This care process model (CPM) was created by the Diabetes Prevention and Management Development Team, a committee of the Medical Specialties and Family Medicine Programs at Intermountain Healthcare. 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.

This CPM is part of Intermountain’s comprehensive, team-based care approach for adults with diabetes in the outpatient setting. Other components of this system include:

- Education materials and programs for providers and patients
- Data systems that allow for population health management of patients with diabetes
- Enhancements to the electronic medical record and other tools to make it easier for clinicians to provide quality care
- Multidisciplinary coordination of diabetes care

What’s New IN THIS UPDATE?

The primary changes to this CPM involve recommendations for:

- **Cardiovascular risk reduction.** The American Diabetes Association (ADA) and the American Association for Clinical Endocrinologists (AACE) recommendations now support prescribing one of three medications as second-line therapy for all patients with type 2 diabetes and cardiovascular disease. Information on these medications is reviewed on page 21.

- **Strategic post-prandial walking to reduce blood glucose.** New studies recommend walking after meals, particularly after the evening meal when carbohydrate intake is higher. See page 9.

- **Metabolic and bariatric surgery (MBS).** Evidence supports MBS as a treatment for type 2 diabetes in appropriate surgical candidates. A study by LDS Hospital researchers, published in the *Journal of the American Medical Association*, showed that MBS may produce remission. See page 11.

- **Weight-loss medications.** Three, new weight-loss medications were added to the market, including lorcaserin (Belviq), phentermin/topiramate (Qsymia), and naltrexone/bupropion (Contrave). These medications give providers and patients more options for better HbA1c control. See page 10 for recommendations regarding their use.

- **New insulins.** Several new insulins have been added to the insulin medication information table, including deglutec (Tresiba), glargine (Basaglar, Lantus, Toujeo), and glargine/lixisenatide (Soliqua) and deglutec/liraglutide (Xultophy). See page 16.
Why Focus ON DIABETES?

- **Diabetes is a growing problem.** The estimated number of Americans with diabetes increased from 12.1 million in 2002 to 29.1 million in 2017.\(^{CDC1}\) The CDC projects that by 2050, as many as 33% of U.S. adults could have diabetes.\(^{CDC2}\)
- **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. It’s estimated that within the next decade, spending will rise to almost $500 billion — 10% of total health spending.\(^{ADAE}\)
- **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 diagnosis. Approximately 25% of type 2 diabetes cases may be currently undiagnosed.\(^{ADA}\)
- **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. Following the diabetes management recommendations set forth in this CPM can help delay or prevent these complications.

### TREATMENT GOALS & MEASURES

**TABLE 1: Treatment Goals**

<table>
<thead>
<tr>
<th>Measure</th>
<th>GOAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HbA1c</strong> (test at least every 6 months)</td>
<td>&lt; 7.0%*</td>
</tr>
<tr>
<td><strong>Blood pressure</strong> (check at each office visit)</td>
<td>&lt; 140/90 mmHg* (lower in some)</td>
</tr>
<tr>
<td><strong>Foot exam</strong> (perform at least every year — every visit if abnormal)</td>
<td>Normal</td>
</tr>
<tr>
<td><strong>Statin medication</strong></td>
<td>Taking statin medication at appropriate level of intensity</td>
</tr>
<tr>
<td><strong>Urine albumin/creatinine ratio</strong> (test at least every year )</td>
<td>&lt; 30 mg albumin / g of creatinine</td>
</tr>
<tr>
<td><strong>Serum creatinine</strong> (every year, estimate GFR)</td>
<td>Normal</td>
</tr>
<tr>
<td><strong>Retinal or dilated eye exam</strong> (check every year or every 2 years if diabetes is well controlled)</td>
<td>Normal</td>
</tr>
</tbody>
</table>

*Although these blood glucose and blood pressure goals are recommended generally for most people with diabetes, these goals should be individualized. See the sidebar discussion on page 6 (HbA1c goal) and pages 24–25 (management of hypertension algorithm and notes).*

Throughout this CPM the icon indicates places where data is collected about each patient.
**SCREENING AND DIAGNOSIS**

Timely, accurate screening and diagnosis is important because it can prevent or delay diabetes complications. The length of time between the onset of hyperglycemia and appropriate treatment can be a significant factor in complication development and severity. Type 2 diabetes is often asymptomatic, and at the time of diagnosis, a significant number of type 2 patients already have complications, such as neuropathy, nephropathy, or retinopathy.

