Joslin Diabetes Center's
Clinical Guidelines for Management of Adults with Diabetes

From the Adult Diabetes and Clinical Research Sections, Joslin Diabetes Center.
Approved February 13th, 2020

OVERVIEW

The Joslin clinical guidelines aim to support clinical practice and influence clinical behaviors in order to improve clinical outcomes and assure that patient expectations are reasonable and informed. The guidelines are developed and approved through the Clinical Oversight Committee, which reports to the chief medical officer of Joslin Diabetes Center. The guidelines are established after careful review of current evidence, medical literature, and sound clinical practice. The Clinical Guidelines for Adults with Diabetes will be reviewed periodically and modified on a yearly basis. This document was approved by the Clinical Oversight Committee on February 13th, 2020.

The guidelines are evidence-based. A modification of the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system1 has been adopted to give the user an evaluation of the evidence used to support each standard of care. The Table describes the categories in which methodological quality and strength of recommendations have been classified. Evidence levels are graded 1A through 2C, as indicated in brackets. Where evidence is not graded, recommendations are made based on the expertise of the Clinical Oversight Committee.

Table: Grading system used in Joslin clinical guidelines

Grade of Recommendation	Clarity of Risk/Benefit	Quality of Supporting Evidence
1A Strong recommendation High quality of evidence	Benefits clearly outweigh risk, and vice versa.	Consistent evidence from well-performed, randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
1B Strong recommendation Moderate quality of evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Evidence from randomized, controlled trials with important limitations (inconsistent results; methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research is likely to have an impact on our confidence in the estimate of the benefit and risk and may change the estimate.

1C Strong recommendation Low quality of evidence	Benefits outweigh risk and burdens, or vice versa.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trials with serious flaws. Any estimate of effect is uncertain.
2A Weak recommendation High quality of evidence	Benefits closely balanced with risks and burdens.	Consistent evidence from well performed, randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
2B Weak recommendation Moderate quality of evidence	Benefits closely balanced with risks and burdens; some uncertainty in the estimates of benefits, risks, and burdens.	Evidence from randomized controlled trials with important limitations (inconsistent results; methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate.
2C Weak recommendation Low quality of evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trials with serious flaws. Any estimate of effect is uncertain.

Reference
Guyatt G, Gutterman D, Baumann MH, et al. Grading strength of recommendations and quality of evidence in clinical guidelines: report from an American College of Physicians task force. Chest. 2006;129(1):174-181.

**Evidence graded less than "A" is acceptable to support clinical recommendations in a guideline. It is also assumed that for many important clinical recommendations, it would be unlikely that level A evidence be obtained because appropriate studies may never be performed.*

Table of Contents

1 APPROACH TO CARE

1.1 INDIVIDUALIZING PATIENT CARE:

The needs and goals of each person with diabetes (PWD) are unique. A treatment plan must be based on a thorough assessment and requires an understanding of not only the individual's medical needs, but also other factors that may influence the treatment plan such as social history, race, cultural issues, ethnicity, education needs (including literacy and numeracy), comorbidities, and barriers to care. The PWD's diabetes management plan should include medical treatment, interventions, follow-up, and ongoing support. Use of the electronic medical record may help facilitate care, by enabling the team to track progress, ensuring goals are met, and facilitating communication flow among team members and the PWD. [1C]

1.2 THE PWD-CENTERED APPROACH:

Diabetes is a condition that requires considerable self- management. A collaborative counseling model that involves the patient in decisions and goal setting helps promote behavioral change. Whenever appropriate, with the PWD's consent, involving family members and nonclinical caregivers in medical visits and education is valuable. [1A]

1.3 WORKING IN A TEAM:

Diabetes is best managed by a team, which may include clinicians, diabetes educators (DEs), (registered dietitians, registered nurses, exercise physiologists) and behavioral health specialists. The PWD should be informed and fully aware of what roles the various team members play. If access to a team is not possible within the office practice, it is useful to identify community resources. Clear communication among all providers is critical to ensure PWDs' needs are being met. [1C]

1.4 FREQUENCY OF MEDICAL VISITS:

While the frequency of visits for ongoing care should be individualized, monitoring the PWD's progress through medical visits is recommended at least 2 to 4 times/year. Telemedicine is effective in providing time and cost-effective access to care. Telemedicine may be an option to increase access to care and can assist with the frequency of medical visits. Special attention should be given to PWDs who do not keep scheduled appointments, have frequent hospitalizations, or miss days of work/school. Since many factors contribute to the PWDs' ability to manage their care, the provider should:

- Engage individuals in identifying and resolving contributing factors or barriers to underutilization or overutilization of healthcare services. PWD with challenging care may benefit from consultation with endocrinologists focused on diabetes care.
- Refer to a DE, social service professional or behavioral health professional to address possible barriers and/or psychosocial issues

Establish a process of follow-up communication regarding adherence to the treatment plan and sustaining behaviors. Evidence: [2C]

2 DIAGNOSIS OF DIABETES MELLITUS

2.1 GENERAL CRITERIA FOR DIAGNOSIS:

The diagnosis of diabetes mellitus can be made based upon:

- Random plasma glucose ≥200 mg/dl (11.1 mmol/L) and symptoms of diabetes (polyuria, polydipsia, ketoacidosis, or unexplained weight loss) OR
- Fasting plasma glucose* ≥126 mg/dl (6.9 mmol/L) OR
- 2-hour 75-gram oral glucose tolerance test* ≥200 mg/dl (11.1 mmol/L) OR
- Glycated hemoglobin* (A1C) ≥6.5% (48 mmol/mol)**

**These tests should be confirmed by a repeat test, unless unequivocally high. The presence of either criterion is acceptable for diagnosis. Those with an A1C of 5.7%-6.4% (39-46 mmol/mol) are considered to have prediabetes, and they are at high risk for developing diabetes. These patients should be treated with lifestyle changes and followed more frequently.*

The A1C test should be performed in a laboratory using a method that is certified by the National Glycohemoglobin Standardization Program and standardized to the Diabetes Control and Complications Trial assay. Point-of-care A1c assay approved for diagnostic or screening purposes should only be considered in settings licensed to perform moderate-to-high complexity tests.

2.2 GOALS:

The A1C target goal should be individualized for each patient.

A goal of <7.0% (53 mmol/mol) is chosen as a practical level for most patients to reduce the risk of long-term complications of diabetes. Achieving this goal is recommended if it can be done safely and practically [1B].

Alternative A1C goals may be set, based upon presence or absence of microvascular and/or cardiovascular complications, hypoglycemic unawareness, cognitive status, and life expectancy [1A]. For patients with longstanding type 2 diabetes (T2D) with preexisting cardiovascular disease (CVD), or high coronary artery disease (CAD) risk (diabetes plus 2 or more additional risk factors), consider revising A1C goals to avoid adverse consequences of tight glycemic control, e.g. hypoglycemia [1A].

Some clinicians may translate patients' A1C level into their estimated average glucose level, based upon the work of the A1C Derived Average Glucose Study. This metric is also a valid tool that may be used to assess the response of patients to their diabetes treatment plan [1C].

