes.org/SOC

Diabetes Self-Management Education



- Find a recognized Diabetes Self-Management program
- Become a recognized DSME program
- Tools and resources for DSME programs
- Online education documentation tools

Professional.Diabetes.org/ERP