**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 three to five 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. 

- **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).** HbA1c measurement does not require the patient to fast or undergo a glucose tolerance test, and required specimens are stable at room temperature. Venipuncture is preferred to point-of-care testing. Further, HbA1c testing can be done even during illness. Limitations of this test are that the HbA1c normal range is modestly higher in certain ethnic groups (e.g., those of African-American or Asian-Indian descent), and 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. False low 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 reproducible, less costly, and easier to administer than the two-hour oral glucose tolerance test (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 algorithm note (d) on page 5.** Note that in the absence of unequivocal hyperglycemia, repeat testing is required to make a diagnosis of diabetes. In an outpatient setting, if a patient has new onset hyperglycemia, causes 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.
ALGORITHM 1: 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

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

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

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

Meets criteria for DIAGNOSIS (d)?

no

PREDIABETES (c)

REFERR to Prediabetes Care Process Model for follow-up plan

yes

Diabetes mellitus

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

See ALGORITHM: Anti hyperglycemic Therapy in Type 2 Diabetes on page 12

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**(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 gestational diabetes mellitus (GDM)
  - 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)

*For SelectHealth patients, obesity must be listed in the first position for billing.

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.
- 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. 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 3 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.5

- **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,6 GER ADVANCE,7 CHA 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.

**MANAGEMENT OVERVIEW**

Diabetes care is complex, requiring regular medical care and follow up. Patients with well-controlled diabetes should be seen at least every six months; those who are not meeting treatment goals should be seen even more frequently.

Good diabetes care focuses on comprehensive management of blood glucose, blood pressure, and lipids and includes regular screening for eye, nerve, and kidney complications. This section of the CPM focuses on some important elements of diabetes care and self-management, namely blood glucose monitoring, medical nutrition therapy (MNT), physical activity, and medication. It emphasizes individualization of treatment to address the patient’s needs, preferences, and values.

**Monitoring blood glucose**

**The role of HbA1c**

HbA1c testing is an indication of the overall trend of blood glucose levels for the previous two to three 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.

**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>
</tr>
<tr>
<td>9 %</td>
<td>212 mg/dL</td>
</tr>
<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>

*Indicates an Intermountain measure

**ALGORITHM 2: MONITORING HBA1C**

Office visit for patient with confirmed diabetes mellitus

- **Good control**
  - In most patients: HbA1c less than 7% (see sidebar at left on individualized goals)
  - MAINTAIN treatment. No changes indicated (unless significant hypoglycemia)
  - REINFORCE previous diabetes education; REFER as indicated*
  - FOLLOW UP HbA1c:
    - If on oral or no medication, at least every 6–12 months
    - If on insulin, every 3–6 months

- **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, CONSIDER referral to endocrinologist or other diabetes specialist

*At least annually, reinforce/update a patient’s diabetes knowledge and skills. Certified diabetes educators (CDEs), RNs, and registered dietitian nutritionists (RDNs) can provide individualized medical nutrition therapy (MNT).
SMBG GUIDELINES

Although we recommend tailoring the frequency and timing of SMBG to individual patients and circumstances, some general guidelines appear below.

Test once a day or less often:
Patients who are controlling their diabetes with oral agents or with diet and exercise alone

Test 3 or fewer times a day:
Patients using less-frequent insulin injections

Test 3 to 4 times a day:
Patients using multiple insulin doses

Test 4 or more times a day:
- Patients using multiple insulin doses and exercise alone
- Patients using less-frequent insulin injections
- Patients who are controlling their diabetes with oral agents or with diet and exercise alone
- Patients having hypoglycemia
- Patients having hypoglycemic unawareness
- Any patient motivated to test this often to achieve best control possible

Coverage for SMBG test strips
- For all patients: Sometimes a durable medical equipment benefit is a better alternative than a pharmacy benefit to obtain test strips. Patients should compare both options.
- For Medicare patients: Medicare allows three test strips daily for patients with type 1 or type 2 diabetes on any form of insulin therapy. To obtain approval for four or more tests per day, Medicare requires proof of higher testing frequency (download from glucose monitor), a statement attesting to the need for added tests, and often a record from office notes demonstrating the provider’s recommendation for high-frequency testing.
- For patients without insurance coverage: Simple meters (usually with no memory or download capability) with names like ReliOn® and Truetrack® can be significantly less expensive for patients lacking insurance coverage for products with added features.