Joslin's A1C target goal for most patients is consistent with that of the American Diabetes Association (ADA). Other expert panels, such as the American Association of Clinical Endocrinologists, suggest that the A1C target goal should be <6.5% in those newly diagnosed with diabetes and without comorbidities.

2.3 CAVEATS:

The A1C may not reflect glycemic control in special patient populations, including pediatric and geriatric populations, patients with anemia or other blood disorders resulting in rapid turnover of red blood cells, in chronic liver and kidney disease, following recent blood transfusions, or while patients are hospitalized. It is therefore important to interpret A1C results accordingly when determining treatment plans and goals.

2.4 MONITORING:

Monitor the A1C 2-4 times a year as part of the scheduled medical visit [1C] to evaluate efficacy of the treatment plan. The A1C may be checked more frequently if the treatment program requires revision, or the advice regarding behavior changes needs reinforcement. Having the A1C result at the time of the visit can be useful in making timely treatment decisions [1C]. Alternatively, the A1C may be performed prior to the medical visit POC method.

3 TREATMENT:

If A1C is ≥7% and <8%, or above the individualized goal, for 6 or more months:

- Review and clarify the management plan with the patient with special attention given to address:
    - Nutrition and meal planning, physical activity, medication administration, schedule, and technique, self-monitoring blood glucose (SMBG) schedule and technique, treatment of hypoglycemia and hyperglycemia, sick day management practices
- Reassess goals and adjust medication as needed [1A]
- Establish and reinforce individualized glycemic goals with patient
- Refer patient to a certified diabetes educator (CDE) for evaluation, diabetes self-management education (DSME), and support for ongoing consultation [1C]
- Consider referral to RD for medical nutrition therapy (MNT) [1B]
- Schedule follow-up appointment within 3-4 months or more frequently as the situation may dictate

If A1C is ≥8%:

- Review and clarify the plan as previously noted.
- Assess for psychosocial stress as a potential barrier to adequate response to treatment [1C]
- Establish and reinforce individualized glycemic goals with the patient
- Intensify therapy
- Refer patient to DE for evaluation, DSME, and support for ongoing consultation.
- Refer patient to RD for MNT [1C]

If the patient has a history of severe recurrent hypoglycemia or hypoglycemia unawareness:

- Assess for changes in daily routine such as reduced food intake or increased physical activity [1C]
- Refer to DE for evaluation, DSME, and hypoglycemia prevention; encourage family/friend attendance
- Review use of glucagon
- Consider revising A1C goal
- Discuss and reinforce goals with patient
- Adjust medications to minimize hypoglycemia risk [1B]
- If insulin-treated, consider use of a more physiologic insulin replacement program, such as basal/bolus therapy
- Consider and screen for other medical causes
- Consider referral for blood glucose awareness training, if available
- Consider use of continuous glucose monitoring [2B]
- Schedule follow-up appointment within 1-2 months. If history of recent, severe hypoglycemia, or change in pattern of hypoglycemia, recommend increase in frequency of communicating blood glucose levels to provider or DE.

3.1 SELF-MONITORING OF BLOOD GLUCOSE

SMBG is an important element of the treatment program for all individuals with diabetes. Its benefits are: to gauge treatment efficacy, to help in treatment design, to provide feedback on the impact of nutritional intake and activity, to provide patterns that assist in medication selection, and, for those on insulin, to assist in daily dose adjustments [1B]. SMBG should be performed with a glucose meter with proven accuracy as FDA approved glucose meters have substantial variability in accuracy.

3.1.1 GOALS:

Table 1: Goals for glycemic control for most individuals with diabetes are:

Fasting glucose	80 to130 mg/dl (4.4-7.2 mmol/L)
2-hour postprandial glucose	<180 mg/dl (9.9 mmol/L)
Bedtime glucose	90 to 150 mg/dl (4.9-8.3 mmol/L)

3.1.2 FREQUENCY:

The frequency of SMBG should be individualized, based on factors such as glucose goals, medication changes, use of continuous glucose sensor, and patient motivation. Most patients with type 1 diabetes (T1D) should monitor (using SMBG or a CGM device) at least 4 to 6 times per day. Some patients may need to monitor even more frequently.

Most patients using intensive insulin therapy should ideally monitor before meals and bedtime, prior to exercise, when they suspect hypoglycemia, after treating hypoglycemia, and prior to driving. In patients with T1D, there is a correlation between increased SMBG frequency and lower A1C. For patients with T2D, the frequency of monitoring is dependent upon such factors as mode of treatment and level of glycemic control [1C]. The results of SMBG must be integrated into a self-management plan to be effective.

Postprandial monitoring:

To obtain meaningful data for treatment decisions, it is helpful for the patient to monitor for several consecutive days). In addition to obtaining fasting and preprandial glucose levels, consider obtaining glucose readings 2 to 3 hours postprandial, as postprandial hyperglycemia has been implicated as an additional cardiovascular risk factor [1B].

Postprandial monitoring is particularly recommended for patients who:

- Have an elevated A1C but fasting glucose is at target
- Are initiating intensive insulin treatment programs
- Are making meal planning or activity adjustments

One-hour postprandial glucose monitoring is recommended:

- During pregnancy [1A]
- For those patients using alpha-glucosidase inhibitors.

Encourage the patient to provide SMBG results (written records or meter for downloading) to each visit for review with provider/educator.

3.1.3 USING ALTERNATE SITES TO MONITOR:

Blood glucose levels from sites such as the upper arm, forearm, and thigh may lag behind those taken from the fingertips, particularly when glucose levels are changing rapidly. Glucose levels may change rapidly with exercise, eating, or hypoglycemia, or after insulin administration. For this reason, alternate site monitoring is not recommended in the following situations:

- When the blood glucose may be changing rapidly
- For patients using intensive insulin treatment programs
- If hypoglycemia is suspected
- In patients with hypoglycemia unawareness

3.1.4 CONTINUOUS GLUCOSE MONITORING (CGM):

CGM measures interstitial glucose levels and correlates with plasma glucose levels. There are two types of CGM devices – real time CGM which continually report glucose levels and include high and low alarms and intermittently scanned CGM which communicates on demand and no automatic alarms. There are now three FDA approved CGM devices (DexCom 5, DexCom 6, and Free Style Libre) for making treatment decisions without SMBG confirmation, so-called non-adjunctive use. The Medtronic systems as well as Eversense sensor are indicated for adjunctive use with confirmatory fingerstick testing. However, confirmatory SMBG is recommended for all CGM devices when CGM reading does not

match symptoms or if user suspects reading may be inaccurate. Also, it is important to emphasize that all CGM systems are less accurate in the lower glucose range. For comparison of CGM systems, please see appendix 1. Use of CGM technology has been shown to decrease A1C in adults aged 25 years older using intensive insulin therapy along with CGM, compared with those using intensive insulin therapy with SMBG. The best predictor of A1C lowering was increased frequency of sensor use. CGM can be helpful in insulin-treated patients with hypoglycemia unawareness and/or frequent severe hypoglycemic episodes. CGM technology should be offered to all patients with type 1 diabetes and should be discussed with all patients on multiple insulin injections. Patients with insulin-treated diabetes aged more than 65 years who would benefit from CGM should also have access to it with insurance coverage. Intensive diabetes education and support are essential for optimal CGM implementation and ongoing use.

