This care process model (CPM) was created by the Diabetes Prevention and Management Development Team, a committee of the Primary Care Clinical Program at Intermountain Healthcare (Intermountain). It summarizes current medical literature and, where clear evidence is lacking, provides expert advice on diagnosing and treating diabetes. It provides clinicians with treatment goals and interventions that are known or believed to favorably affect health outcomes for adult patients with diabetes.

What’s New IN THIS UPDATE?

The primary changes to the 2015 ADA Standards are outlined below:

- **Statin treatment recommendations are now driven primarily by cardiovascular risk status, not by LDL level.** The 2015 Standards support the 2013 American College of Cardiology/American Heart Association guidelines on blood cholesterol. See page 20.

- **The recommended goal for diastolic blood pressure changed from 80 mm Hg to 90 mm Hg,** to better reflect evidence from randomized clinical trials. Lower diastolic targets may still be appropriate for certain individuals. See page 22.

- **Additional medication for glycemic control — SGLT2 inhibitors.** The type 2 management algorithm was updated to include this recent class of drugs. See page 13.

- **New emphasis on limiting sedentary time.** The physical activity section was revised to reflect evidence that all individuals, including those with diabetes, should limit time being sedentary. See page 9.

- **New screening recommendations for Asian Americans.** The BMI cut point for screening Asian Americans was changed to 23 kg/m² (vs. 25 kg/m²) to reflect evidence that this population is at increased risk for diabetes at lower BMI levels relative to general population. See page 5.

- **Diabetes in remission.** A new sidebar discusses the definition and treatment recommendations for patients whose glycemic measures have fallen below diagnostic thresholds. See page 9.
Why Focus ON DIABETES?

• Diabetes is a growing problem. The estimated number of Americans with diabetes increased from 12.1 million in 2002 to 17.5 million in 2007 to 23.5 million in 2012.\textsuperscript{HER} The CDC projects that by 2050, as many as 33% of U.S. adults could have diabetes.\textsuperscript{CDC1}

• The healthcare cost burden is high and increasing. The American Diabetes Association estimated the economic burden of diabetes in 2012 at $245 billion. This is a 41% increase over 2007.\textsuperscript{ADAE} It’s estimated that within the next decade, spending will rise to almost $500 billion, or 10% of total health spending.

• Late diagnosis negatively affects outcomes. Better screening and early diagnosis of diabetes is crucial to improving patient outcomes. Many patients with type 2 diabetes develop complications just before or immediately after a diagnosis is made. Approximately one-fourth of type 2 diabetes cases may be currently undiagnosed.\textsuperscript{ADA}

• Good management can preserve and improve quality of life. Uncontrolled diabetes can result in catastrophic health problems including heart disease, stroke, blindness, kidney disease, nervous system disease, amputations, dental disease, and pregnancy complications. Managing diabetes following the recommendations set forth in this CPM can help delay or prevent these complications.

TREATMENT GOALS & MEASURES

\begin{table}[h]
\centering
\begin{tabular}{ |l|c| }
\hline
\textbf{Measure} & \textbf{GOAL} \\
\hline
\textbf{HbA1c} (test at least every 6 months) & <7.0%* \\
\hline
\textbf{Blood pressure} (check at each office visit) & <140/90 mm Hg* (lower in some) \\
\hline
\textbf{Foot exam} (perform at least every year — every visit if abnormal) & Normal \\
\hline
\textbf{Statin medication} & Taking statin medication at appropriate level of intensity \\
\hline
\textbf{Urine albumin/creatinine ratio} (test at least every year) & <30 mg albumin/g of creatinine \\
\hline
\textbf{Serum creatinine} (every year, estimate GFR) & Normal \\
\hline
\textbf{Retinal or dilated eye exam} (check every year, or every 2 years if diabetes is well controlled) & Normal \\
\hline
\end{tabular}
\end{table}

\textsuperscript{*}Although these blood glucose and blood pressure goals are recommended generally for most people with diabetes, we also recommend individualizing these goals. See the sidebar discussions on page 6 (HbA1c goal) and page 23 (blood pressure goal).

Throughout this CPM the \includegraphics{icon} icon indicates places where data is collected about each patient.
SCREENING AND DIAGNOSIS

Timely, accurate screening and diagnosis is important because it can:

- **Identify those at risk for diabetes.** Therapeutic lifestyle changes may delay or prevent development of diabetes in people with prediabetes.
- **Prevent or delay diabetes complications.** The length of time between the onset of hyperglycemia and appropriate treatment for the condition can be a significant factor in the development and severity of complications. Type 2 diabetes is often asymptomatic, and at the time of diagnosis a significant number of type 2 patients already have complications such as nephropathy, neuropathy, or retinopathy.
- **Identify those at risk for other causes of hyperglycemia.** Hyperglycemia can be chronic, pathogenic, asymptomatic, and can be caused by conditions other than diabetes. Screening for hyperglycemia can also detect patients at risk for complications from vascular, neurological, and renal conditions.

Screening

This CPM recommends:

- **Routine screening for type 2 diabetes.** Note that in addition to testing the patients specified in the algorithm on page 4, physicians should consider testing adults older than age 30 every 3 to 5 years. This is a cost-effective strategy; the benefits of early detection of type 2 diabetes include a reduced incidence of myocardial infarction and microvascular complications.\(^{6,11}\)
- **No routine screening for type 1 diabetes.** People with type 1 typically present with acute symptoms and markedly elevated blood glucose, and most cases are diagnosed soon after the onset of hyperglycemia.

For pregnant patients, routine screening for gestational diabetes is recommended per the Intermountain care process model *Management of Gestational Diabetes*.

Diagnosis

Recommended diagnostic tools for type 2 diabetes include:

- **Hemoglobin A1c (HbA1c).**\(^{6A}\) HbA1c measurement does not require the patient to fast or undergo a glucose tolerance test, and the required specimens are stable at room temperature. Further, the results are not affected by intercurrent illness or stress and correlate with the development of subsequent retinopathy. Limitations of this test are that HbA1c’s normal range is modestly higher in certain ethnic groups (e.g., African-Americans, Asian Indians) and it increases with age. HbA1c is elevated in patients with untreated hypothyroidism, and among U.S. adults with diabetes it tends to be slightly higher in winter.\(^{15}\) False negative values can occur in patients with rapid red cell turnover, some anemias, and recent onset of diabetes.
- **Fasting plasma glucose (FPG).** The FPG is more convenient for patients, more reproducible, less costly, and easier to administer than the 2-hour OGTT.
- **Other acceptable diagnostic tests include a two-hour, 75-gram oral glucose tolerance test (OGTT).** This test may be required when evaluating patients with impaired fasting glucose (IFG) or if diabetes is still suspected despite a normal FPG or HbA1c result.

Diagnostic criteria for diabetes are listed in note (d) on the algorithm on the following page. Note that in the absence of unequivocal hyperglycemia, repeat testing is required to make a diagnosis of diabetes.\(^{6A}\) In an outpatient with new onset of hyperglycemia, causes of hyperglycemia other than diabetes should be considered. The differential diagnosis of hyperglycemia includes type 1 and type 2 diabetes, Cushing’s syndrome, electrolyte abnormalities, acromegaly, pheochromocytoma, and pancreatic cancer.

**PROFILES: TYPE 2, TYPE 1, LADA**

Most new diabetes patients over the age of 30 will have type 2. Nevertheless, when the type of diabetes is uncertain by clinical presentation, we recommend antibody testing. Key considerations:

**Type 2:**
- Onset is usually slow.
- Occurs mainly in older adults, but can occur in children.
- Common features at diagnosis are obesity, insulin resistance, and neuropathy.
- Family history usually includes a first-degree relative with type 2 diabetes.
- Condition usually responds to oral medications for years.

**Type 1:**
- Onset is usually rapid (over the course of days or weeks).
- Occurs primarily in children and younger adults.
- Common features at diagnosis are DKA, recent weight loss, and insulin deficiency.
- Family history including a first-degree relative with diabetes is less common.
- Condition requires insulin from onset.

**LADA** (latent autoimmune diabetes in adults):
- Onset is slow.
- Occurs in adults age 30 and older (does not occur in children).
- Prevalence among patients with adult-onset diabetes is about 10%.\(^{6W}\)
- In LADA patients, glutamic acid decarboxylase (GAD) antibodies are present close to 90% of the time, with only a small additional fraction of patients having other autoantibodies.\(^{6W}\)
- In comparison to diabetic patients without autoantibodies, LADA patients are more often female, younger at diagnosis, have a smaller waist circumference (are overweight but not obese), and do not exhibit DKA.
- Family or personal history often includes autoimmune disorder.
- Condition may initially respond to oral medications and other therapies, but will eventually require insulin.

**To order antibody testing:**
- GAD antibody: ARUP # 0070211, Sunquest code GADAB, CPT 83519
- If GAD is negative, then order insulinoma associated-2 antibodies and/or Zinc transporter 8 antibodies
ALGORITHM: SCREENING AND DIAGNOSIS

Patient appropriate for SCREENING or with symptoms (a)

TEST by measuring one of the following:
• Plasma glucose (not capillary glucose): FPG or 2-hour OGTT
• HbA1c

In the absence of unequivocally elevated blood glucose, REPEAT same or alternative test using a new blood sample

NORMAL
• HbA1c <5.7%
• FPG <100 mg/dL
• 2-hour OGTT <140 mg/dL

• EDUCATE on lifestyle management
• REPEAT TESTING every 3 years for: (a)
  – all adults age ≥45 OR
  – adults of any age if overweight and ≥1 other risk factors

ABNORMAL (b) but below diagnostic threshold
• HbA1c 5.7%–6.4%
• FPG 100–125 mg/dL
• 2-hour OGTT 140–199 mg/dL

ABNORMAL (b) meets criteria for diagnosis
• HbA1c ≥6.5%
• FPG ≥126 mg/dL
• 2-hour OGTT ≥200 mg/dL

Meets criteria for DIAGNOSIS (d)?

no

yes

PREDIABETES (c)

DIABETES MELLITUS

If suspected type 1 or LADA (see profiles page 3), CONSIDER ANTIBODY TESTS (e)

Refer to Prediabetes Care Process Model for follow-up plan

See ALGORITHM: Treatment of Type 2, page 11

Indicates an Intermountain measure
(a) Diabetes Screening

Screen these patients at least every 3 years or more frequently depending on initial results and risk status:

- Adults ≥45 years
- Adults of any age who are overweight or obese (BMI ≥25 kg/m² or ≥23 kg/m² in Asian Americans) and have any of these additional risk factors:
  - Hypertension >140/90 mm Hg or on therapy for hypertension
  - Family history: first-degree relative with diabetes
  - Habitual physical inactivity
  - High-risk ethnicity (African American, Latino, Native American, Asian American, Pacific Islander)
  - Previous GDM or delivery of baby >9 pounds
  - Dyslipidemia (HDL-cholesterol <35 mg/dL and/or triglycerides >250 mg/dL)
  - Polycystic ovary syndrome (PCOS)
  - History of vascular disease
  - Other clinical conditions associated with insulin resistance, e.g., acanthosis nigricans, sleep apnea, multiple skin tags, peripheral neuropathy, and gout.
  - Use of second-generation antipsychotic medication (SGAs); see page 17

Screen these patients annually

- History of elevated HbA1c ≥5.7%, impaired fasting glucose (≥100 mg/dL), or impaired glucose tolerance (≥140 mg/dL)

(b) Investigating Abnormal Values

- Ensure the integrity of plasma glucose values: must be obtained from a correctly collected/stored specimen, NOT from finger stick.
- If repeat testing is indicated by an abnormal value, use ICD-10 code R79.89 “other specified abnormal findings of blood chemistry” to order follow-up test.
- Hemoglobinopathy. If patient has hemoglobinopathy and diabetes is suspected based on blood glucose or symptoms, measure two FPG values for confirmation.