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 depends 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. A 1

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. See sidebar at left 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, potentially reducing 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:

1. Personal CGM devices belong to the patient and display subcutaneous glucose values to the patient in real time. An alarm feature alerts patients when their subcutaneous glucose values cross a prespecified threshold. In addition, these monitors have alarms that warn patients 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. A 1

Most commercial insurance carriers cover CGM; however, the majority of Medicaid plans do not.

2. 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, they 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, and LDL cholesterol control. A large retrospective study found that with a face-to-face counseling rate of at least one time per month, patients reached goals much faster than with less-frequent rates.\textsuperscript{MOR}

| % of Patients with A1c ≥ 7.0% SBP/DBP ≥ 130/85 mmHg or LDL ≥ 100 mg/dL |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| ≥ 1 per month   | (2, 154/3, 434) | between 1 per month | (13, 455/29, 546) | < 1 per 6 months | (24, 687/52, 807) |

Average face-to-face lifestyle counseling rate (unique patients / combined periods)

Nutrition counseling

All patients with diabetes should be referred for nutrition education.

Medical Nutrition Therapy (MNT) is an integral component of diabetes management and is covered by most commercial insurance providers and by Medicare. It 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. At a minimum, a meal plan addresses the following:

- **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. A number of dietary interventions exist. This CPM recommends referral to a registered dietitian nutritionist (RDN) for implementation as well as patient guidance and support.

- **Timing of meals and snacks.** Monitoring and maintaining a consistent pattern of carbohydrate intake 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 one to two pounds per week. Mediterranean, low-fat, calorie-restricted, or low-carbohydrate diets may be effective for weight loss.\textsuperscript{ADA} Until an RDN can provide an individualized meal plan, counsel overweight patients to reduce calories. Recommendations include:
  - As a temporary guideline, an initial goal is to reduce dietary intake by 500 total calories per day from their current intake until a plan can be individualized by an RDN.
  - 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 can also help patients track nutrients and physical activity.

SUPPORT FOR LIFESTYLE MANAGEMENT

The 2015 Lifestyle and Weight Management CPM provides detailed strategies and tools to help build a team process around evidence-based guidelines for behavior change, physical activity, nutrition, weight management, and other lifestyle factors.

Click the image to open the document, or see \texttt{page 34} for ordering information.

THE LOOK AHEAD TRIAL

The Look AHEAD trial was a large clinical trial designed to examine the long-term effects of an intensive lifestyle intervention (ILI) in overweight volunteers with type 2 diabetes.\textsuperscript{DEL} Although the trial showed no difference in CVD endpoints compared to the control group, study participants who received ILI experienced:

- Average weight loss of 8.6%\textsuperscript{MOR}
- Significant reduction of HbA1c
- Reduction in several CVD risk factors

The Look AHEAD findings suggest that ILI is associated with partial diabetes remission in patients with type 2 diabetes, particularly in those whose diabetes is of short duration, who have lower HbA1c levels, and who do not yet require insulin therapy.
RECOMMENDATIONS

• 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 three days per week, with no more than two 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 (see sidebar on page 8) 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 iCentra. Casual walking below moderate intensity does not count toward the weekly goal.

• Gradually increase activity. Patients who are currently sedentary should start with 10 minutes of walking at moderate intensity three days per week, gradually increasing to five 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 two 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. A brisk walk for 30 minutes after meals is associated with clinically meaningful decreases in blood glucose levels.

• Patients taking insulin or sulfonylureas should 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.

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 encouraged to engage in regular physical activity. Preexercise health screening should be based on the following three factors:

1. The individual’s current level of physical activity
2. The presence of signs or symptoms and/or known cardiovascular, metabolic, or renal disease
3. Desired exercise intensity. The table below outlines recommendations from the American College of Sports Medicine regarding recommendations for pre-exercise evaluation.

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.