4 HYPOGLYCEMIA

4.1 CLASSIFICATION AND TREATMENT

Prompt action is recommended for the treatment of hypoglycemia. When possible, the patient should confirm symptoms with SMBG to document hypoglycemia. All patients with T1D should ensure that a family member/companion/caregiver knows how to administer a glucagon injection or nasal spray in the event that the patient is unable or unwilling to take carbohydrate orally [1C]. The International Hypoglycemia Study Group recently recommended that hypoglycemia be classified as:

Table 2: Hypoglycemia classification

Level	Glucose Threshold		Treatment
Level 1	Glucose :) <70 mg/dL (3.9 mmol/L)	sufficiently low for treatment with fast-acting carbohydrates	with 15-20 grams of carbohydrate (1/2 cup juice or regular soft drink; 3-4 glucose tabs) [1C]
Level 2	Glucose < 54 mg/dL (3.0 mmol/L)	Serious and clinically important hypoglycemia	consume 20-30 grams of carbohydrate [1C]
Level 3	severe hypoglycemia, no threshold	cognitive impairment requiring external assistance	glucagon and/or intravenous glucose [1C]

Caution patient to avoid alternate site monitoring with blood glucose meter when hypoglycemic.

If glucose at bedtime is less than 90 mg/dl in a patient at risk for hypoglycemia treat as mild hypoglycemia

- Treat with carbohydrates as in table 2
- Recheck blood glucose after 15 minutes [1B]
- Repeat hypoglycemia treatment if blood glucose does not return to normal range after 15 minutes [1C]
- Follow with additional carbohydrates if next meal is more than 1 hour away [1C]If hypoglycemia persists after 2 to 3 treatments, patient or companion should be instructed to contact their healthcare provider or seek emergency care
- For patients with hypoglycemia unawareness, the threshold for treatment of hypoglycemia needs to be individualized [1C]
- For patients using real-time CGM, check 15 minutes post treatment using a finger stick and not the sensor reading. Due to the physiologic lag between blood and interstitial glucose, the sensor will yield a lower result and can lead to overtreatment [1B]
- For patients with gastroparesis, treat hypoglycemia with oral glucose gel
- The patient's treatment plan should be revised if hypoglycemic events are frequent, or if they have hypoglycemia unawareness

4.2 EDUCATION:

- Instruct the patient to obtain and wear or carry diabetes identification
- Instruct patient to carry treatment for hypoglycemia at all times

- Instruct all patients with T1D, and patients with T2D who are at risk for hypoglycemia, to check blood glucose before operating a motor vehicle or other potentially dangerous equipment. In addition, advise them to check blood glucose regularly if driving for 1 or more hours. Hypoglycemia should be treated immediately, and patients should not drive until their blood glucose has reached and remained at a safe range for at least 30 minutes and/or until cognitive function is restored [1B]
- Identify potential causes of hypoglycemia to prevent its occurrence [1C]Be clear in communicating modified treatment goals in individuals with hypoglycemia unawareness
- Glucagon (injection or nasal) should be prescribed to all patients at increased risk for level 2 hypoglycemia. Education on its use should be provided to the patient and to their caregivers/household members/family members if possible. Care needs to be taken to ensure that glucagon kit has not exceeded expiration date.

5 DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT (DSME/S)

According to the National Standards for Diabetes Self-Management Education and Support (DSME/S), all people with diabetes should receive DSME/S to facilitate knowledge and to assist in implementing and sustaining self-care skills and problem-solving [1B]. Critical time points recommended for DSME/S are [1C]:

- At diagnosis
- Annually for assessment of education, nutrition and emotional needs
- When new complicating factors arise
- When transitions in care occur

Multiple visits with a DE are recommended to evaluate progress toward goals [1B]. Group education sessions are encouraged for cost effectiveness and efficiency of staff utilization. Group education is a benefit to patients as it allows them to share ideas and concerns and enables them to learn from one another [1B].

5.1 MEDICAL NUTRITION THERAPY (MNT)

Individuals with newly diagnosed diabetes should receive either individualized or group MNT, preferably by a registered dietitian nutritionist who is knowledgeable and skilled in providing diabetes-specific MNT. MNT delivered by a registered dietitian is associated with an A1C decrease of 0.3%-1% for those with T1D and 0.5%-2% for patients with T2D [1A]. Goals of MNT are to promote healthy eating patterns while addressing the unique nutrition needs of each patient based on their health condition, life stage, personal preferences, cultural background, health literacy, barriers to change, and ability to make changes in their eating habits. There is no one size fits all eating pattern, together the RD and the PWD should collaborate on an individualized healthy eating plan, rather than focusing on specific macronutrients or micronutrients.

Weight management is important for individuals with overweight and obesity living with diabetes. There is strong evidence that achieving and maintaining >5% (modest and sustained) weight loss is beneficial to the management of T2D and can delay the progression from prediabetes to T2D.

5.2 PHYSICAL ACTIVITY

- All adults should consult their healthcare provider and/or see an exercise physiologist to discuss a safe exercise program that is appropriate to their abilities [1C].
- Physical activity for healthy adults. Physical activity should be an integral component of the diabetes care plan to optimize glucose control, decrease cardiovascular risk factors, and achieve or maintain optimal body weight [1A].
- A moderate-intensity aerobic (endurance) physical activity minimum of 30 minutes 5 days (150 minutes) per week or vigorous-intensity aerobic physical activity for 75 minutes per week should be achieved unless contraindicated. Activity can be accumulated toward the 30-minute minimum by performing bouts, each lasting 10 or more minutes [1A]
- All adults should decrease the amount of time spent in daily sedentary behavior. Prolonged sitting should be interrupted with 3 minutes activity every 30 minutes for blood glucose benefits.

- A target of 300 min of moderate or 150 minutes of intense aerobic training and beyond for additional health benefits [1A]
- To increase lean body mass, full body resistance training should be incorporated into the activity plan 3 days per week. It should include upper-body, core, and lower-body strengthening exercises using free weights, resistance machines, or resistance bands [1B].
- Beginning training intensity should be moderate, involving 10 to 15 repetitions per set, with increases in weight or resistance undertaken with a lower number of repetitions (8-10) only after the target number of repetitions per set can consistently be exceeded; increase in resistance can be followed by a greater number of sets and, lastly, by increased training frequency
- Stretching exercises should be done when muscles are warm or at the end of the activity plan to loosen muscles and prevent soreness [1B]

For adults with medical or physical limitations, resistance training should be incorporated into the activity plan 3 days per week, as feasible, to increase lean body mass. It should include upper-body, core, and lower-body strengthening exercises using free weights, resistance machines, or resistance bands [1B]

Incorporate balance exercises to prevent falling and injury.

Functional Fitness Testing is useful to assess patients' functionality and track their progress. Testing such as the 6-Minute Walk Test, 2-Minute Step Test, Balance Assessment, and Hand Strength should be included at baseline and post intervention [1C]

5.2.1 RECOMMENDATIONS FOR HYPOGLYCEMIA MANAGEMENT WITH EXERCISE

Check BG before, during and after exercise, unless using CGM and tracking BG trend with exercise. Reduce bolus by 25-50% close to exercise/physical activity time, based on trial and error.