(c) Prediabetes

Prediabetes is not a clinical entity of itself. It is the term used for individuals with impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT), which are risk factors for developing diabetes and cardiovascular disease in the future. The Prediabetes Care Process Model provides system-wide support for helping patients prevent these conditions. Criteria for prediabetes include:

- HbA1c <5.7%–6.4% OR
- FPG <100–125 mg/dL OR
- 2-hour OGTT <140–199 mg/dL

(d) Criteria for Diabetes Diagnosis

Criteria for diabetes diagnosis:

- TWO HbA1c values ≥6.5% OR
- TWO FPG values ≥126 mg/dL OR
- TWO 2-hour OGTT values >200 mg/dL

Remember: Plasma glucose values must NOT come from a finger stick.

(e) Antibody Testing

- Glutamic acid decarboxylase (GAD) antibodies account for 90% of diabetes-associated autoantibodies.
- Insulinoma associated-2 antibodies and zinc transporter 8 antibodies account for only the remaining 10%.
- See sidebar on page 4 for more further discussion of LADA and information on ordering tests.
HbA1c: INDIVIDUALIZED GOALS
Current ADA Standards stress individualizing management goals for specific circumstances, including duration of diabetes, life expectancy, comorbid conditions, CVD, hypoglycemia, and patient self-care capacity.

- For most nonpregnant adults, aim for HbA1c less than 7.0%.
- Consider more stringent goals (e.g., 6.0% to 6.5%) for selected individual patients such as those with short duration of diabetes, long life expectancy, and no significant CVD. For pregnant patients aim for less than 6.0%.
- Consider less stringent goals (e.g., 7.5% to 8.0%) for patients with a history of severe hypoglycemia, long disease duration, limited life expectancy, advanced complications, or extensive comorbid conditions.

Results of the ACCORD, ADVANCE, and VADT studies did not show increased cardiovascular benefits from tight control of diabetes. However, tight control has consistently been shown to reduce the risk of microvascular and neuropathic complications.

Approximate comparison of HbA1c and plasma glucose values

<table>
<thead>
<tr>
<th>HbA1c</th>
<th>Plasma Glucose</th>
</tr>
</thead>
<tbody>
<tr>
<td>6%</td>
<td>126 mg/dL</td>
</tr>
<tr>
<td>7%</td>
<td>154 mg/dL</td>
</tr>
<tr>
<td>8%</td>
<td>183 mg/dL</td>
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<tr>
<td>9%</td>
<td>212 mg/dL</td>
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<tr>
<td>10%</td>
<td>240 mg/dL</td>
</tr>
<tr>
<td>11%</td>
<td>269 mg/dL</td>
</tr>
<tr>
<td>12%</td>
<td>298 mg/dL</td>
</tr>
</tbody>
</table>

Monitoring blood glucose

The role of HbA1c
HbA1c testing is an indication of the overall trend of blood glucose levels for the previous 2 to 3 months and usually reflects overall diabetes control during that period.

HbA1c measurement can validate or call into question a patient’s home record of glucose testing or glucose testing performed in the office. In situations where higher home glucose readings do not match in-office HbA1c, consider conditions causing rapid RBC turnover.

ALGORITHM: MONITORING HbA1c

Office visit for patient with confirmed diabetes mellitus

Draw HbA1c

Good control
In most patients: HbA1c less than 7%
(see sidebar at left on individualized goals)
- NO CHANGES indicated (unless significant hypoglycemia)
- REINFORCE previous diabetes education, refer as indicated*

Inadequate control
In most patients: HbA1c more than 7%
(see sidebar at left on individualized goals)
- INITIATE or ADJUST medications
- REFER to diabetes educator*

FOLLOW-UP HbA1c every 3 months
- If HbA1c more than 8% for 6–9 months, CONSULT endocrinologist or other diabetes specialist

* At least annually, reinforce/update patients’ diabetes knowledge and skills. Consider using diabetes educators who are registered dietitians and can provide individualized medical nutrition therapy (MNT).

Indicates an Intermountain measure
The role of self-monitoring blood glucose systems (SMBG)
SMBG helps patients evaluate their individual response to therapy, avoid hypoglycemia, and make necessary adjustments to insulin therapy, medication, medical nutrition therapy (MNT), and physical activity. However, the accuracy of SMBG is dependent on the user and the instrument. Physicians or diabetes educators should teach patients how to do SMBG accurately, and routinely evaluate patients’ technique and ability to use the data to adjust their therapy.\textsuperscript{ADA}

Providers who manage insulin-treated patients — especially patients using multiple daily injection therapy or insulin pumps — must be able to appropriately analyze patients’ SMBG data, including control over specific time intervals, control by time of day (modal day), testing frequency, and glucose variability. Software for this purpose is provided by device manufacturers at no cost. \textit{See sidebar at right for testing guidelines.}

The role of continuous glucose monitoring systems (CGM)
Continuous glucose monitoring (CGM) devices provide continuous feedback to the patients about their glycemic control. When used consistently and in combination with an intensive insulin regimen, they can help lower HbA1c in adults age 25 and older. (Though there is less evidence supporting benefit in children, teens, and young adults, success correlates with consistent use.) In addition, CGM devices can be a valuable supplemental tools for patients with frequent hypoglycemic episodes and/or hypoglycemic unawareness — and significantly reduce the burden of diabetes by reducing fear of hypoglycemia and the pain of frequent testing.

A CGM device consists of a sensor electrode that is inserted into the subcutaneous tissue, a small radiofrequency transmitter, and a monitoring device that stores and displays the data. There are two types of CGM devices:

- **Personal CGM** devices belong to the patient and display subcutaneous glucose values to the patient in real time. An alarm feature alerts the patient when his or her subcutaneous glucose value crosses a prespecified threshold. In addition, these monitors have alarms that will warn the patient when glucose values are changing rapidly, potentially averting hypoglycemia. Several short-term studies have demonstrated their efficacy in lowering HbA1c levels and reducing frequency of hypoglycemia.\textsuperscript{BEC,TAM} Most commercial insurance carriers cover CGM; however, the majority of Medicaid plans do not cover it.

- **Professional CGM** devices belong to the clinic or hospital and are used for short periods to give providers detailed information on a patient’s glucose control. These devices can help identify patterns leading to hypoglycemia, hyperglycemia, and significant glucose variability. In addition, it can provide quick information on glucose patterns during pregnancy.

The role of continuous subcutaneous insulin infusion (CSII)
CSII (also called insulin pump therapy) is recommended for selected patients with type 1 diabetes and for some patients with insulin-treated type 2 diabetes. These should only be prescribed by experienced clinicians who have the knowledge, skills, and resources to monitor for failure. Adequate pump programs should involve a multidisciplinary team of providers — not just the services of industry-employed trainers and salespersons. Most insurance carriers, including SelectHealth, have liberal criteria for approval of CSII and rely on physician discretion to identify patients who are likely to benefit. Identifying patients appropriate for this technology is complex and beyond the scope of this discussion.
FREQUENT LIFESTYLE COUNSELING HELPS PATIENTS ACHIEVE TARGETS FASTER

Lifestyle counseling in the primary care setting is strongly associated with faster achievement of HbA1c, blood pressure, LDL cholesterol, and weight, as well as improved overall well-being.\textsuperscript{MOR}

The two principal goals of lifestyle intervention are to achieve a mean loss of ≥7% of initial body weight in overweight patients and to increase patient physical activity to ≥175 minutes of moderate intensity a week. Key components of lifestyle management are medical nutrition therapy, physical activity, behavior modification and accountability, and intensive lifestyle interventions.

Medical nutrition therapy (MNT)

Medical nutrition therapy is an integral component of diabetes management and is covered by most commercial insurance providers and by Medicare.

All patients with prediabetes or diabetes should be referred to a registered dietitian — preferably one specializing in diabetes education — for individualized MNT. MNT includes an individualized meal plan that accommodates the patient’s medications and metabolic needs, as well as their eating habits, lifestyle, and readiness to change. Meal plans are adjusted as needed to help patients comply with needed changes and meet goals.

A meal plan includes the following, at a minimum:

- **Amount and type of carbohydrates consumed.** Both quality and quantity of carbohydrate in foods influence blood glucose levels and glycemic response. However, there is no standard regarding the ideal amount of carbohydrate intake for people with diabetes.\textsuperscript{ADA} Individualized recommendations should address the total amount of carbohydrate that should be distributed through the day. Consistency in method of carbohydrate monitoring should be encouraged.

- **Timing of meals and snacks.** Monitoring and maintaining a consistent pattern of carbohydrate use is key to achieving glycemic control. Meals should include a mix of macronutrients (carbohydrate, protein, and fat) individualized to meet the patient’s metabolic goals and personal preferences.

- **Caloric restriction combined with physical activity to support any needed weight loss.** Weight loss should be gradual and slow. Aim for a rate of 1 to 2 pounds per week. Mediterranean, low-fat, calorie-restricted, or low-carbohydrate diets may all be effective for weight loss.\textsuperscript{ADA}

Until a dietitian can provide an individualized meal plan, counsel overweight patients to reduce calories.

- As a temporary guideline, an initial goal is 1200 to 1500 total calories per day for patients <250 pounds, and 1500 to 1800 calories per day for patients >250 pounds.

- Additional recommendations could include limiting fat to <30% of calories (with <7% from saturated fat), and limiting carbohydrates per meal (or split between meal and snack) to 45 to 60 grams for women, and 60 to 75 grams for men.

- Resources such as \texttt{CalorieCount.com} can provide nutrition content of foods. Assistance with healthy food choices is available at \texttt{ChooseMyPlate.gov}. Smart phone apps such as \texttt{MyFitnessPal} can also help patients track nutrients.
Physical activity
Regular physical activity improves blood glucose control and can prevent or delay type 2 diabetes. Regular activity also positively affects cholesterol, blood pressure, cardiovascular risk, mortality rates, and quality of life.

Preexercise evaluation. Sedentary patients should be evaluated by a physician before beginning a moderate- to vigorous-intensity exercise program. See the Exercise is Medicine Physical Activity Questionnaire for a sample screening tool. Refer to appropriate specialists or provide suggestions for adapting exercise based on individual needs. Note: even patients with known coronary artery disease and stable angina benefit from regular physical activity.

Recommendations. Counsel patients to:

- Increase activity to ≥175 minutes per week of moderate- to vigorous-intensity aerobic activity — heart beating faster than normal and breathing harder than normal, such as a brisk walk. Spread activity over at least 3 days per week, with no more than 2 consecutive days between bouts of aerobic activity. While the ADA guidelines recommend ≥150 minutes per week, Intermountain endorses the target of ≥175 minutes used in the Look AHEAD trial based on findings that higher levels of physical activity significantly improve weight loss maintenance and other health outcomes. Record patient activity in the Physical Activity Vital Sign in the electronic medical record. Casual walking that does not meet at least moderate intensity does not count toward the weekly goal.

- Increase activity gradually. Patients who are currently sedentary should start with 10 minutes of walking at moderate intensity 3 days per week, gradually increasing to 5 days per week. Once they are walking on most days, patients should add minutes to achieve 20 minutes on most days, and build toward the goal of 30 to 60 minutes on most days of the week.

- Unless contraindicated, undertake resistance training 2 days per week, focusing on major muscle groups and core body conditioning.

- Decrease time sitting and increase daily movement. All individuals should be encouraged to break up extended amounts of time sitting (≥90 minutes). Taking a two- to three-minute walk every 20 minutes has been demonstrated to reduce postprandial glucose and insulin levels in overweight and obese adults. Individuals can increase daily movement through activities such as taking the stairs, walking rather than riding in a car, etc.

- At first, monitor blood glucose before, during, and after physical activity. Once patients have a sense of how exercise works with their medication, food choices, and other factors that affect blood glucose, they won’t need to check levels as often.