<table>
<thead>
<tr>
<th>TABLE 2. Recommendations based on pre-exercise evaluation&lt;sup&gt;REI, USDH, PES&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current exercise status</strong></td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td>Does NOT participate</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Participates</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Medical status</td>
</tr>
<tr>
<td>A. No cardiovascular (CV), metabolic (e.g., diabetes), or renal disease AND no signs or symptoms suggestive of CV, metabolic disease or renal disease</td>
</tr>
</tbody>
</table>

1 Light-intensity exercise, 35–50% of age-predicted maximal heart rate, an intensity that causes slight increases in HR and breathing
2 Moderate-intensity exercise, 50–70% of age-predicted maximal heart rate, an intensity that causes noticeable increases in HR and breathing
3 Vigorous-intensity exercise, 70–85% of age-predicted maximal heart rate, an intensity that causes substantial increases in HR and breathing
Age-predicted maximal heart rate: 220 - age = HR (max)
Behavior modification and accountability

Diabetes self-care requires modification to daily behaviors that most patients find challenging. For detailed, evidence-based support of 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 at left for more information.

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. The Affordable Care Act (ACA) requires commercial payers 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 cover medical nutrition therapy for select patients.

Weight-loss medications HAN, ADA

Weight-loss medications (see table 2 below) may be used in conjunction with lifestyle modification to support weight-loss goals. This CPM recommends that a patient should either see a loss of at least 5% in three months or the medication should be stopped. Check the patient’s insurance coverage before ordering medications as they are costly and rarely covered. The ADA and AACE recommend:

- **ADA**: Weight-loss medications may be effective as adjuncts to diet, physical activity, and behavioral counseling for selected patients with type 2 diabetes and BMI ≥ 27. Potential benefits must be weighed against the potential risks of the medications. (Grade A)
- **AACE**: Weight-loss medications should be considered as an adjunct to lifestyle therapy in all patients with type 2 diabetes as needed for weight loss sufficient to improve glycemic control, lipids, and BP. (Grade A)

### TABLE 2. Weight-loss medications used in the treatment of type 2 diabetes

<table>
<thead>
<tr>
<th>Medication name — generic (Brand)</th>
<th>Δ Weight</th>
<th>Δ A1c</th>
<th>Δ DM medications</th>
<th>Δ SBP</th>
<th>Δ LDL</th>
<th>Risk of hypoglycemia</th>
<th>Drug interactions</th>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>locaserin (Belviq)</td>
<td>-3 kg</td>
<td>-0.5%</td>
<td>No difference</td>
<td>No difference</td>
<td>No difference</td>
<td>Increased</td>
<td>Antidepressants</td>
<td>Pregnancy, Severe hepatic disease, CrCl &lt; 30 mL/min</td>
</tr>
<tr>
<td>liraglutide (Saxenda)*</td>
<td>-4 kg</td>
<td>-0.9%</td>
<td>Decreased</td>
<td>-2.4 mmHg</td>
<td>No difference</td>
<td>Increased</td>
<td>N/A</td>
<td>Pregnancy, Severe hepatic disease</td>
</tr>
<tr>
<td>naltrexone/bupropion (Contrave)*</td>
<td>-3 kg</td>
<td>-0.5%</td>
<td>Decreased</td>
<td>No difference</td>
<td>No difference</td>
<td>No difference</td>
<td>Antidepressants, Opioids</td>
<td>Pregnancy, Severe hepatic disease, CrCl &lt; 30 mL/min</td>
</tr>
<tr>
<td>phentermine/topiramate (Qsymia)*</td>
<td>-6 kg</td>
<td>-4.0%</td>
<td>Decreased</td>
<td>-4.8 mmHg</td>
<td>No difference</td>
<td>Increased</td>
<td>Antidepressants</td>
<td>Pregnancy, Severe hepatic disease, CrCl &lt; 30 mL/min</td>
</tr>
<tr>
<td>orlistat (Xenical or Alli)</td>
<td>-3 kg</td>
<td>-0.4%</td>
<td>Decreased</td>
<td>No difference</td>
<td>-4.9 mg/dL</td>
<td>Increased</td>
<td>Vitamins A, D, E, K, Warfarin, Levotyroxine Anticonvulsants</td>
<td>Pregnancy, Severe hepatic disease</td>
</tr>
</tbody>
</table>

Δ = change in measure; * = new
DIABETES IN REMISSON

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 considered to be in remission. An ADA consensus statement defines remission as complete remission. Hyperglycemia below diagnostic thresholds for at least one year with no active pharmacologic intervention. Partial remission. Hyperglycemia below diagnostic thresholds for at least one year with active pharmacologic intervention. Complete remission. Normal glycemia measures for at least one year with no active pharmacologic therapy. Prolonged remission. Complete remission for at least five years.