For those on a pump: reduce basal rate 30-50% at least 60min in advance, also for the duration of the exercise, while tracking BG trend. If not on a pump, long acting insulin may be reduced by 10-20% if necessary for long duration activities.

Target BG pre exercise will vary based on type of exercise, intensity and duration:

1. If performing aerobic activities that lead to hypoglycemia, start at BG of 150-200mg/dl. Value will vary based on individual basis.
2. If performing anaerobic exercise such as CrossFit, heavy weight lifting or other intense exercise, and BG increases through activity, pre exercise BG would be lower: 110-120mg/dl with the assumption that BG will raise.

It is important to replenish muscle glycogen. For long duration activities, patients are required to consume 20-60g of carbs/hr. This varies based on activity and BG response. Patients on sulfonylureas or glinides may also require adjustments of medications on days of exercise.

6 CARDIOVASCULAR HEALTH

(Also see sections on Lipids, Blood Pressure, Physical Activity, and Smoking)

6.1 ANTIPLATELET THERAPY:

In primary prevention: The role of a daily enteric-coated aspirin (ASA) (75-162 mg) is controversial and has been associated with increased risk of bleeding. It may be considered in patients at high risk for cardiovascular disease after discussion on associated benefits and risks [2A]. Patients at high risk for cardiovascular disease are men aged >50 years and for women>60 years of age with 1 or more of the following risk factors:

- Family history of premature* CAD or stroke
- Hypertension
- Current cigarette smoker
- Albuminuria
- Hyperlipidemia

In secondary prevention: Recommend a daily enteric-coated ASA (75-162 mg) or clopidogrel (75 mg, if aspirin-intolerant), or another agent of the class for anyone with 1 or more of the following [1A]:

- History of myocardial infarction (MI), angina, or documented CAD
- Vascular revascularization
- Non-hemorrhagic stroke
- Transient ischemic attack (TIA)
- Peripheral artery disease (PAD)

Possible contraindications for antiplatelet therapy may include allergy, bleeding tendency, anticoagulant therapy, recent gastrointestinal bleeding, and clinically active hepatic disease. Eye disease is usually not a contraindication for ASA therapy

**Premature: 1st-degree male relative aged less than 55 years; 1st-degree female relative aged less than 65 years.*

Recommend a P2Y12 receptor antagonist in combination with aspirin for at least 1 year in patients following an ACS. This could be either ticagrelor or clopidogrel if no percutaneous coronary intervention was performed and clopidogrel, ticagrelor, or prasugrel if a percutaneous coronary intervention was performed [1C]

6.2 OTHER THERAPEUTIC CONSIDERATIONS:

- Consider using beta-blockers in all patients with a history of MI or with documented CAD unless contraindicated [1A].
- Consider using angiotensin-converting-enzyme (ACE) inhibitors (or angiotensin receptor blockers [ARBs] if ACE inhibitors not tolerated) in patients with known CAD or cardiovascular risk factors and aged >55 years [1B].
- Thiazolidinediones (TZDs) (i.e., pioglitazone, rosiglitazone) are contraindicated in patients with heart failure defined as New York Heart Association (NYHA) classes III and IV [and conditions of fluid overload (i.e., congestive heart failure).*
- Consider recommending aerobic activity if not clinically contra-indicated and a weight-loss program if patient is overweight or obese. [1A]
- In the presence of cardiovascular disease or if age > 55 and multiple atherosclerotic cardiovascular risk factors, use or glucagon-like peptide 1 receptor agonists or sodium–glucose cotransporter 2 inhibitors with demonstrated cardiovascular disease benefit as part of the anti-hyperglycemic regimen and to reduce the risk of major adverse cardiovascular events 1B].* In the presence of heart failure, sodium–glucose cotransporter 2 inhibitors are preferred to reduce the risk of hospitalization for heart failure [1B]
  **(See Clinical Guidelines for pharmacologic management for more details)*

6.3 SCREENING ASYMPTOMATIC PATIENTS

Based on current research and understanding of CAD in diabetes, it is reasonable to screen patients with diabetes who [1C]:

- Complain of typical or atypical chest pain
- Have an abnormal electrocardiogram (ECG)
- Have a diagnosis of peripheral artery disease (PAD) or carotid artery disease
- Are aged >35 years with sedentary lifestyle about to start a rigorous exercise program

Currently, no strong evidence supports screening asymptomatic patients with T2D for silent myocardial ischemia [1C].

Patients with autonomic neuropathy may have increased risk of asymptomatic ischemia and therefore warrant careful attention [1B].

If stress testing is performed, either nuclear imaging or echocardiography with ECG monitoring is recommended. An exercise stress test is preferred, if resting ECG is normal and patient is able to exercise, because the response to exercise is an important prognostic factor. If the patient cannot adequately exercise, pharmacologic stress testing is warranted.

Computed tomography calcium scoring may improve cardiovascular risk assessment in people with type 2 diabetes.

6.4 LIPID MANAGEMENT:

Screening for lipid disorders:

Adults should be screened annually for lipid disorders with measurements of serum cholesterol, triglycerides, and low-density lipoprotein cholesterol (LDL-C) and high-density lipoprotein cholesterol (HDL-C), preferably fasting [1B].

Treatment:

- All patients should receive information about a meal plan designed to improve glycemic and lipid control, physical activity recommendations, and cardiovascular risk reduction strategies (with an emphasis on smoking cessation and blood pressure control). Consultation with appropriate education discipline is preferred [1A].
- Initiate therapy after abnormal values are confirmed.

All patients with any form of clinical diagnosis of atherosclerotic cardiovascular disease (ASCVD), or with LDL-C ≥ 190 mg/dl:

- Treat with maximally tolerated statin to reduce LDL-C to < 70 mg/dl [1A].
- Add ezetimibe if LDL-C goal not achieved [2 A].
- Add PCSK-9 inhibitor if LDL-C goal not achieved on statin + Ezetimibe [1B]. Consider cost/benefit concerns.
- Consider bempedoic acid, if LDL-C goal not achieved on statin + ezetimibe [2C] (caveat: ASCVD outcome trial in progress).

Patients aged 40 to 75 years without clinical evidence of ASCVD, with LDL-C 70-189 mg/dl: Treat with moderate intensity statin to reduce LDL-C by ≥30%. Consider high- intensity stain to achieve reduction of ≥ 50% if 1 or more of the following additional major risk factors are present [2A].

Calculate 10-year risk of ASCVD, if ≥20 %, using the American College of Cardiology/American Heart Association risk equation calculator http://tools.acc.org/ASCVD-Risk-Estimator-Plus [1B]

Family history of premature ASCVD

- High blood pressure
- Tobacco use
- CKD or albuminuria
- LDL-C ≥ 100 mg/dl-Consider addition of ezetimibe if ≥ 50% reduction in LDL-C not achieved with statin and 10-year ASCVD risk ≥20 %
- Consider bile acid sequestrants, if goal not achieved after statin and ezetimibe [2C]

In patients aged 20-39 years, consider statin if LDL-C ≥100 mg/dl and multiple ASCVD risk factors are present [2B]

In patients aged >75 years, it may be reasonable to begin statin therapy, based on potential benefits and risks, if multiple CV risk factors [2C]

Recheck lipids after drug initiation or dose escalation in 6 to 12 weeks. Thereafter, check lipids every 3 to 12 months to monitor adherence. May down-titrate statin dose if LDL-C <40 mg/dl

No evidence exists for benefits of statin therapy in patients on hemodialysis or those with heart failure (NYHA class II-IV) [1B]

Statins are contraindicated during pregnancy or if contemplating pregnancy.