Behavior modification and accountability
Diabetes self-care requires modification to daily behaviors that most patients find challenging. For detailed, evidence-based support in this process, see the Behavior Change Techniques and Tools section of the Lifestyle and Weight Management CPM.

Patients experiencing difficulty adhering to diet and exercise recommendations, or who lose <1% of weight per month, may require additional assistance. Referral to an intensive lifestyle intervention program (such as The Weigh to Health) or additional contact with a clinician may help. See sidebar on page 10 for more information.

DIABETES IN REMISSION
In patients who have had gastric bypass surgery or banding or who have implemented lifestyle and weight management changes, glycemia measures may fall below diagnostic thresholds. Because chronic conditions such as diabetes are never considered to be completely cured, these patients are considered to be in remission. An ADA consensus statement defines remission as the following:

- Partial remission
  - Hyperglycemia below diagnostic thresholds for at least 1 year, with no active pharmacologic intervention

- Complete remission
  - Normal glycemia measures for at least 1 year, with no active pharmacologic therapy

- Prolonged remission
  - Complete remission for at least 5 years

Follow-up for patients in remission
The science is limited regarding risk for macro and microvascular complications for patients in remission. The ADA currently recommends the following care:

- Until the patient is in prolonged remission, continue the same follow-up practices as a patient with diabetes.

- Once the patient is in prolonged remission, make a shared decision with the patient on how to monitor based on personal risk factors. At a minimum, this should include HbA1c monitoring every 3 years, which matches the preventive care guidelines.

This shared decision-making tool will help you and your patients to decide on a follow-up plan together.

Diabetes in Remission
Fact Sheet. For ordering information see page 31.
Intensive lifestyle intervention (ILI)

An intensive lifestyle intervention (also referred to as behavioral intervention) can provide the support and follow-up necessary for behavior modification. With passage of the Affordable Care Act (ACA), commercial payers are required to cover an intensive lifestyle intervention at no cost to patients with BMI ≥30 or with BMI ≥25 and one or more cardiovascular disease risk factors. Intermountain’s The Weigh to Health® program (see sidebar) is an example of an intensive lifestyle intervention that may be covered by a plan. Medicare and Medicare Advantage do not cover The Weigh to Health®, but may have coverage for medical nutrition therapy for select patients.

Bariatric surgery for people with type 2 diabetes

Studies show that bariatric surgery can produce a remission in type 2 diabetes (normal or near-normal glycemia in approximately 55% to 95% of patients with type 2, depending on the surgery). Rates of remission tend to be greater with malabsorptive (bypass) procedures versus restrictive procedures. Additionally, patients with type 2 diabetes of less than two years duration tend to have the best response to bariatric surgery, while those who have had type 2 diabetes for more than 10 years or require insulin therapy may be less responsive. For further discussion of diabetes in remission, see the sidebar on page 9.

Clinical efficacy. A 2012 study by LDS Hospital researchers published in JAMA showed:

- **Diabetes benefits are enduring.** Among diabetes patients who had diabetes before surgery, 62% were in remission after six years. That compares to 8% and 6% for the nonsurgical groups. Gastric bypass patients who did not have diabetes before the surgery were 5 to 9 times less likely to develop the disease than nonsurgical participants.
- **Weight loss benefits are enduring.** Surgical patients lost an average of 34.9% of their initial weight after surgery, and kept off 27.7% 6 years after surgery. Nearly all the surgical patients, 96%, had maintained more than 10% weight loss from baseline, and 76% had maintained more than a 20% weight loss. By contrast, patients who did not have bariatric surgery either lost no weight or gained weight over the next 6 years.

For primary care providers, we recommend the following:

- **Consider bariatric surgery for patients with type 2 diabetes who have BMI ≥35,** particularly when diabetes or its comorbidities haven’t been controlled with medication or lifestyle modifications. This recommendation follows national guidelines.
- **Refer patient candidates to a bariatric surgery center** with (a) a Board-certified physician with a practice devoted to bariatric medicine; (b) the ability to provide presurgical consultation with dietitians, social workers, and other staff who can help patients with nutritional, psychological, and logistical (insurance) issues; and (c) follow-up processes and consults to manage postoperative complications and dietary regimens. For more information visit the ASMBS website or the LDS Hospital Bariatric Surgery website.
- **Postsurgery, ongoing lifestyle support is critical.**

Medication

Medication therapy includes oral and injectable antidiabetic agents as well as several classes of insulin.

- **For type 2 diabetes,** oral medication is required for glycemic control if lifestyle modifications don’t achieve glycemic control within 2 to 3 months (see page 11). Prescribing considerations include the patient’s age, weight, any renal or hepatic impairment, and cardiopulmonary comorbidities. Insulin may be used initially (often temporarily) for significant hyperglycemia and is a long-term option for patients on oral agents who still have HbA1c values more than 1% above goal.
- **For type 1 diabetes,** insulin therapy is essential. A regimen that combines long-acting, peakless insulin (basal) and rapid-acting insulin (bolus) most closely mimics normal physiologic insulin production (see page 15).
- **For LADA,** insulin therapy will be required eventually, if not immediately. Frequent follow-up is required to assess the patient’s blood glucose control and the timing of insulin initiation.
**ALGORITHM: TREATMENT OF TYPE 2 DIABETES—a patient-centered approach**

- **EDUCATE** on lifestyle modifications (see page 8) and diabetes self-management skills and **CONSIDER REFERRAL** to a qualified diabetes educator and a registered dietitian.
- **SCREEN** for and treat diabetes-related conditions (such as dyslipidemia). See pages 18 to 28.
- **ADDRESS** psychological and social issues.

### (a) Initial drug monotherapy
- Begin metformin monotherapy at or soon after diagnosis (unless explicitly contraindicated).
- In patients intolerant of or with contraindications for metformin, select initial drug from other classes depicted and proceed accordingly.
- Metformin use has been associated with a 3-fold increase in vitamin B12 deficiency, which is associated with peripheral neuropathy. Periodic B12 testing is prudent to consider. Clinicians should be aware, however, that the B12 assay has highly variable results. We recommend repeat testing and methylmalonic acid or homocysteine levels to confirm diagnosis, especially in patients with low normal B12 levels. Treatment options include cyanocobalamin 1000 mcg pill taken daily, or 1000 mcg solution injected weekly for a month, then monthly indefinitely.16

### (b) Two-drug combinations
- If HbA1c target is not achieved after ~3 months, consider one of the six treatment options combined with metformin.
- Drug choice is based on patient and drug characteristics, with the overriding goal of improving glycemic control while minimizing side effects. Shared decision-making with the patient may help in the selection of therapeutic options.
- Consider beginning therapy with a two-drug combination in patients with HbA1c ≥9%.

### (c) Medication Alternatives
- Other drugs not shown (α-glucosidase inhibitors, colesevelam, dopamine agonists, pramlintide) may be used where available in selected patients but have modest efficacy and/or limiting side effects.

### (d) Insulin
- Usually basal insulin (NPH, glargine, detemir) in combination with noninsulin agents.
- Insulin is likely to be more effective than most other agents as a third-line therapy, especially when HbA1c is very high (e.g., ≥9%). The therapeutic regimen should include some basal insulin before moving to more complex insulin strategies.

### (e) An effective triple therapy
An especially effective option is the combination of metformin + GLP1 receptor agonist + basal insulin. This therapy is associated with less weight gain and greater reduction in HbA1c.

### (f) Progression to multiple daily doses of insulin
Consider a more rapid progression from a two-drug combination directly to multiple daily insulin doses—or consider beginning at this stage—in patients with severe hyperglycemia (e.g., HbA1c ≥10% to 12%).
This section gives detailed information on medication — oral agents, non-insulin injectables, and insulin — for the treatment of adult diabetes. **If the patient has chronic kidney disease beyond Stage G2, refer to the Chronic Kidney Disease CPM for necessary dose adjustments.**