Follow up for patients in remission

The science is limited regarding patient risk for macrovascular and microvascular complications in remission. The ADA currently recommends the following care: 

- Until the patient is in prolonged remission, continue the same follow-up practices as for 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 three years, which matches the preventive care guidelines.

This Diabetes in Remission fact sheet (see ordering information on page 34) is a shared decision-making tool that can help providers and patients decide together on an appropriate follow-up plan.

METABOLIC AND BARIATRIC SURGERY (MBS)

Lifestyle modifications are often not enough to help people who are severely overweight. Metabolic surgery should be recommended to treat type 2 diabetes in appropriate adult surgical candidates as follows: 

- BMI > 40 regardless of the level of glycemic control or complexity of glucose-lowering regimens
- BMI of 35–39.9 when hyperglycemia is inadequately controlled despite lifestyle and optimal medical therapy
- Type 2 diabetes and a BMI of 30–34.9 if hyperglycemia is inadequately controlled despite optimal medical control by either oral or injectable medications, including insulin

Clinical efficacy. Studies show that MBS 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 at left.

A study by LDS Hospital researchers, published in the Journal of the American Medical Association showed the following benefits for patients who underwent gastric bypass (Roux-en-Y): 

- Diabetes benefits are enduring. Among diabetes patients who had diabetes before surgery, 62% were in remission after six years and 52% at 12 years. That compares to 8% and 6% for the nonsurgical groups. Gastric bypass patients who did not have diabetes before the surgery were five to nine 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 by two years after gastric bypass surgery, maintaining a loss of 27.7% of the weight at 6 years and 26.9% at 12 years. Of these patients, 96% maintained more than 10% weight loss from baseline, and 76% maintained more than a 20% loss. By contrast, patients who did not have bariatric surgery either lost no weight or gained weight over the next six years.
- Other health risks: Surgical patients also showed improvements in hypertension, cholesterol, and triglyceride levels — three factors associated with an increased risk of heart disease and stroke.

Primary care recommendations. This CPM recommends:

- Considering bariatric surgery for patients ≥ 18 with type 2 diabetes who have a BMI ≥ 35, particularly when diabetes or its comorbidities are present. This recommendation follows national guidelines.
- Referring patient candidates to an accredited Intermountain bariatric surgery center. These centers provide a board-certified physician with a practice devoted to bariatric medicine, presurgical consultation with RDNs, social workers, and other staff who can help patients with nutritional, psychological, and logistical (insurance) issues as well as robust postoperative processes. A list of accredited Intermountain centers is available in the Metabolic and Bariatric Surgery for the Treatment of Obesity CPM.
- Offering and referring to ongoing lifestyle support. This is critical for long-term weight-loss success.
GLUCOSE CONTROL WITH MEDICATION

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

- For type 2 diabetes, oral medications are required for glycemic control if lifestyle modifications don’t achieve glycemic control within two to three months (see page 8). 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. Metformin is first-line therapy. Recommendations now support prescribing one of three medications as second-line therapy for all patients with type 2 diabetes and cardiovascular disease. (See page 21.) For those without cardiovascular disease, follow algorithm 3 below.

- For type 1 diabetes, insulin therapy is essential. A regimen that combines peakless insulin (also called long-acting or basal insulin) and rapid-acting insulin (bolus) most closely mimics normal physiologic insulin production (see page 17).

- 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 3: ANTIHYPERGLYCEMIC THERAPY IN TYPE 2 DIABETES

GENERAL RECOMMENDATIONS

Start with Monotherapy unless:
- A1C is greater than or equal to 9%, consider Dual Therapy.
- A1C is greater than or equal to 10%, blood glucose is greater than or equal to 300 mg/dl, or patient is markedly symptomatic, consider Combination Injectable Therapy (See Figure 8.2).