Patients with LDL-C at goal and fasting triglycerides

≥150 mg/dl or HDL-C < 40 mg/dl in men, < 50 mg/dl in women:

Optimize glycemic control [1A]

Refer to RD for dietary modification and therapeutic lifestyle changes [1A]

Consider referral to an exercise specialist for an appropriate exercise regimen

Consider secondary causes and manage appropriately.

Recheck lipids within 6 to 12 weeks

In patients with fasting triglyceride levels 200 to 499 mg/dl and/or HDL-C <35 mg/dl after optimal statin therapy; calculate non-HDL-C, intensify statin if non-HDL-C not in goal before considering addition of a fibrate [2B]

Niacin or Fibrates to raise HDL-C not recommended [1B]

If triglycerides are persistently ≥500 mg/dl, initiate treatment with a very low-fat meal plan and with a fibrate for prophylaxis against acute pancreatitis; reassess lipid status when triglycerides <500 mg/dl [1B]

If fasting triglycerides remain ≥500 mg/dl after initiation of fibrate, consider the addition of fish oil (to provide 2 to 4 grams omega-3 fatty acids daily) or niacin [2B]

A highly purified ethyl ester of EPA (eicosapentaenoic acid) may have unique cardioprotective benefits in statin treated patients with fasting triglyceride ≥ 135- 499 mg/dl, with pre-existing ASCVD, or diabetes with multiple risk factors [1A]

6.5 BLOOD PRESSURE MEASUREMENT:

Check blood pressure (BP) at all routine visits after patient has been seated for at least 5 minutes. Use proper-size cuff and arm position. Postural BP (sitting, then standing) should be checked initially, and as clinically indicated:

In cases of known or suspected orthostatic hypotension (defined as a fall in systolic BP [SBP] of >20 mmHg or diastolic BP [DBP] of >10 mmHg within 3 minutes of standing)

In cases where standing upright is associated with lightheadedness, syncope, or signs of brain hypoperfusion [1C]

Initiate lifestyle changes if BP >120/80 mm/Hg

Consider initiating pharmacologic therapy if the average of 3 blood pressure measurements is ≥140/90 mmHg on 2 separate occasions. Schedule for follow-up blood pressure check within 1 month [1B]

6.5.1 Blood pressure targets:

BP goal for each patient aged >18 years is ≤140/90 mmHg [1B] The recent recommendation for achieving BP target of < 130/80 by the American College of Cardiology and others is controversial for most patients with diabetes and not endorsed by the Joslin Clinical Oversight Committee or the ADA.

SBP <130 mmHg may be appropriate for individuals without CVD or without multiple risk factors [1B]

No clear evidence exists for significant benefits to be gained by lowering SBP to <120 mmHg in those with coronary heart disease or multiple risk factors [1B]

BP goal for patients with albuminuria >300mcg/mg is <130/80 mmHg, if tolerated [1C]

Initial goal for patients with isolated systolic HTN (SBP >180 mmHg and DBP <80 mmHg) is a SBP <160 mmHg [2B] or < 140 mmHg if safely achieved.

Initial goal for patients with SBP 160-179 mmHg is to lower SBP by 20 mmHg. If well tolerated, lower BP goals may be indicated [1B]

6.5.2 TREATMENT:

- If SBP >140 mmHg or DBP >90 mmHg, a 3-month trial of lifestyle modification is warranted as follows [1C]:
- Counsel about meal plans, use of Dietary Approaches to Stop Hypertension (DASH), the DASH low- sodium diet, and sodium reduction in general. Also, counsel about physical activity, weight loss, alcohol use, and stress reduction
- Consider referral to RD for MNT
- Encourage home BP self-monitoring and providing documentation during clinic visits
- Instruct patient to have BP checked 2 times a week prior to the next appointment
- Follow-up with healthcare provider within 2 to 4 weeks
- Initiate or adjust therapy with antihypertensive agents as clinically indicated if BP remains above goal
- Studies have shown that aggressive management and control of BP may result in long-term benefits.

6.5.3 PHARMACOTHERAPY:

Efficaciousness is the most important consideration in choosing an initial antihypertensive drug. In that sense, any available antihypertensive drug can be an appropriate choice. However, other considerations (e.g., presence of albuminuria, coexisting CAD, cost) may dictate a preference for an ACE inhibitor, ARB, calcium channel blocker, or thiazide-type diuretic [1A]. In general, ACE inhibitors and ARBs should not be used in combination.

Consider ACE inhibitors or ARBs for patients with persistent urine albumin/creatinine ratio >30 mcg/mg. These drugs require monitoring of serum creatinine and K+ within 1 week of starting therapy and periodically thereafter [1A].

ACE inhibitors/ARBs are contraindicated during pregnancy or if contemplating pregnancy.

Manage resistant hypertension, defined as BP that remains above goal despite concurrent use of 3 antihypertensive agents of different classes (1 of which should be a diuretic. All should be at maximum dose tolerated)

7 KIDNEY HEALTH

7.1 SCREENING FOR KIDNEY HEALTH:

7.1.1 CREATININE AND EGFR:

- Measure serum creatinine at least annually to estimate glomerular filtration rate (eGFR) regardless of degree of urine albumin excretion.) [1C]Measure eGFR using chronic kidney disease epidemiology (CKD-EPI) calculation. If eGFR is <60 ml/min, evaluate for complications of kidney disease (anemia, hyperparathyroidism, acid base status, and vitamin D deficiency).

7.1.2 URINE ALBUMIN:

- Screen for albuminuria by checking urine albumin/creatinine (A/C) ratio as follows:
    - Patients with T1D within 5 years after diagnosis and then yearly [1C]
    - Patients with T2D at diagnosis (after glucose has been stabilized) and then twice yearly [1C]
- Annually in all patients up to age 70 years [2C]As clinically indicated in patients aged >70 years. Albuminuria is recognized as a major independent risk factor for CAD in patients with diabetes. Albuminuria may be measured with a spot or timed urine collection. Spot urine is preferred for simplicity. Continue use of routine urinalysis as clinically indicated [2C].Patients should be advised that BP control, glycemic control, and management of albuminuria may slow the progression of CKD.
    - Consider testing first morning urine

7.2 EVALUATION AND TREATMENT OF DIABETES KIDNEY DISEASE (DKD)

If A/C ratio <30 mcg/mg or timed urine albumin <30 mg/24 hours: recheck in 1 year

If A/C ratio 30-299 mcg/mg or timed urine albumin 30-299 mg/24 hours:

- Confirm presence of albuminuria with at least 2 of 3 positive collections done within 3-6 months.
- Rule out confounding factors that cause a false positive, such as urinary tract infection, pregnancy, excessive exercise, menses, or severe hypoglycemic event [1C]
- Consider consult with nephrologist for blood pressure control, successive increases in albumin and eGFR <30 mL/min/1.73m^2,[2C]
- Once DKD confirmed:
    - Valuate BP and initiate/modify aggressive blood pressure treatment to achieve a BP of <130/80 mmHg [2B]
    - Recommend that patient self-monitor BP with portable cuff and maintain a record/log. The monitoring schedule should be determined with the health- care provider and is based on patient circumstance
    - Strive to improve glycemic control with an optimal goal A1C of <7% or as otherwise clinically indicated [1A]
    - Initiate/modify ACE inhibitor or ARB treatment if albuminuria persists. Check K+ and creatinine about 1 week after making these medication changes [1A]
    - Repeat A/C ratio at least every 6 months. Consider increase in frequency when changes in medication are made [2C]

If A/C ratio≥300 mcg/mg (≥300 mg/24 hours) or persistent albuminuria presents (positive dipstick for protein or ≥30 mg/dl):

- Follow all guidelines as stated for A/C ratio 30-300 mcg/mg
- Evaluate for patient adherence, with emphasis on avoidance of high sodium and of very high protein intake
- Consider referral to RD for MNT
- Refer to nephrologist to:
    i. Assess cause(s) of impaired kidney function, including assessing for DKD
    ii. Maximize therapies aimed at slowing progression of kidney disease (e.g., BP control; reduction of urine protein level)
    iii. Treat complications of kidney disease (hyperphosphatemia, anemia, etc.)
- Evaluate any rapid rise in serum creatinine, abnormal sediment, or concomitant hematuria, or sudden increase in albuminuria
- Assess side effects with ACE inhibitor/ARB use and difficulties in management of high BP or hyperkalemia

Recent studies show that SGLT2 inhibitors may be used as adjuvant therapy to decrease proteinuria and slow CKD progression in individuals with DKD already on RAAS blockade therapy with ACE inhibitor or ARB. This benefit was seen beyond the glucose lowering effect at GFR 30-60 ml/min with significant proteinuria (>UACR 300 mg/gr) [2A]

8 OCULAR HEALTH

8.1 SCREENING FOR EYE DISEASE:

Refer patient for comprehensive dilated eye exam or validated retinal imaging to determine level of retinopathy.

- T1D: initial eye exam at start of puberty or once patient is 10 years of age or older, whichever is earlier, within 3 to 5 years of diagnosis. Annual eye exam thereafter [1A]
- T2D: at diagnosis and annually thereafter [1A]
- Pregnancy in woman with preexisting diabetes: several exams, including prior to conception; during first trimester; follow-up during pregnancy as determined by first-trimester exam; and 6 to 12 weeks postpartum [1B]

- For physiologic insulin therapy (pump therapy or multiple daily injections): Consult with patient's eye care provider or evaluate retinal status with validated retinal imaging to determine level of retinopathy and appropriate follow-up care prior to initiating physiologic insulin therapy [1A]

8.2 TREATMENT:

- Aggressively treat known medical risk factors for onset and progression of retinopathy:
- Strive to improve glycemic control with optimal A1C goal of <7% [1A]
- Monitor eye disease carefully when intensifying glycemic control [1A]
- Strive for BP <130/80 mmHg [1B]
- Treat albuminuria [1B]
- Strive to maintain total cholesterol, LDL-C, HDL-C, and triglyceride levels as per the recommendations outlined in the Lipids section of this guideline [1A]
- Treat anemia [1B]
- Activity programs that involve strenuous lifting; harsh, high-impact components; or activities that place the head in an inverted position for extended periods of time may need to be revised depending on the level of retinopathy.
- Reinforce follow-up with eye-care provider for any level of retinopathy, including no apparent retinopathy. The frequency of follow-up is dependent upon the level of retinopathy and presence of risk factors for onset and progression of retinopathy and is determined by the eye care provider.

8.2.1 For high-risk proliferative diabetic retinopathy, prompt scatter (panretinal) laser photocoagulation and/or intravitreous injection of vascular endothelial growth factor (VEGF) inhibitor is generally indicated [1A]

8.2.2 For central involved diabetic macular edema (ci DME):

- Intravitreous injection of vascular endothelial growth factor (VEGF) inhibitor and/or focal/grid laser photocoagulation is generally indicated regardless of level of retinopathy [1A]

8.2.3 The level of diabetic retinopathy and diabetic macular edema (DME) generally determines follow-up [1A]. See suggested follow-up time spans in table 3. The presence of known risk factors for onset and progression of retinopathy may suggest follow-up at shorter intervals for all levels of retinopathy.

Table 3: Eye exam follow-up schedule

	Follow-up	
Level of diabetic retinopathy	Without DME	With DME
None	12 months	
Mild Nonproliferative Diabetic Retinopathy	12 months	monthly if undergoing anti-VEGF treatment; otherwise, 3 to 4 months*
Moderate Nonproliferative Diabetic Retinopathy	6-9 months	monthly if undergoing anti-VEGF treatment; otherwise, 3 to 4 months*
Severe-to-Very Severe Nonproliferative Diabetic	3-4 months**	monthly if undergoing anti-VEGF treatment; otherwise, 3 to 4 months*

Retinopathy		
Proliferative Diabetic Retinopathy Less Than High-Risk	1 week to 3 to 4 months	1 week to 1 month if undergoing anti-VEGF treatment; otherwise, 3 to 4 months*
High-Risk Proliferative Diabetic Retinopathy	scatter (panretinal) laser photocoagulation and/or intravitreous injection of VEGF inhibitor is generally indicated with follow-up in 1 month and monthly thereafter if undergoing VEGF inhibitor treatment or 3 months if undergoing laser photocoagulation	

**Focal laser surgery and/or intravitreous VEGF inhibitor injection is generally indicated for central involved macular edema. If receiving VEGF inhibitor treatment, follow-up is generally monthly.*
***Scatter laser photocoagulation and/or intravitreous injection of VEGF inhibitor may be indicated, especially for T2D or T1D of long duration*

9 NERVOUS SYSTEM HEALTH

9.1 SCREENING FOR NEUROPATHY

9.1.1 METHODS:

- Ask patient about loss of sensation in the limbs, symptoms of pain, tingling, paresthesia, weakness, or gait instability.
- Evaluate feet for sensation using a 128 Hz tuning fork and Semmes-Weinstein 5.07 monofilament [1B]
- Evaluate reflexes
- Laboratory screening with complete blood count, lipid panel, thyroid panel, B12 level (methylmalonic acid and/or homocysteine if low-normal B12), and serum and urine protein electrophoresis, as clinically indicated
- Neurophysiologic testing (electromyogram, nerve conduction studies, or skin biopsy analysis of intra-epidermal nerve fiber density) should be considered in atypical cases
- Assess for symptoms of autonomic neuropathy such as erectile dysfunction, gastroparesis, or postural hypotension. If symptoms of autonomic neuropathy are present, refer for evaluation by formal autonomic testing (including heart rate variability testing, blood maneuver, and the blood pressure response to upright tilt table testing or standing) [1B]

9.1.2 FREQUENCY:

- For patients with T1D and T2D without complications, conduct symptom and examination screen at time of diagnosis and at least annually [1C]
  *For “at-risk patients,”conduct symptom and examination screen at all routine interval visits [1C]
- Laboratory screening at the time of diagnosis of diabetes or with change in symptoms or examination [1C]
- Screen for cardiovascular autonomic neuropathy at the time of diagnosis of T2D, or 5 years after diagnosis of T1D. Screening should be repeated yearly or with development of symptoms [1C]. If symptoms of autonomic neuropathy are present, refer for evaluation by formal autonomic testing (including heart rate variability testing, blood pressure and heart rate response to a Valsalva maneuver, and the blood pressure response to upright tilt table testing or standing) [1B]

Neurophysiologic testing only for atypical cases [1C]

* For “At-risk patients” include patients who smoke; who have vascular insufficiency, neuropathy, retinopathy, nephropathy, structural deformities, infections, skin/nail abnormalities, or a history of ulcers or amputations; who are on anticoagulation therapy; or who cannot see, feel, or reach their feet.