### TABLE 2. Oral Agents and Non-insulin Injectable Medications

<table>
<thead>
<tr>
<th>Class</th>
<th>Generic name</th>
<th>Brand name</th>
<th>Usual dosing</th>
<th>2015 AWP cost for 30-day supply* (MAC Cost for generics)</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Biguanides</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>metformin</td>
<td></td>
<td>Glucophage (Tier 3)</td>
<td>500 mg twice a day (once a day to start) to 1000 mg twice a day</td>
<td>Generic: 500 mg twice a day: $3 850 mg twice a day: $4 1000 mg twice a day: $4 Brand name: 500 mg once a day: $2 750 mg once a day: $4 1000 mg once a day: $4</td>
<td>Extensive experience  No hypoglycemia  ↓ Weight (preferred for obese patients — most type 2 diabetics)  Favorable lipid effects  Maximum PG effect at 3–4 weeks.  ↓ insulin resistance  Consensus first-line agent</td>
<td>GI distress (nausea/diarrhea)  B12 deficiency — suggest periodic testing  CHF patients should be stable  Risk of acidosis; STOP with acute illness, dehydration, or IV contrast dyes  Multiple contraindications. Do not use for patients with chronic liver disease, alcoholism, or chronic kidney disease (eGFR &lt;30)</td>
</tr>
<tr>
<td>metformin ER (Tier 1)</td>
<td></td>
<td>Glucophage XR (Tier 3)</td>
<td>500 mg to 1500 mg once a day at dinner</td>
<td>Generic: 500 mg once a day: $2 750 mg once a day: $4 1000 mg (2 × 500 mg): $4 1500 mg (2 × 750 mg): $8 Brand name: 500 mg once a day: $35 750 mg once a day: $52</td>
<td>Extensive experience  Well tolerated  Maximum PG effect at 5 to 7 days</td>
<td>↑ Hypoglycemia, especially with reduced GFR  ↑ Weight  Do not use with Prandin, Starlix, or other sulfonylureas  Limited duration of effect</td>
</tr>
<tr>
<td><strong>Sulfonylureas</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>glipizide XL (Tier 1)</td>
<td></td>
<td>Glucotrol XL (Tier 3)</td>
<td>5 mg to 20 mg once a day (max) [may give dose twice a day]</td>
<td>Generic: 5 mg once a day: $5 10 mg once a day: $8 Brand name: 1 mg once a day: $2 4 mg once a day: $3</td>
<td>Option for patients intolerant of metformin  No hypoglycemia  ↓ Serum insulin  Durability  ↓ Triglycerides  Possible ↓ CVD events</td>
<td>Edema, especially if given with insulin; Adding spironolactone can help  Fluid retention may lead to or exacerbate heart failure or macular edema (If so, discontinue)  Bone fractures  May change metabolism of birth control pills  Slow onset: max effect in 6–12 weeks</td>
</tr>
<tr>
<td>glimepiride (Tier 1)</td>
<td></td>
<td>Amaryl (Tier 3)</td>
<td>1 mg to 8 mg (max) once a day [may give dose twice a day]</td>
<td>Generic: 1 mg once a day: $2 4 mg once a day: $3</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Thiazolidinediones</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pioglitazone</td>
<td></td>
<td>Actos (Tier 3)</td>
<td>15 mg to 45 mg once a day (dosing at bedtime may decrease edema)</td>
<td>Generic: 15 mg once a day: $11 30 mg once a day: $13 45 mg once a day: $14</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DPP-4 inhibitors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>sitagliptin phosphate</td>
<td></td>
<td>Januvia (Tier 3, step edit)</td>
<td>100 mg once a day [as monotherapy or as combination therapy with metformin or glitazones]</td>
<td>Generic: 25 mg, 50 mg, or 100 mg once a day: $397</td>
<td>Can be taken with or without food  No hypoglycemia  No weight gain  Most PG effect within 1–2 weeks of initiation</td>
<td>Increased cost  Can be used only for type 2 diabetes  Reduce dose with decreasing creatinine clearance &lt;50 — except linagliptin  Possible acute pancreatitis  Possible ↑ Heart failure hospitalizations</td>
</tr>
<tr>
<td>saxagliptin</td>
<td></td>
<td>Onglyza (Tier 3, step edit)</td>
<td>2.5 mg or 5 mg once a day</td>
<td>Generic: 2.5 mg or 5 mg once a day: $390</td>
<td></td>
<td></td>
</tr>
<tr>
<td>linagliptin</td>
<td></td>
<td>Tradjenta (Tier 2)</td>
<td>5 mg once a day</td>
<td>Generic: 5 mg once a day: $397</td>
<td></td>
<td></td>
</tr>
<tr>
<td>alogliptin</td>
<td></td>
<td>Nesina (Tier 2)</td>
<td>6.25 mg to 25 mg orally once a day</td>
<td>All strengths: $374</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*AWP = Average Wholesale Pricing; MAC = Maximum Allowable Cost. Many patients may benefit from manufacturers’ discounts or patient assistance programs.*
<table>
<thead>
<tr>
<th>Class</th>
<th>Generic name</th>
<th>Brand name</th>
<th>Usual dosing</th>
<th>2015 AWP cost for 30-day supply* (MAC Cost for generics)</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>SGLT2 inhibitors</td>
<td>canagliflozin</td>
<td>Invokana</td>
<td>100 mg or 300 mg once a day</td>
<td>All strengths: $411</td>
<td>• Non-insulin dependent — novel MOA</td>
<td>• ↑ Female genital mycotic infections, UTIs, and increased urination</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Tier 2, step edit)</td>
<td></td>
<td></td>
<td>• Low incidence of hypoglycemia</td>
<td>• Volume depletion; Use cautiously in elderly and patients already on diuretic</td>
</tr>
<tr>
<td></td>
<td>dapagliflozin</td>
<td>Farxiga</td>
<td>5 mg or 10 mg once a day</td>
<td>All strengths: $412</td>
<td>• ↓ Weight</td>
<td>• Possible ↑ risk of bladder cancer (dapagliflozin)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Tier 3, step edit)</td>
<td></td>
<td></td>
<td></td>
<td>• Requires normal renal function (&gt;45 ml/min for empagliflozin and canagliflozin and &gt;60 ml/min for dapagliflozin)</td>
</tr>
<tr>
<td></td>
<td>empagliflozin</td>
<td>Jardiance</td>
<td>10 mg or 25 mg once a day</td>
<td>All strengths: $411</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLP-1 receptor agonists</td>
<td>exenatide</td>
<td>Byetta</td>
<td>5 mcg twice a day [within 60 minutes before breakfast and dinner; may be increased to 10 mcg twice a day after 1 month]</td>
<td>5 mcg twice a day: $574</td>
<td>• No hypoglycemia</td>
<td>• Exenatide: Use caution when initiating or when increasing dose from 5 mcg to 10 mcg in CKD Stage G3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Tier 3, step edit)</td>
<td></td>
<td></td>
<td>• ↓ Postprandial glycemia</td>
<td>• All in this class:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Exhibits many of the same glucoregulatory actions of naturally occurring hormones</td>
<td>– Gastrointestinal side effects (nausea, vomiting, diarrhea)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>– Training requirements</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>– ↑ Heart rate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>– Possible acute pancreatitis</td>
</tr>
<tr>
<td></td>
<td>exenatide ER</td>
<td>Bydureon</td>
<td>2 mg once every 7 days</td>
<td>2 mg once a week: $570</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>liraglutide</td>
<td>Victoza</td>
<td>1.2 mg or 1.8 mg once a day</td>
<td>1.2 mg once a day: (18 mg/3mL pen): $513</td>
<td>• No hypoglycemia</td>
<td>• Exenatide: Use caution when initiating or when increasing dose from 5 mcg to 10 mcg in CKD Stage G3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Tier 2, step edit)</td>
<td></td>
<td>1.8 mg once a day: (18 mg/3mL pen): $769</td>
<td>• ↓ Postprandial glycemia</td>
<td>• All in this class:</td>
</tr>
<tr>
<td></td>
<td>albiglutide</td>
<td>Tanzeum</td>
<td>30 mg or 50 mg once every 7 days</td>
<td>30 mg or 50 mg once every 7 days: $391</td>
<td>• Exhibits many of the same glucoregulatory actions of naturally occurring hormones</td>
<td>– Gastrointestinal side effects (nausea, vomiting, diarrhea)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Tier 3, step edit)</td>
<td></td>
<td></td>
<td></td>
<td>– Training requirements</td>
</tr>
<tr>
<td></td>
<td>dulaglutide</td>
<td>Trulicity</td>
<td>0.75 mg or 1.5 mg once every 7 days</td>
<td>0.75 mg or 1.5 mg once every 7 days: $586</td>
<td>• Exhibits many of the same glucoregulatory actions of naturally occurring hormones</td>
<td>– ↑ Heart rate</td>
</tr>
<tr>
<td>amylin mimetic</td>
<td>pramlintide acetate</td>
<td>Symlin</td>
<td><strong>See below</strong></td>
<td>60 injection pen (1.5 mL): $708</td>
<td>Very positive effect on weight loss</td>
<td>Symlin should only be used by providers with significant knowledge of its properties.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Tier 2, step edit)</td>
<td></td>
<td></td>
<td></td>
<td>3 injections per day brings significant risk of severe nausea and hypoglycemia</td>
</tr>
</tbody>
</table>

**Dosing instructions for Symlin:**
- Type 1: 15 mcg immediately prior to major meals; increase at 15 mcg increments to a maintenance dose of 60 mcg or as tolerated.
- Type 2: 60 mcg immediately prior to major meals; increase to 120 mcg as tolerated.
- When initiating Symlin, reduce insulin dosages, including premixed insulins (70/30).

**AWP = Average Wholesale Pricing; MAC = Maximum Allowable Cost. Many patients may benefit from manufacturers' discounts or patient assistance programs.**
Insulin therapy

Patients with type 1 diabetes will require an insulin regimen that combines different insulins to meet basal and meal-time bolus needs. Most patients with type 1 diabetes will be on physiologic regimens. See the notes and algorithm on the following pages for more information on a physiologic insulin regimen. To treat patients with type 2 diabetes, keep these general principles in mind when using oral agents with insulin:

- A basal insulin regimen (bedtime dose of peakless insulin) is our recommended first choice when adding insulin to treatment with oral agents.
- Consider the timing of the patient’s hyperglycemia when adding or adjusting insulin.
  - Use glargine or detemir at bedtime to control morning FPG.
  - When morning FPG is controlled with peakless insulin, daytime PPG readings frequently come under control with an oral agent and dietary modification. To control daytime PPG, sulfonylureas, DPP-4 inhibitors, and GLP-1 agonists are most effective.
  - If 2-hour postprandial PG is still above goal with FBG >100 mg/dL, consider physiologic insulin regimen with or without metformin.

TABLE 3. Insulin Profiles

<table>
<thead>
<tr>
<th>Insulin type</th>
<th>Generic (Brand) name</th>
<th>Description</th>
<th>Onset</th>
<th>Peak</th>
<th>Usual effective duration</th>
<th>2015 30-Day AWP</th>
<th>SelectHealth commercial formulary status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid-acting</td>
<td>aspart (NovoLog)</td>
<td>Clear</td>
<td>10 to 20 minutes</td>
<td>1 to 2 hours</td>
<td>3 to 5 hours</td>
<td>10 mL: $244</td>
<td>Tier 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>FlexPen 15 mL: $471</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>glulisine (Apidra)</td>
<td>Clear</td>
<td>10 to 20 minutes</td>
<td>1 to 2 hours</td>
<td>3 to 5 hours</td>
<td>10 mL: $243</td>
<td>Tier 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SoloSTAR pen 15 mL: $471</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>lispro (Humalog)</td>
<td>Clear</td>
<td>10 to 20 minutes</td>
<td>1 to 2 hours</td>
<td>3 to 5 hours</td>
<td>10 mL: $243</td>
<td>Not covered</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>KwikPen 15 mL: $470</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>human (Afrezza)*</td>
<td>Inhalation powder</td>
<td>10 to 15 minutes</td>
<td>1 hour</td>
<td>2 to 3 hours equivalent to 1000 units: $630</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>Regular (short-acting)</td>
<td>Novolin R</td>
<td>Clear</td>
<td>30 to 60 minutes</td>
<td>2 to 4 hours</td>
<td>4 to 8 hours</td>
<td>10 mL: $132</td>
<td>Novolin R: Tier 2</td>
</tr>
<tr>
<td></td>
<td>Humulin R</td>
<td></td>
<td></td>
<td></td>
<td>ReliOn R 10 mL: $28</td>
<td></td>
<td>Humulin R: not covered</td>
</tr>
<tr>
<td></td>
<td>ReliOn R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ReliOn R: Not covered†</td>
</tr>
<tr>
<td>Intermediate-acting</td>
<td>NPH (Novolin N)</td>
<td>Cloudy</td>
<td>1 to 3 hours</td>
<td>4 to 10 hours</td>
<td>10 to 18 hours</td>
<td>10 mL: $132</td>
<td>Novolin N: Tier 2</td>
</tr>
<tr>
<td></td>
<td>NPH (Humulin N)</td>
<td></td>
<td></td>
<td></td>
<td>ReliOn N 10 mL: $28</td>
<td></td>
<td>Humulin N: not covered</td>
</tr>
<tr>
<td></td>
<td>ReliOn N</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ReliOn N: Not covered†</td>
</tr>
<tr>
<td>Peakless</td>
<td>detemir (Levemir)‡</td>
<td>Clear</td>
<td>1 hour     peakless</td>
<td>18 to 24 hours</td>
<td>10 mL: $298</td>
<td>FlexPen 15 mL: $447</td>
<td>Tier 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SoloSTAR pen 15 mL: $447</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>glargine (Lantus)‡</td>
<td>Clear</td>
<td>2 to 3 hours</td>
<td>peakless</td>
<td>24 + hours</td>
<td>10 mL: $298</td>
<td>Tier 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SoloSTAR pen 14.5 mL: $403</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>glargine U-300 (Toujeo)</td>
<td>Clear</td>
<td>develops over 6 hours</td>
<td>peakless</td>
<td>24 + hours</td>
<td>10 mL: $253; pen: $471</td>
<td>10 mL: $252; pen: $470</td>
</tr>
</tbody>
</table>

*Afrezza contraindications: asthma, COPD, smokers. Requires PFT monitoring at baseline, 6 months, then yearly. Supplied in 4-unit and 8-unit single-dose cartridges. Dose adjustments are made in 4-unit increments.
†ReliOn is available at Walmart and is a possible option for cash-paying patients. Cash price is about $25–$30 per vial.
‡Peakless insulin (detemir and glargine):
- Administer detemir insulin twice a day for type 1 diabetes and at bedtime for type 2 diabetes. Administer glargine insulin once a day for type 1 and type 2 diabetics who require long-acting insulin for control of hyperglycemia.
- Peakless insulin cannot be diluted or mixed with other types of insulin or solutions.
- Administer peakless insulin subcutaneously only — DO NOT give it intravenously.
Physiologic insulin regimen: peakless + rapid-acting insulins

Using multiple daily injections (MDI), a physiologic insulin regimen most closely mimics normal insulin physiology. This intensive regimen uses peakless insulin as the basal dose and rapid-acting insulin for control with meals. Almost all type 1 patients require this physiologic (basal/bolus) regimen. Most type 2 patients who require insulin will attain good control with this regimen. For this regimen, we recommend the following:

- **Use peakless insulin to control blood glucose when not eating.** The period between bedtime and breakfast is the best reflection of how this method is working — prebreakfast blood glucose should approximate bedtime blood glucose. A bedtime snack is not required; if desirable, match its carb content with a rapid-acting insulin dose.