9.2 TREATMENT:

- For patients with acute problems or who are “at risk”, consider referral to neurologist for:
- Atypical neuropathy
- Rapidly progressive symptoms
- Severe pain unresponsive to first-line therapy
- Weakness suggestive of diabetic amyotrophy For patients with symptoms related to diabetic peripheral or autonomic neuropathy:
- Consider medications, because they improve quality of life [1A]

10 FOOT HEALTH

10.1 INITIAL SCREENING SHOULD INCLUDE: (TABLE 4)

- Questions about loss of sensation in the limbs, or symptoms of pain, including claudication, tingling, or other paresthesia
- Foot evaluation for sensory function (Semmes-Weinstein 5.07 monofilament and 128 Hz tuning fork) [1B]
- Evaluation of reflexes, skin and soft-tissue integrity, nail condition, callus formation, pedal pulses and structural deformities.
- Examination of shoes for wear and appropriateness

Table 4: Foot Exam

Evaluation / Risk	Blood flow	Neurological status	Musculoskeletal abnormalities or lesions
Low (3 out of 3)	Normal	Intact	None
Moderate (1 out of 3)	Diminished	Abnormal Semmes-Weinstein or vibratory sensation	Any (bunions, hammertoes, without calluses, corns…)
High (2 out of 3)	Absent	Abnormal Semmes-Weinstein and vibratory sensation	Any prior history of ulcerations Presence of prior amputations

10.2 FREQUENCY:

For patients with T1D and T2D without complications or significant risk factors, conduct foot screen at time of diagnosis and at least annually thereafter [1C]

For “at-risk patients,”* check feet at all routine interval visits [1C]

Evaluate pedal pulses, skin integrity including swelling, skin color and temperature, callus formation, structural deformities.

*“At-risk patients” include patients who smoke; who have vascular insufficiency, neuropathy, retinopathy, nephropathy, structural deformities, infections, skin/nail abnormalities, or a history of ulcers or amputations; who are on anticoagulation therapy; or who cannot see, feel, or reach their feet.

10.3 TREATMENT:

For patients with non-acute problems or who are “at moderate or high risk”:
Refer to podiatric physician for ongoing foot care and evaluation [1B]
Refer to DE for foot care training** [1C]
Consider referral to neurologist for:

atypical neuropathy
rapidly progressive symptoms
severe pain unresponsive to first-line therapy
weakness suggestive of diabetic amyotrophy
For current ulcer or infection** [1C]
** Mild ulcer or infection is characterized by: (a) superficial lesion (no foul odor), (b) no significant ischemia, (c) no bone or joint involvement, (d) no systemic toxicity, (e) minimal or no cellulitis (<2 cm)
For plantar ulcers, instruct patient to remain nonweight-bearing
Apply local dressings with topical antiseptic
Instruct patient to keep foot dry
Consider baseline x-ray to evaluate for bone integrity and possible osteomyelitis
Consider systemic antibiotic therapy
Refer to podiatric physician for further evaluation and definitive treatment
Refer to DE for foot-care training
Ensure follow-up appointments are kept
For limb-threatening*** ulcer or infection [1C]:
***Limb-threatening ulcer or infection is characterized by
deep ulcer, (b) bone or joint involvement, (c) gangrene, (d) lymphangitis, (e) cellulitis (>2 cm), (f) systemic toxicity, (g) significant ischemia, (h) no social support system, (i) immunocompromised, (j) foul odor in ulcer.
Osteomyelitis is presumed to be present if able to probe through the ulcer to the bone.
[1B]
Urgent hospitalization for systemic antibiotics
Consult a podiatric physician or vascular surgeon for immediate evaluation and treatment

10.4 PREVENTION;

Foot care training should address:
Avoidance of foot trauma
Daily foot inspection
Nail care
Callous formation
Proper footwear
Impact of loss of protective sensation on morbidity
Need for smoking cessation
Action to take when problems arise
Importance of glucose control on disease progression

11 ORAL HEALTH

Periodontal disease is associated with suboptimal diabetes control and may be a risk factor for cardiovascular disease. There is mixed evidence on the impact of treatment of periodontal disease on glycemic control. Referral to a dentist should be considered an essential component of a comprehensive diabetes care plan. At initial visit and annually, discuss need for dental cleaning at least every 6 months [1C]

Refer to dental specialist for oral symptoms and findings such as sore, swollen, or bleeding gums, loose teeth, or persistent mouth ulcers [1C]

If edentulous, refer to dental specialist for restoration of functional dentition

11.1 BEHAVIORAL HEALTH

11.2 BEHAVIORAL HEALTH

Psychosocial evaluation should be an integrated component of the initial assessment and the ongoing care of all patients with diabetes. Behavioral health intervention should be strongly considered in the following situations:

- Newly diagnosed diabetes: Assess the following [1C]:
    - Ability to cope with the diagnosis and follow the new treatment regimen (ex. medication , BGM, CGM, diet changes, exercise)
    - Potential psychosocial barriers to treatment and self-management (behavioral, developmental, social, economic)
    - Cultural background and practices (ex. beliefs about medicine, diabetes, dietary practices)
    - Presence of coping skills for living with the emotional impact of diabetes
    - Level of family and social support
    - Non-diabetes related life stressors
- Ongoing care: During times of significant stress or transition (ex. hospitalizations, intensification in treatment regimen, significant life change, problems with self- management, significant deterioration in glycemic control, newly diagnosed complications, onset of mental health/behavioral health condition). Assess the following:
    - Ability to follow the treatment regimen
    - Psychosocial barriers to treatment and self-management
    - Coping skills for living with the emotional impact of living with diabetes. (ex. diabetes burnout and distress: consider using PAID as a screening tool)
    - Level of family and social support (ex. assess for family conflict, diabetes police, positive and negative supports)
    - Fear of hypoglycemia: consider referral for blood glucose awareness training
    - Non-diabetes life stressors
    - Depression: consider using PHQ-9 or PHQ-2 as a screening tool
    - Anxiety
    - Disordered eating/eating disorder: consider inquiry about insulin omission or bingeing if A1c>9% or recurrent DKA
    - Substance abuse: consider use of CAGE (alcohol screening tool)

Consider making a referral to a behavioral and mental health counselor familiar with the challenges of living with diabetes if patients are struggling with a new diagnosis or during follow-up care. Patients may also benefit from a support group or a psychopharmacological evaluation. Patients using second generation or atypical antipsychotic medications should be monitored for weight gain with resulting increases in glucose, lipid and blood pressure levels

12 WOMEN'S HEALTH

(Refer to Joslin Guideline for Detection and Management of Diabetes in Pregnancy [Chapter 3]).