- **Add rapid-acting insulin prior to each meal and planned snack.**
  - Adjust this insulin to prevent post-meal hyperglycemia or hypoglycemia. Blood glucose levels 4 hours after a meal should approximate premeal levels.
  - Determine premeal rapid-insulin doses by counting carbohydrates and using an insulin-to-carbohydrate ratio. Alternatively, base premeal insulin dose on a fixed meal plan (budgeted carbohydrates).
  - Train patients in MNT and insulin use; support with referral to diabetes educator/registered dietitian.
  - Train patients in use of correction dose to treat hyperglycemia. (At bedtime, the correction dose may be reduced to as much as 50% of the usual correction dose.)

- **Teach patients how to modify insulin doses** when exercising, on sick days, to combat significant premeal hypoglycemia, or to prevent delayed postmeal hyperglycemia due to higher fat meals (see sidebar on page 17). Support with referral to diabetes educator/registered dietitian.

**ALGORITHM: INITIAL PHYSIOLOGIC INSULIN REGIMEN**

- **Use recommended starting doses:** for patients with type 1, the total daily dose (TDD) of insulin is approximately 0.5 U/kg; for those with type 2, TDD is approximately 0.5 to 0.7 U/kg.
- **Teach injection technique.**
- **Divide dose as follows:** One-half of total daily dose as peakless basal insulin dose (glargine once a day or detemir twice a day regimen). Use carbohydrate ratio and correction factor to calculate premeal and bedtime rapid-acting insulin doses.
- **Instruct patient to carefully record SMBG** (before meals, at bedtime).

**Follow up in 2 to 5 days**

**Morning FPG = bedtime PG?**
- **yes**
- **no**

**Premeal PG = 3–4 hour postmeal PG?**
- **yes**
- **no**

**Consistent hypoglycemia or hyperglycemia?**
- **yes**
- **no**

**Initial return visit in 2 weeks, then every 3 months:** Review patient’s blood glucose record. Repeat HbA1c.

**Using the 1700 Rule**

The 1700 Rule can be used to calculate:

- A correction dose of rapid-acting insulin for a high PG reading.
- An insulin-to-carb ratio to approximate the carbohydrate content of a meal.

To calculate one of these doses:

- **Determine the current total daily dose (TDD):** Add up ALL the insulin (rapid and long-acting) the patient takes in a 24-hour period.

- **Divide 1700 by the TDD.** This is the predicted amount (mg/dL) the PG will decrease for each unit of rapid-acting insulin added (correction factor).

To calculate a correction dose:

- **Increase rapid-acting insulin** by the number of units needed to reduce the PG to the desired goal. Encourage patient to keep careful records of resulting PG readings, especially morning FPG, premeal 2-hour PPG, and bedtime PG.

**Correction dose example:**
- Patient takes 50 units of insulin per day: TDD = 50
- 1700 ÷ 50 = 34 (round to 35, which means that 1 unit of insulin will lower PG by 35 points — correction factor 35)
- If goal is 130 and PG is 165, use 1 extra unit of insulin to drop PG to about 130. If PG is 200, use 2 extra units, and so on.

To calculate an insulin-to-carb ratio:

- **Multiply predicted PG lowering (mg/dL) by 0.33.** This is the number of grams of carbohydrate covered by 1 unit of insulin. For most people, a starting dose would be 1 unit of rapid-acting insulin for every 10 to 15 grams of carbohydrate to be eaten.

**Insulin-to-carb ratio example:**
- Patient takes 50 units of insulin per day: TDD = 50
- 1700 ÷ 50 = 34 (round to 35, which means that 1 unit of insulin will lower PG by 35 points)
- 35 × 0.33 = 12, which means that you’ll need 1 unit of insulin for every 12 grams of carbohydrate anticipated in a meal.

Insulin requirements vary considerably from patient to patient depending on the degree of insulin deficiency and resistance. These formulas are guidelines for estimating insulin doses. You will likely need to make adjustments to these estimates.
Glucose management in special circumstances

Some circumstances — such as when a patient is preparing for a test or procedure, has had a cortisone injection, etc. — may require temporary adjustment to diabetes treatment. We advise the following:

- **Before surgery:** Optimize glycemic control and temporarily stop metformin if appropriate.
- **When patient receives a steroid (injection or oral):** Advise more frequent SMBG and adjust medications as needed. Patients often experience a worsening of glycemic control after an injection.
- **When patient is fasting prior to a test or procedure:** Adjust glucose-lowering medications as needed.
- **Illness:** Consider increasing frequency of blood glucose monitoring. Metformin may need to be held if the patient is at risk for dehydration.

Basic (nonphysiologic) regimen: NPH + rapid-acting insulin

Basic insulin therapy is not designed to mimic normal insulin physiology. Although a basic regimen is not recommended for type 1 patients, it may provide adequate control for type 2 patients who have not been successful with oral medication combinations or with patients who are not able to manage a multiple daily dose regimen as required in physiologic insulin therapy.

For a basic insulin therapy regimen to be successful, a patient must be consistent with meals and adhere to a medical nutrition therapy plan.

Sample basic insulin regimens

Following are some sample basic insulin regimens.

- **Premixed insulins:** These insulins are all given twice a day (before breakfast and before the evening meal)
  - 70% aspart protamine suspension / 30% aspart injection (NovoLog Mix 70/30)
  - 70% NPH / 30% regular (Novolin 70/30)
- **Split-mixed insulins:** NPH is given twice a day (either morning and before the evening meal, or morning and bedtime) with:
  - Regular insulin before breakfast and before the evening meal
  - Rapid-acting insulin before breakfast and before the evening meal

HIGHER DIETARY FAT AND POSTMEAL HYPERGLYCEMIA

Higher dietary fat intake can cause late postprandial hyperglycemia. This can be addressed either by reducing fat intake (especially for type 2 patients on nonphysiologic regimens) and/or by adjusting premeal insulin doses (for type 1 patients on rapid-acting insulin). Practical ways to compensate for a high-fat meal include splitting premeal insulin into 2 injections from 1 to 3 hours apart, or using an extended bolus. The total amount of insulin provided may need to be increased from the usual dose as well. The response to dietary fat will vary according to the individual and the specific foods, so defining insulin adjustments may require multiple attempts.

Glucose management in special circumstances

A large, randomized controlled trial showed that systematically titrating bedtime basal insulin added to oral therapy can safely achieve 7% HbA1c in overweight patients with type 2 diabetes as compared to 7.5% to 10% HbA1c in those patients on oral agents alone.

- **Start with 10 IU at bedtime.**
- **Tritate weekly based on FBG values over 3 days,** as shown in the table below.

### Forced weekly insulin titration schedule
(for treat-to-target FBG of <120 mg/dL)

<table>
<thead>
<tr>
<th>Mean of FBG values over 3 days</th>
<th>Increase of insulin dosage (IU/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;180 mg/dL</td>
<td>+8</td>
</tr>
<tr>
<td>160–180 mg/dL</td>
<td>+6</td>
</tr>
<tr>
<td>140–159 mg/dL</td>
<td>+4</td>
</tr>
<tr>
<td>120–139 mg/dL</td>
<td>+2</td>
</tr>
</tbody>
</table>

Use glargine or detemir with this titration schedule to significantly reduce nocturnal hypoglycemia. Using insulin can help achieve recommended standards of diabetes care more quickly.
SGAs and metabolic abnormalities

Although the second-generation antipsychotic medications (SGAs) have many notable benefits compared with their earlier counterparts, their use has been associated with reports of significant weight gain, diabetes (even DKA), and a worsened lipid profile (increased LDL and triglyceride levels and decreased HDL cholesterol). This has led to growing concern about a possible link between these metabolic effects and therapy with SGAs. There are also data that suggest these agents elevate the risk for sudden cardiac death.

The table below shows the metabolic abnormalities associated with various SGAs. Given these findings and the increased use of SGAs, we recommend the following:

### TABLE 4. SGAs and Metabolic Abnormalities

<table>
<thead>
<tr>
<th>Generic (brand) name</th>
<th>Weight gain</th>
<th>Risk for diabetes</th>
<th>Worsening lipid profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>clozapine (Clozaril)</td>
<td>+++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>olanzapine (Zyprexa)</td>
<td>+++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>risperidone (Risperdal)</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>quetiapine (Seroquel)</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>aripiprazole (Abilify)*</td>
<td>+/-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ziprasidone (Geodon)*</td>
<td>+/-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

+ = increased effect     − = no effect
* newer drugs with limited long-term data

- Monitor patients regularly (perhaps monthly) after SGA therapy is initiated. Measure weight, glucose, blood pressure, and lipids.

- Consider switching the SGA if a patient gains ≥5% of his or her initial weight at any time during therapy. Note that abruptly discontinuing clozapine has the potential for serious psychiatric sequelae.

### IMMUNIZATIONS

Influenza and pneumonia are common and preventable infectious diseases. These diseases are associated with high mortality and morbidity in people with chronic diseases such as diabetes. This CPM recommends the following vaccinations for patients with diabetes:

- **Annual influenza vaccination for all patients over 6 months of age.** Patients with diabetes show an increased rate of hospitalization for influenza. The influenza vaccine can reduce hospital admissions for these patients by as much at 79% during flu epidemics.

- **Pneumococcal vaccine for all adult patients with diabetes.** Patients with diabetes may be at increased risk of bacterial pneumonia and have a high reported risk of nosocomial bacteremia, which has a mortality rate as high as 50%. Patients with diabetes need the following pneumococcal vaccines:
  - Age 19 to 64: one dose PPSV23.
  - Age 65 or older: one dose PPSV23.

Note: CMS-Medicare Part B now covers both PCV13 and PPSV23, given at least one year apart.

- **Hepatitis B vaccination for unvaccinated adults with diabetes under age 60.** In 2013, the Advisory Committee on Immunization Practices of the CDC recommended that all previously unvaccinated adults with diabetes aged 19 through 59 years be vaccinated with 3 doses of hepatitis B vaccine, and that vaccination be considered for those aged ≥60 years, after assessing risk and likelihood of an adequate immune response. This acknowledges increased risk of Hepatitis B in institutionalized (e.g., nursing home, prison) patients.
PREVENTION AND MANAGEMENT OF RELATED CONDITIONS

Patients with diabetes are likely to have related conditions such as:

- Cardiovascular disease (p. 18)
- High cholesterol (p. 20)
- High blood pressure (p. 22)
- Kidney disease (p. 24)
- Retinopathy (p. 25)
- Low testosterone in men (p. 25)
- Foot problems (p. 26)
- Obstructive sleep apnea (p. 28)
- Conditions associated with type 1 diabetes (p. 28)

This section gives an overview of risks, goals, and management options for these conditions that often accompany or result from diabetes.

Cardiovascular disease

Diabetes is considered a cardiovascular disease equivalent, and patients with diabetes have a 2 to 8 times higher prevalence of, incidence of, and mortality from all forms of cardiovascular disease than those without diabetes. All patients with diabetes should be assessed annually for cardiovascular risk. Treat all risk factors aggressively, and perform further screening and diagnostic testing as suggested in the algorithm below.
Multifactorial risk reduction for cardiovascular disease

In patients with diabetes, risk factors for cardiovascular disease and cardiovascular events are similar to those in patients without diabetes. However, the magnitude of risk may be greater. Research suggests that long-term control of blood glucose, blood pressure, and lipids can substantially reduce these risks in all patients, but that patients with diabetes may benefit to an even greater extent.\(^{ADAM, GAE}\)

We recommend helping patients lower their cardiovascular risk by promoting lifestyle modifications as needed (smoking cessation, weight loss, etc.) and following the guidelines in this CPM for good management of glucose, lipids, and blood pressure. Also consider using proven medications in appropriate patients; see the discussion below.