All women of reproductive age should be assessed for the possibility of pregnancy prior to initiating new medications, and they should be counseled on potential risks to the developing fetus.

Counsel women with the potential for conception about contraception use and relationship of blood glucose control to fetal development and pregnancy outcomes [1C]

At initial and annual visit, discuss sexual function

Assess for infectious, hormonal, psychological, or structural etiologies if dysfunction exists

Refer to specialist as indicated [1C]

Follow appropriate guidelines for pap/pelvic and mammography screening for primary care patients [1B]

Individualize approach to bone health for women with risk factors for osteoporosis, including surgical and natural menopause [1B]

Ensure adequate intake of calcium and vitamin D

13 MEN'S HEALTH

At initial and annual visit, discuss sexual function and any fertility concerns

Assess for hormonal, psychological, or structural etiologies if dysfunction exists [1C]

For men with type 2 diabetes, consider screening for low testosterone [1B]

Screen for total testosterone and sex- hormone–binding globulin

Refer to specialist as indicated

14 ADDITIONAL CONSIDERATIONS

14.1 TOBACCO DEPENDENCE:

- Screen: Assess patient's use of tobacco and e-cigarettes at initial and follow-up visit
- Treatment:
    - Discuss rationale for and strongly recommend smoking cessation [1A]
    - Review options available to assist in smoking cessation, including medications and cessation programs [1B]

14.2 IDENTIFYING SLEEP DISORDERS:

At initial visit and annually, inquire about sleep quality, level of fatigue, and symptoms such as snoring and restless sleep [1C].

Obstructive sleep apnea is more frequent in the setting of central obesity and is a risk factor for ASCVD

Refer for sleep study if indicated

The evidence surrounding the impact of sleep apnea treatment on diabetes control has been so far inconclusive

Pay special attention to shift workers. An individualized care plan should be tailored to their schedules, and the effect of shift work on glycemic control should be assessed at each visit

14.3 IMMUNIZATIONS:

Recommend the following vaccines:

- Influenza vaccine: yearly for all adult patients with diabetes [1B]
- Pneumococcal vaccine with pneumococcal polysaccharide vaccine (PPSV23): once for all patients with diabetes [1B]:
    - Patients > 65 years of age should receive pneumococcal conjugate vaccine (PCV13) at least 1 year after vaccination with PPSV23, followed by a 1-time revaccination if they received the previous dose > 5 years earlier [1C]
    - Repeat vaccination should be considered for those with nephrotic syndrome, chronic kidney disease, and other immuno- compromised states
- Hepatitis B Vaccine 3-dose series: for unvaccinated adult patients with diabetes (age 19-59 years) [1C]. May also consider for unvaccinated adults > 60 years [2C]
- Shingrix (recombinant zoster vaccine) 2-dose series: for all adults 50 years or older with diabetes unless contraindication or precaution exists. [1B]

Working group: Joanna Mitri, MD, MS, Om P. Ganda, MD, Richard Beaser, MD, Deborah Butler, MSW, LICSW, CDE, Jerry Cavallerano, OD, PhD, Christopher Gibbons, MD, John Giurini, DPM, Medha Munshi, MD, Aliza Phillips-Stoll, PhD, Sylvia Rosas, MD, MSCE, Cara Schrager, MPH, RD LDN, CDE, Jacqueline Shahar, MEd, RCEP, CDE, William Sullivan, MD

Joslin Clinical Oversight Committee	
Om Ganda, MD – Co-chair Joanna Mitri, MD, MS Co-chair Richard Beaser, MD Jerry Cavallerano, OD, PhD Nuha El Sayed, MD, MMSc. Lori Laffel, MD, MPH	Medha Munshi, MD Jo-Anne Rizzotto, MEd, RD, CDE Sylvia Rosas, MD Susan Sjostrom, JD William Sullivan, MD Robert Gabbay,MD, *ex officio*

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Joslin Diabetes Center

Continuous Glucose Monitoring (CGM) Comparison Sheet

Features	Abbott FreeStyle Libre www.freestylelibre.us	Dexcom G5™ www.dexcom.com	Dexcom G6™ www.dexcom.com	Guardian Connect www.medtronicdiabetes.com	Eversense www.senseonics.com
Startup initialization time	1 hour	2 hours	2 hours	35 min up to 2 hours	24 hours
Sensor Life	14 day	7 day	10 day	7 day	≤ 90 days
Calibration	Factory calibrated	Every 12 hours	Factory Calibrated	Every 12 hours, optimally 3-4 times per day	Every 12 hours
Displays rate of change	Only when scanned	Yes		Yes	Yes
Predictive/Rate of change alarms	No	Yes		Yes (10-60 min predictive)	Yes
Alarm features	No	Audible and vibrate alarms. May be set at different levels.		Audible and vibrate alarms. May be set at different levels.	Yes – Audio and Vibrate on smartphone also via smart transmitter on-body vibrate alerts
Batteries	No	Receiver- internal rechargeable battery (holds up to 5 days of charge) Transmitter-warranty for 3 months		Transmitter- 7 day rechargeable battery, warranty for 1 year	No, smart transmitter rechargeable
Computer Software	LibreVew	Dexcom Clarity		Medtronic Carelink	Eversense DMS (home version)
Sites	Back of the arm	Abdomen, hips (<18 yr.)		Abdomen, back of arm	Back of upper arm
Drug Interference	Ascorbic acid Vit C falsely raises salicylic acid falsely lowers	Acetaminophen- can falsely elevate sensor values	None	Acetaminophen and paracetamol- can falsely elevate sensor values	Antibiotics of tetracycline class may cause falsely lower readings
Visualization	Reader and/or Smartphone (iPhone)	Receiver and/or Smartphone		Smartphone (iPhone)	Smartphone
Event Marker	Yes	Yes		Yes	Yes
Communication	Nearfield Technology	Bluetooth		Bluetooth	Bluetooth
MARD **FDA Approval**	≥ 18yrs. 10.0%	≥2 yrs. 9%	≥2 yrs. 9%	≥7 yrs. 10.6%	≥ 18 yrs. 8.5%
Communication with smartphone	Yes-iPhone 7 or later and Android OS 5.0 or later FreeStyle LibreLink	Yes – iPhone, iPad, iPod and some Android Clarity Mobile App		Yes – iPhone Guardian Connect App Sugar IQ	Yes, IOS and Android Eversense Mobile App
Share Capability	Yes for both 10 and 14 day LibreLinkUp App	Yes - iPhone and some Android		Yes, limited, text message only	Yes, Eversense NOW remote monitoring app
Out of pocket cost	Reader $75-$85, Sensors no more than $75/month	Receiver $599, Transmitter (2) $599, Sensors $349/box, $1047/3 boxes	Receiver $365, Transmitter(2) $475, Sensors (3 boxes) $1047	Starter Kit (transmitter) - $775 Sensors $1659 – 3 boxes	Sensor - $850-1000/quarterly Transmitter - $550-800/annually Initial Sensor Placement -$150-300 Sensor Removal and new sensor placement - $250-400
Insertion	Self – one button inserter	Self – multi-step inserter	Self – one button inserter	Self – one button inserter	In clinic by provider