ACE inhibitors

Several studies have shown that ACE inhibitors can reduce cardiovascular complications even more than can be explained by blood pressure reduction alone. For example, the HOPE trial showed a reduction in cardiovascular events in diabetes patients over 55 years of age with normal blood pressure. If not contraindicated, consider an ACE inhibitor in all patients over 55 years of age, with or without hypertension, with any additional risk factor such as history of cardiovascular disease, dyslipidemia, increased urinary albumin, or smoking.\(^{DAG}\)

Beta blockers

Patients with diabetes and significant coronary artery disease may benefit from beta blockers, especially those who have had a coronary event within the previous 2 years.

Aspirin therapy\(^{UTA}\)

For secondary prevention in people with atherosclerotic vascular disease, low-dose aspirin provides a substantial 20% relative risk reduction (RRR) and 1.5% per year absolute risk reduction (ARR) in recurrent cardiovascular disease (CVD) events. However, for primary prevention the relative and absolute benefits of aspirin are much lower — just 12% RRR and 0.06% per year ARR in CVD events. For primary prevention in people with diabetes, recent randomized trials and meta-analyses of available trials have found a similar 10% RRR in CVD events. Given the uncertain efficacy of aspirin for primary prevention of CVD in adults with diabetes and its recognized risk for upper gastrointestinal bleeds and hemorrhagic stroke, a 2010 expert consensus document suggested that for primary prevention, aspirin therapy should be guided by a combined assessment of either age, sex, and other CVD risk factors or by an estimate of absolute 10-year CVD risk. Risk can be calculated via the resources noted at right.

For patients with no history of CVD who are not at increased risk for bleeding (no history of prior gastrointestinal bleeding, no prior peptic ulcer disease, no concurrent warfarin or NSAID therapy), we recommend aspirin at a dose of 75 to 162 mg/day following the guidelines below.

### Beyond CVD

In addition to heart disease, many complex factors contribute to reduced cardiopulmonary function in patients with diabetes, including:
- Obstructive sleep apnea
- Diastolic dysfunction
- Reduced pulmonary diffusing capacity
- Functional restrictive lung disease

These conditions are commonly underdiagnosed in patients with diabetes. However, they can aggravate hypertension, cause fatigue, and reduce exercise capacity. The cornerstones of therapy are:
- Tight blood pressure control
- Blood glucose control
- Weight loss

Calculate 10-year CVD risk

The American Heart Association and American College of Cardiology\(^{ACC}\) recommend the new Pooled Cohort Risk Equation to evaluate 10-year and lifetime risk of ASCVD. It is available at: tools.cardiosource.org/ASCVD-Risk-Estimator

<table>
<thead>
<tr>
<th>Aspirin is <strong>recommended</strong> for:</th>
<th>Aspirin may be <strong>considered</strong> for:</th>
<th>Aspirin is <strong>not recommended</strong> for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Adults with &gt;10% 10-year CVD risk* or for</td>
<td>• Adults with 5–10% 10-year CVD risk* or for</td>
<td>• Adults with &lt; 5% 10-year CVD risk* or for</td>
</tr>
<tr>
<td>• Most men &gt;50 years and women &gt;60 years with any of these risk factors:</td>
<td>• Men &gt;50 years or women &gt;60 years with none of the risk factors noted in the first column</td>
<td>• Men &lt; 50 years and women &lt; 60 years with none of the risk factors noted in the first column</td>
</tr>
<tr>
<td>- Smoking</td>
<td>- High cholesterol</td>
<td>- Smoking</td>
</tr>
<tr>
<td>- High blood pressure</td>
<td>- Family history of premature CVD</td>
<td>- High blood pressure</td>
</tr>
<tr>
<td>- Albuminuria</td>
<td></td>
<td>- Family history of premature CVD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Albuminuria</td>
</tr>
</tbody>
</table>
High cholesterol

Diabetes mellitus is associated with multiple lipid abnormalities, most typically hypertriglyceridemia, low HDL cholesterol, and increased numbers of small, dense LDL cholesterol particles. Insulin resistance, insulin deficiency, hyperglycemia, and obesity are common contributing factors for dyslipidemia in people with diabetes. Multiple studies have demonstrated that treating dyslipidemia can improve cardiovascular disease outcomes in people with diabetes.

Recommendations on cholesterol management have recently changed. In 2013 the American Heart Association and American College of Cardiology revised their cholesterol treatment guidelines to recommend that treatment initiation and initial statin dose be driven primarily by risk status, not by LDL cholesterol level. The 2015 ADA Standards recommend following this guideline for diabetes treatment.

The algorithm below is taken directly from Intermountain’s Cardiovascular Risk and Cholesterol CPM.

Some controversy exists around the new recommendations. The National Lipid Association (NLA) continues to recommend initiation of statin therapy based on lipid targets. For a detailed comparison of AHA and NLA recommendations, visit www.lipid.org/recommendations.
### ALGORITHM NOTES

#### (a) Clinical ASCVD

**Clinical ASCVD is defined as one or more of the following:**
- Acute coronary syndromes
- History of MI
- Stable or unstable angina
- Coronary or other arterial revascularization
- Atherosclerotic stroke
- Atherosclerotic TIA
- Atherosclerotic peripheral artery disease
- Abdominal aortic aneurysm

**Treatment fundamentals for patients with clinical ASCVD:**
- **A** — Aspirin/antiplatelet therapy
- **B** — Blood pressure control
- **C** — Cholesterol control and Cigarette smoking cessation
- **D** — Diet and weight management and Diabetes and blood glucose control
- **E** — Exercise

#### (b) Statin Therapy<sup>ACC</sup>  (Do not prescribe if patient is pregnant or lactating)

<table>
<thead>
<tr>
<th>High-intensity statin therapy</th>
<th>Moderate-intensity statin therapy</th>
<th>Low-intensity statin therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>(For patients with clinical ASCVD and age &lt;75, LDL-C &gt;190, diabetes and age 40 to 75 with other risk factors, or &gt;7.5% 10-year ASCVD risk)</td>
<td>(For patients with clinical ASCVD and age &gt;75, diabetes and age 40 to 75 without other risk factors, or 5%–7.5% 10-year ASCVD risk)</td>
<td>(For patients with &lt; 5% 10-year ASCVD risk and other risk factors)</td>
</tr>
<tr>
<td>Daily dose lowers LDL-C on average by approximately 50% or more*</td>
<td>Daily dose lowers LDL-C on average by approximately 30% to 50%*</td>
<td>Daily dose lowers LDL-C on average by up to 30%*</td>
</tr>
</tbody>
</table>
| • **Atorvastatin (40t)—80 mg**  
  • Rosuvastatin 20 (40) mg | • **Atorvastatin 10 (20) mg**  
  • Simvastatin 20 mg–40 mg†  
  • **Pravastatin 40 (80) mg**  
  • **Lovastatin 40 mg**  
  • Fluvastatin XL 80 mg  
  • Fluvastatin 40 mg bid  
  • Pitavastatin 2 mg–4 mg  
  • Rosuvastatin (5) 10 mg | • **Pravastatin 10 mg–20 mg**  
  • Lovastatin 20 mg  
  • Simvastatin 10 mg  
  • Fluvastatin 20 mg–40 mg  
  • Pitavastatin 1 mg |

Bold text indicates preferred drug.

#### (c) New Pooled-Cohort Risk Calculator

The American Heart Association and American College of Cardiology<sup>ACC</sup> recommend the new Pooled Cohort Risk Equation to evaluate 10-year and lifetime risk of ASCVD and more accurately identify higher-risk patients who may benefit from statin therapy. **Available at:** [tools.cardiosource.org/ASCVD-Risk-Estimator](tools.cardiosource.org/ASCVD-Risk-Estimator)

#### OTHER ISSUES

**Triglycerides:** If triglycerides are over 500 mg/dL, treat to reduce risk of pancreatitis. There is no evidence of cardiovascular risk reduction from treatment.

**Blood glucose:** The impact of statins on blood glucose is small and should not influence the decision to prescribe.

**Other classes of lipid-lowering medications:**
- **Fibrates.** Gemfibrozil should not be initiated in patients on statin therapy because of an increased risk for muscle symptoms and rhabdomyolysis. Fenofibrates may be considered concurrent with low- or moderate-intensity statin only if benefits are judged to outweigh risks.
- **Ezetimibe.** May show some benefit. Make shared decision with patient.
- **Omega-3 fatty acids** (fish oil supplements). Not recommended.
- **Bile acid sequestrants.** Consider using colesuvelam for statin-intolerant patients.
High blood pressure

High blood pressure affects most patients with diabetes. Aggressive treatment of high blood pressure has been convincingly shown to reduce cardiovascular risk in these patients to an extent equal to or greater than the effect of glucose control.\textsuperscript{UKPDS, JAMA}

The 2015 ADA Standards of Medical Care in Diabetes changed the recommended goal for diastolic blood pressure in most patients with diabetes from 80 mm Hg to 90 mm Hg, reflecting the clearest evidence from randomized clinical trials.

The algorithm below is a shortened version of the algorithm in the \textit{High Blood Pressure CPM} and is consistent with the recommendations in the ADA Standards. Using the same treatment protocol across the system has been shown to facilitate consistent team-based care.

### ALGORITHM: MANAGEMENT OF HYPERTENSION

**General approach for most patients under 80 years old**

**Check BP at each office visit (a)**

- **Systolic ≥140 or Diastolic ≥90?**
  - No
  - **RECHECK to confirm high BP (b)**
    - Follow-up office visit
    - Home BP readings
  - **High BP confirmed?**
    - No
    - **TREAT high BP to management target: <140/<90 (c)**
    - **INITIATE therapeutic lifestyle changes (TLC) (d)**
      - Start meds concurrently with TLC.
      - Maintain TLC throughout course of treatment.

**Treatment process:**

- Evaluate BP every 2 weeks while titrating or switching medications. \textsuperscript{(d)}
- Order BMP 2–3 weeks after initiation or dose changes of lisinopril or HCTZ.
- Consider divided dosing (AM/PM) when patient is on more than one medication.
- When BP is at target, maintain current therapy and evaluate BP every 6 months.

**Special populations:**

- Consider individualized target as needed based on patient’s clinical circumstances.
- Consider secondary causes of high BP \textsuperscript{(g)}

**ACEI (or ARB): lisinopril (or losartan) (e)**

- Lisinopril titration: 10 mg daily → 20 mg daily

For patients who require additional medications to manage high blood pressure, refer to the \textit{High Blood Pressure CPM}.

\textsuperscript{UKPDS, JAMA}
Special Populations

Prediabetes
Consider avoiding thiazides and beta blockers, as they can increase blood glucose. However, if a beta blocker is used, carvedilol is preferred as it may help with insulin resistance.

The recommendations below are for patients with both diabetes and the condition listed

Coronary artery disease
Consider adding carvedilol (preferred) or metoprolol succinate to ACEI/ARB. As needed, add amiodipine and then a diuretic.

Heart failure
If ejection fraction ≤40%, ACEI/ARB, plus carvedilol (preferred) or metoprolol succinate, plus spironolactone (if not contraindicated). If needed for BP, add amiodipine

Kidney disease
Treat to <140/<90; consider <130/80 if ACR >300. Monitor K+ and creatinine with ACEI/ARBs.

Black (African ancestry)
Consider starting with CCB or thiazide, then add thiazide or CCB as 2nd line.

Age >80 years
Consider target of <150/<90 and individualized approach; consider starting with CCB or thiazide.

Pregnancy
Avoid ACEI/ARB medications. Consider labetalol, CCB (nifedipine preferred), hydralazine, or methyldopa.
Kidney Disease
Diabetic nephropathy occurs in 20% to 40% of patients with diabetes and is the leading cause of end-stage renal disease. Increased urinary albumin excretion, a marker for development of nephropathy in type 2 diabetics, is also a well established marker for increased cardiovascular disease risk.

Screening and management recommendations

Detect the onset of diabetic kidney disease at its earliest stage with an annual albumin creatinine ratio. (Morning spot urine specimens are preferred.) In addition, we recommend measuring serum creatinine with calculation of estimated Glomerular Filtration Rate (eGFR) at least every year. Some patients with diabetic kidney disease will have normal albumin excretion in the presence of reduced renal function. GFR is also used to monitor for improvement or progression of preexisting nephropathy and to establish stages of chronic kidney disease (as defined by the National Kidney Foundation).

To reduce the risk of progression of diabetic nephropathy, we recommend the following:

- Optimizing blood glucose control (HbA1c less than 7%).
- Optimizing blood pressure control. In patients with increased urinary albumin excretion or nephropathy, treat to a blood pressure goal of 130/80 or lower.
- Using ACE inhibitors or ARBs in nonpregnant patients, even in patients with normal blood pressure. If one class of medication is not tolerated, substitute the other class.
- Restricting dietary protein. Reducing protein to 0.8 to 1 g/kg/day for patients in earlier-stage CKD and to 0.8 g/kg/day for patients in later stages of CKD may improve measures of renal function, including eGFR.

COMBINATION RENIN-SYSTEM THERAPY FOR ALBUMINURIA

A combination of drugs that block the renin-angiotensin-aldosterone system (e.g., ACEI plus an ARB, or a mineral corticoid antagonist [SARA]) has been shown to provide additional lowering of albuminuria. However, long-term cardiovascular or renal benefit has not been proven and may lead to increased adverse effects.

ALGORITHM NOTES

(a) The Modification of Diet in Renal Disease (MDRD) equation may significantly underestimate the filtration rate in patients with increased urinary albumin excretion or obesity, and in the elderly. The calculations have been validated only to age 70. When eGFR <60 ml/min/1.73 m² body surface area, evaluate further.

(b) Two specimens — collected three months apart — should be positive before considering a patient to have increased urinary albumin excretion. Vigorous exercise within 24 hours of the test, infection, fever, CHF, marked hyperglycemia, and marked hypertension all may elevate urinary albumin excretion. Note that a 24-hour urine testing for albumin is no longer typically recommended.

(c) Consider other causes of chronic kidney disease when patients have:
- No diabetic retinopathy
- No albuminuria
- Low or rapidly decreasing eGFR
- Rapidly increasing proteinuria or nephrotic syndrome
- Refractory hypertension
- Active urinary sediment present
- Signs or symptoms of other systemic disease
- Greater than 30% reduction in eGFR within 2 to 3 months after initiation of an ACEI or ARB

ALGORITHM: Nephropathy Screening

ANNUAL: test of urine albumin/creatinine ratio (ACR) AND test of serum creatinine and eGFR

ACR <30? (a)

no

yes

ACR <30?

no

yes

CONSIDER secondary causes of nephropathy (c)

DIABETIC NEPHROPATHY CONFIRMED

Refer to Chronic Kidney Disease CPM
Retinopathy

In the U.S., diabetes is the leading cause of new cases of blindness for adults ages 20 to 74 years. Good glycemic and blood pressure control can help prevent or slow the progression of diabetic retinopathy; early treatment of retinopathy can be the key to preventing blindness. We recommend the following practices:

- **Screening.** Early signs of retinopathy frequently go unnoticed by patients, but can be seen on a dilated fundus exam or with optical coherence tomography. These tests, with remote reading by an ophthalmologist or optometrist, are acceptable for screening but do not replace comprehensive in-person exams; follow the schedule below.
  - **For type 2 diabetes, initial screening should occur at diagnosis.** Repeat dilated eye exam every 1 to 2 years if under good control and no retinopathy; every 2 years in those with good blood pressure, blood glucose, and lipid levels.
  - **For type 1 (over age 10), initial screening should occur within 5 years of diagnosis.** Repeat dilated eye exam every year, or every 2 to 3 years following one or more normal eye exams. If retinopathy is progressing, more frequent exams are required.
  - **For women with diabetes who are pregnant or considering pregnancy,** dilated eye exams should occur before conception, during the first trimester of pregnancy, and every 3 months thereafter or as recommended by the ophthalmologist.

- **Referral.** Refer the following patients to an ophthalmologist experienced in managing diabetic retinopathy.
  - **Patients with diabetes who become pregnant.** (Women who develop gestational diabetes are not at increased risk.)
  - **Patients with macular edema or any retinopathy.**

Low testosterone in men

Men with type 2 diabetes may develop low testosterone levels. Consider evaluating male diabetic patients with symptoms and signs of hypogonadism or osteoporosis, including low energy, low libido, fatigue, and sexual dysfunction. We recommend the following:

- **Diagnose.** Measure early morning (8 AM) free or bioavailable testosterone using a validated testosterone assay. (Free and bioavailable testosterone values are more reliable than total testosterone.) If the level is below the reference range, repeat the same test plus LH in 1 or 2 months. Further testing after 2 or more months may be necessary. Hypogonadism should be confirmed as unequivocal and persistent over at least several months. Check prolactin. Differentiate primary from secondary disease. Consider an endocrine consult to avoid an unnecessary MRI. Natural testosterone variations, transient decreases, and equivocal testosterone values can be misleading. Low testosterone values are often functional, reversible, or self-limited.

- **Treat.** Comorbid conditions, including obesity, obstructive sleep apnea, hypertension, poor health habits, and acute illness, can be associated with or cause low testosterone. Improving treatment of these conditions often results in improved testosterone levels. Testosterone therapy recommendations and contraindications are detailed in the sidebar at right.

- **Follow-up.** The goal of treatment is to normalize testosterone levels. Repeat the appropriate testosterone and other measurements after 2–3 months of therapy and reevaluate. If symptoms have not significantly improved with normal testosterone levels, discontinue testosterone treatment. With daily topical preparations in the morning, an afternoon testosterone in the mid-normal range for a younger man and in the lower-normal range for an older man are reasonable. With weekly testosterone injections, check a mid-week testosterone, with the above stated goals. Parenteral testosterone, if given every 2 weeks, results in wide variations in testosterone levels during the 2-week interval, making it more difficult to use testosterone measurements to guide therapy. General follow-up should include monitoring testosterone, hematocrit, PSA, and rectal exam.

TESTOSTERONE THERAPY RECOMMENDATIONS

A conservative approach to the diagnosis and treatment of low testosterone is recommended. There is currently a lack of consensus among experts regarding the risk-benefit ratio for testosterone therapy in all but the most unequivocal of situations.

- Testosterone therapy is reasonable for men with unequivocally low early morning free or bioavailable testosterone values over a substantial period of time. Choose an approved testosterone formulation, taking into account the patient’s preference, pharmacokinetics, treatment burden, and cost.
- The safety of testosterone therapy has not been established for men with low-normal or borderline-low testosterone.
- There are unresolved questions about cardiovascular risk. New FDA product labeling is planned.

TESTOSTERONE THERAPY CONTRAINDICATIONS

Men with the following history or conditions should not receive testosterone:

- History of prostate cancer or breast cancer. Defer to oncology opinion.
- Rising or elevated PSA. PSA above 4 ng/mL or PSA above 3 ng/mL with high risk factors of prostate cancer (African Americans, men with a history or family history of prostate cancer). Defer to urology opinion.
- Untreated sleep apnea, or with untreated IPSS above 19 and uncontrolled heart failure. Defer to sleep specialist opinion.
- Hematocrit over 50%. Seek hematology opinion.
- Significant lower urinary tract symptoms. Seek urology opinion.
Foot problems

Foot problems are a frequent cause of morbidity and mortality in patients with diabetes. In the U.S., diabetes patients account for over 60% of non-traumatic, lower-limb amputations. Foot problems derive from a combination of factors:

- **Peripheral vascular disease** causes changes in skin tone, impaired wound healing, and greater susceptibility to infection.
- **Peripheral neuropathy** allows for nonpainful rubbing and callus formation, which often result in asymptomatic diabetic foot ulcers, over time.
- **Impaired wound healing** is a result of glycosylation of proteins and of peripheral vascular disease.

Ulceration and failure of wounds to heal frequently lead to lower extremity amputation. Once the amputation of one limb occurs, the prognosis for the contralateral limb is poor.

**Prevention is key.** Neglect is by far the most common reason for severe diabetic foot problems. Patients with diabetes often have decreased sensation and proprioception. They develop calluses over areas of friction, which can lead to ulcers. Often they don’t seek care until a serious infection has been established — one that may have already reached a bone. The CDC estimates that comprehensive foot care programs can have a positive impact for those with diabetes — reducing amputations by 45% to 85%.

Refer patients with any open ulcers or wounds to a podiatrist. Most of these wounds will require debridement and off-weighting techniques to heal. Diabetic patients with neuropathy or peripheral vascular disease qualify for routine nail care every 61 days. This allows regular follow-up and prevention of problems.

**We recommend treating painful neuropathy per the ADA guidelines shown in the table below.**

**TABLE 5: Options for Treating Painful Neuropathy**

<table>
<thead>
<tr>
<th>Class</th>
<th>Examples</th>
<th>Typical Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tricyclic drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amitriptyline</td>
<td>10–75 mg at bedtime</td>
<td></td>
</tr>
<tr>
<td>Nortriptyline</td>
<td>25–75 mg at bedtime</td>
<td></td>
</tr>
<tr>
<td>Imipramine</td>
<td>25–75 mg at bedtime</td>
<td></td>
</tr>
<tr>
<td>Anticonvulsants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gabapentin</td>
<td>300–1,200 mg 3 times a day</td>
<td></td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>200–400 mg 3 times a day</td>
<td></td>
</tr>
<tr>
<td>Pregabalin</td>
<td>100 mg 3 times a day</td>
<td></td>
</tr>
<tr>
<td>5-hydroxytryptamine and norepinephrine uptake inhibitor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duloxetine</td>
<td>60–120 mg a day</td>
<td></td>
</tr>
<tr>
<td>Substance P inhibitor</td>
<td>Capsaicin cream</td>
<td>0.025–0.075% applied 3 to 4 times a day</td>
</tr>
</tbody>
</table>

**Note:** Peripheral neuropathy has been associated with vitamin B12 deficiency, a potential side-effect of metformin use. See note (a) on page 12.
ALGORITHM: ROUTINE FOOT EXAMS

OFFICE VISIT

Vascular exam:
Grade edema and feel for both dorsal pedal and posterior tibial pulses

- Document as "palpable pedal pulses" and record edema grade
- Document as "nonpalpable pedal pulses" and record edema grade

Sensory exam:
See method (a)

- Document as "protective threshold present"
- Document as "protective threshold absent"

Vibratory sensation exam:
See suggested method (b)

- Record number of seconds
- Record number of seconds

Dermatology exam:
Check for calluses on bony prominences on the ball of the foot. Check between all toes for hyperkeratosis or small corns. Check the heels for cracking.

- Document as "no hyperkeratosis, no open lesions"
- Document as appropriate

Skeletal exam:
Look for deformities.

- Document as "no bony abnormalities"
- Document as "bony abnormalities"

Continue routine foot exams at least annually

Refer to a podiatrist for complete foot-care workup, education, and follow-up care

ALGORITHM NOTES

(a) HOW TO PERFORM SENSORY EXAM

Using a Semmes-Weinstein 5.07 monofilament, test several toes on each foot, being careful not to test directly over a callus, ulcer, scar, or necrotic tissue.

Apply the monofilament perpendicular to the skin’s surface forcefully enough to bend the filament. Do not let it slide or make repetitive contact.

(b) HOW TO PERFORM VIBRATORY SENSATION EXAM

Patients with low vibratory sensation are at increased risk of falls. Use a 128-Hz tuning fork to test vibratory sensation.

One suggested method of testing: [LEW, ADAM2]

1. Explain the test to patient; mention that fork vibration may feel like “buzzing.” (Consider demonstrating feel of vibrating/nonvibrating fork on patient’s forehead or wrist.)

2. Have the patient close eyes.

3. Strike the fork forcefully (on a desk or other hard surface) to set off a strong vibration. Instruct the patient: “Tell me when you no longer feel the buzzing.”

4. Holding the fork by the stem, place the base of the fork on the patient’s large toe.

5. Repeat the test on the other side.

6. Record the number of seconds the patient can feel the vibration. Ten or more seconds is normal.
Obstructive sleep apnea (OSA)

Individuals with diabetes or insulin resistance have a 2- to 4-fold higher prevalence of OSA compared with the general population. Prevalence in obese patients is significantly higher.

While no study has shown that having OSA causes diabetes, there is mounting evidence that OSA, along with sleep deprivation in general, is associated with insulin resistance, increased insulin secretion, and impaired glucose metabolism. 

- **Screening.** All patients with diabetes should be screened for OSA, particularly those patients with waist circumference above normal. Intermountain recommends using the STOP-BANG screening questionnaire because it is concise, easy to use, and has been validated in a presurgical setting. In general, the more of these symptoms a patient has and the more severe the symptoms are, the greater the pretest probability that a patient will have moderate or severe OSA.

- **Referral.** For patients with 3 or more STOP-BANG risk factors, consider referral to a sleep specialist.

### Evaluate Patient and Administer STOP-BANG OSA screening questionnaire

- **Snoring:** Do you snore loudly (louder than talking or loud enough to be heard through closed doors)?
- **Tired:** Do you often feel tired, fatigued, or sleepy during the daytime, even after a “good” night’s sleep?
- **Observed:** Has anyone observed you stop breathing during your sleep?
- **Pressure:** Do you have or are you being treated for high blood pressure?
- **Body mass index (BMI)** greater than 35?
- **Age** older than 50 years?
- **Neck circumference** greater than 16 inches (41 cm) for females or 17 inches (43 cm) for males?
- **Gender = male**?

### Treatment

Treatment of sleep apnea significantly improves quality of life and blood pressure control. Evidence for an effect on glycemic control is mixed, and preliminary evidence is hopeful that treatment can improve visual acuity in those struggling with diabetic retinopathy.

Treating OSA should be done according to standard guidelines for OSA, as outline in the Intermountain care process model *Management of Obstructive Sleep Apnea*. Extra effort toward weight loss, however, will likely be of great benefit to patients who suffer from diabetes and its comorbidities.

### Conditions associated with type 1 diabetes

- **Thyroid disease.** Perform thyroid-stimulating hormone (TSH) testing as part of an initial evaluation. If the diagnosis of diabetes is confirmed, repeat this testing periodically.

- **Celiac disease (sprue).** This disease is common in patients with type 1 diabetes (1% to 16% of individuals compared with 0.3% to 1% in the general population). Perform a tissue transglutaminase test as the initial screening for this disease in all patients with type 1 diabetes. Repeat testing may be appropriate. Symptoms of celiac disease may be subtle and include diarrhea, abdominal pain, and chronic fatigue.
**DATA AND REPORTS**

The Intermountain Primary Care Clinical Program maintains a database of 80,000 patients with diabetes who have been seen within the Intermountain system (see sidebar at right for inclusion criteria). The purpose of the database is to improve clinical care. It includes information on HbA1c, lipids, blood pressure, urinary albumin excretion, eye exams, foot exams, and ACEI or ARB use. Using this information, reports are developed for primary care physicians and endocrinologists to identify patients who may not have had testing done, or who have test results outside standards of good diabetes management.

Data for the reports is obtained from insurance claims, billing records, lab results, and the electronic medical record (EMR). Physicians can review their data and submit corrections if needed (see sidebar at right).

**The diabetes bundle**

Good management of diabetes is key to delaying and preventing complications, and thus improving patient satisfaction, medical outcomes, and appropriate utilization of healthcare resources. The "diabetes bundle" is a set of four elements that together represent a measure of an individuals' diabetes control. This set allows for comparison of management within the Medical Group and with other groups nationally, and leads to more coordinated and accountable team-based care. One of the quality measures for the Primary Care Clinical Program is to increase the percentage of diabetes patients age 18 to 75 who meet the targets indicated in the bundle.

**The diabetes bundle targets are set to allow for appropriate individualization of care.**

The diabetes bundle consists of the following targets:

1. Hemoglobin A1c less than 8%
2. Blood pressure less than 140/90 mm Hg
3. Nephropathy evaluation and care (one of the following):
   - Spot urine or 24-hour urine microalbumin-to-creatinine ratio in the measurement period
   - Nephropathy care as determined by ICD-10 diagnosis or patient visit with nephrologist
   - Patient is on an ACEI or ARB
4. Eye exam: A retinal or dilated eye exam by an ophthalmologist or optometrist within the last two years

For most patients with diabetes, recommended treatment goals for HbA1c are lower than those in the diabetes bundle. For some patients with diabetes, recommended treatment goals for blood pressure goals are lower as well. The bundle targets were selected so care plans could be individualized for each patient as clinically indicated. Most patients with diabetes should be treated to at least the levels indicated in the diabetes bundle.

**SelectHealth support**

SelectHealth is actively partnering with healthcare providers to care for patients with diabetes. SelectHealth uses interactive voice response telephone calls, diabetes care managers, and newsletters to reach out to members with diabetes — actively promoting good self-management, proper medical follow-up, and continued education.

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**THE DIABETES LIST**

A patient is included on the diabetes list if they:

- Have 1 abnormal HbA1c
- Have 2 outpatient visits with diabetes as the diagnosis
- Have 1 acute inpatient or ED visit with diabetes as the diagnosis
- Have filled a prescription for insulin or an oral hypoglycemic/antihyperglycemic agent other than metformin

**THE DIABETES REPORT**

Throughout this CPM, the icon indicates places where data is collected about each patient. Reports are updated monthly and are available to Intermountain-employed providers through the report portal. Affiliated providers receive their reports through SelectHealth. If you have questions about your report, please contact Brett Reading at 801-442-2989 or Brett.Reading@imail.org.

**How to submit corrections**

If you have corrections to the report (e.g., not your patient, does not have diabetes, in remission, deceased, moved away, etc.):

- Intermountain-employed providers can access the corrections tool directly and indicate the changes on the form.
  - Go to the Primary Care Clinical Program home page and download the Diabetes Data Management Tool
  - OR, when within the Intermountain firewall, enter either PCCPCT or CorrectionTool in your browser to go directly to the correction tool
- Affiliated providers can send their corrections along with documentation to SelectHealth Quality Improvement by faxing them to 801-442-0920.
COLLABORATIVE PHARMACY MANAGEMENT

The collaborative pharmacy model of disease management is an emerging program to help providers achieve clinical goals and improve satisfaction for patients with dyslipidemia, diabetes, and/or hypertension.

This program allows providers to partner with a pharmacist for support in selecting, titrating, and monitoring medications. For more information on this program, contact jeff.olson@imail.org.

PROPOSED ORDERS

iCentra will have the following advisories and the MA should propose orders to assist with the following advisories if they fire:
- Creatinine blood test (yearly)
- ACE/ARB
- HbA1c (every 6 months, or every 3 months if HbA1c is greater than 9)
- Urine ACR (yearly)
- See ophthalmology for 2-year exam, or enter date of last eye exam for eye professional

ADDITIONAL SUPPORT FROM THE CARE MANAGEMENT TEAM

The care management team should support the team by:
- Collaborating with physician on patient management and education
- Collaborating with physician to identify and refer patients who need specialty care
- Working the diabetes bundle reports

CLINIC TEAM ROLES

A clinic visit for a patient with diabetes requires the support of the entire team to assure comprehensive care. The following algorithm suggests general responsibilities to help a clinic team share accountability for diabetes management.

ALGORITHM: PATIENT VISIT

Prior to visit
- PSR prints worksheet for diabetes appointments and PATIENT completes in waiting room
- CARE MANAGEMENT TEAM scrubs schedule to identify patient needs

Patient check in

Patient Rooming (Medical Assistant)

Data
- Enter responses from patient worksheet
- Record vital signs, including height, weight, BP, and PAVS
- Download data from glucose meter, if applicable
- Document problems as directed by provider

Medications and allergies
- Reconcile medications
- Verify and document allergies
- Any additional education

Orders and tests
- Propose orders as prompted by iCentra (see sidebar at left)
- Perform A1c test as needed
- Administer PHQ-2 to patients who have not had one in the last 12 months
- If PHQ-2 is positive, administer PHQ-9

Patient preparation
- Have patient remove shoes and socks in preparation for foot exam
- Notify care manager of patients requesting any additional education

Patient Visit (Primary Care Provider)

Data
- Review responses to diabetes questionnaire
- Document diabetes in the problem list (if not already done), including date of onset if possible

Orders and tests
- Review and sign all proposed orders
- Consider preordering labs for next visit
- Perform foot exam and record results

Management
- Manage diabetes based on CPM guidelines
- Collaborate with pharmacist as needed (see sidebar at left)
- Identify patients whose comorbid conditions or age may be a contraindication to pursing treatment goals
- Determine compliance with diet and exercise recommendations
- Determine need for vaccinations

Follow-up
- Schedule quarterly follow-up appointment for patients who are not at goal per CPM
- Encourage patients to work with care manager or health advocate as needed (see sidebar at left)
DIABETES EDUCATION RESOURCES

The Intermountain Diabetes Workgroup, diabetes educators, and Patient and Provider Publications team have developed patient education materials to directly support the treatment recommendations in this care process model. Education for patients and families increases patient compliance with a treatment plan.

Patient education materials

The following patient education resources can be accessed and ordered online at minimal cost. See access and ordering information in the sidebar at right:

- **Living Well: A Diabetes Care Handbook**
  - Available in English and Spanish
  - Intermountain’s comprehensive guide to diabetes and diabetes self-management.

- **BG Tracker**
  - Available in English and Spanish

- **Carb Counselor: Advice and Tools for Counting Carbs**
  - Available in English and Spanish

- **Diabetes Care Card**
  - Available in English and Spanish

- **Food Finder**
  - Available in English and Spanish

- **Meal Plan**
  - Available in English and Spanish

- **FACT SHEETS from Intermountain**
  - All available in English and Spanish

- **HealthSheets from Krames StayWell**
  - All are available in English and Spanish, and many are available in several other languages.

HOW TO ACCESS PATIENT EDUCATION MATERIALS

For Intermountain materials, go to: intermountainphysician.org/clinicalprograms and select “Diabetes - Adult” from the topic list, or visit jprintstore.org

For both Krames StayWell and Intermountain fact sheets, go to the Patient Education Library at: intermountainphysician.org/PEN, choose Krames On-Demand, and enter "diabetes" in the search bar. Intermountain materials appear under "Client Custom Content" and Krames StayWell materials appear under "HealthSheets."

Call 801-442-3300 for help ordering Intermountain or Krames StayWell printed materials.

PROVIDER RESOURCES

Go to:

- IntermountainPhysician.org/ClinicalPrograms and select “Diabetes - Adult” from the topic list.

This care process model appears under "ClinicalPrograms" and select

- **Outpatient Management of Adult Diabetes Mellitus**
- **Gestational Diabetes CPM**
- **Prediabetes CPM**
- **Living Well PowerPoint Teaching Slides**
**Diabetes educators and diabetes education programs**

Diabetes education and medical nutrition therapy are covered by most commercial insurance providers and by Medicare. For help locating diabetes educators in the area of your practice, call Intermountain's Primary Care Program at 801-442-2990.

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<td>9844 South 1300 East, #200</td>
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This CPM presents a model of best care based on the best evidence available at the time of publication. It is not a prescription for every patient, and it is not meant to replace clinical judgment. Although physicians are encouraged to follow the CPM to help focus on and measure quality, deviations are a means for discovering improvements in patient care and expanding the knowledge base. Send feedback to Wayne Cannon, MD, Intermountain Healthcare, Primary Care Medical Director (Wayne.Cannon@imail.org).