Monotherapy

| Metformin |
| EFFICACY* | high |
| HYPO RISK | low risk |
| WEIGHT | neutral/loss |
| SIDE EFFECTS | GI/lactic acidosis |
| COSTS* | low |

If A1C target not achieved after approximately 3 months of monotherapy, proceed to 2-drug combination (order not meant to denote any specific preference — choice dependent on a variety of patient- & disease-specific factors):

Dual Therapy

| Metformin + |
| Sulfonylurea | Thiazolidinedione | DPP-4 inhibitor | SGLT2 inhibitor | GLP-1 receptor agonist | Insulin (basal) |
| EFFICACY* | high | high | intermediate | intermediate | high |
| HYPO RISK | moderate risk | low risk | low risk | low risk | high risk |
| WEIGHT | gain | gain | neutral | loss | gain |
| SIDE EFFECTS | hypoglycemia | edema, HF, fxs | rare | GU, dehydration, fxs | GI |
| COSTS* | low | high | high | high | high |

If A1C target not achieved after approximately 3 months of dual therapy, proceed to 3-drug combination (order not meant to denote any specific preference — choice dependent on a variety of patient- & disease-specific factors):

Triple Therapy

| Metformin + |
| Sulfonylurea + | Thiazolidinedione + | DPP-4 inhibitor + | SGLT2 inhibitor + | GLP-1 receptor agonist + | Insulin (basal) + |
| TZD | SU | SU | SU | SU |
| or | or | or | or | or |
| or | or | or | or | or |
| or | or | or | or | or |

If A1C target not achieved after approximately 3 months of triple therapy and patient (1) on oral combination, move to basal insulin or GLP-1 RA, (2) on GLP-1 RA, add basal insulin or (3) on optimally titrated basal insulin, add GLP-1 RA or mealtime insulin. Metformin therapy should be maintained, while other oral agents may be discontinued on an individual basis to avoid unnecessarily complex or costly regimens (i.e. adding a fourth antihyperglycemic agent).

Combination Injectable Therapy

See Algorithm Notes below

Antihyperglycemic therapy in Type 2 Diabetes: general recommendations. The order in the chart was determined by historical availability and the route of administration, with injectables to the right; it is not meant to denote any specific preference. Potential sequences of antihyperglycemic therapy for patients with type 2 diabetes are displayed, with the usual transition moving vertically from top to bottom (although horizontal movement within therapy stages is also possible, depending on the circumstances). *See original source for description of efficacy categorization. §Usually a basal insulin (NPH, glargine, detemir, degludec). Adapted with permission from Inzucchi et al. Diabetes Care 2015;38:140–149.
Algorithm 3, Continued: Antihyperglycemic Therapy in Type 2 Diabetes: Combination Injectable Therapy

### Initiate Basal Insulin

**Usually with metformin +/- other noninsulin agent**

- **Start:** 10 U/day or 0.1–0.2 U/kg/day
- **Adjust:** 10–15% or 2–4 units once or twice weekly to reach FBG target
- **For hypo:** Determine & address cause; if no clear reason for hypo, ↓ dose by 4 units or 10–20%

#### Add 1 rapid-acting insulin injection before largest meal

- **Start:** 4 units, 0.1 U/kg, or 10% basal dose. If A1C <8%, consider ↓ basal by same amount
- **Adjust:** ↑ dose by 1–2 units or 10–15% once or twice weekly until SMBG target reached
- **For hypo:** Determine and address cause; if no clear reason for hypo, ↓ corresponding dose by 2–4 units or 10–20%

#### Add GLP-1 RA

- **If not tolerated or A1C target not reached,** change to 2 injection insulin regimen

#### Change to premixed insulin twice daily (before breakfast and supper)

- **Start:** Divide current basal dose into ½ AM, ½ PM or ½ AM, ½ PM
- **Adjust:** ↑ dose by 1–2 units or 10–15% once or twice weekly until SMBG target reached
- **For hypo:** Determine and address cause; if no clear reason for hypo, ↓ corresponding dose by 2–4 units or 10–20%

#### Add ≥2 rapid-acting insulin injections before meals (‘basal-bolus’)

- **Start:** 4 units, 0.1 U/kg, or 10% basal dose/meal. If A1C <8%, consider ↓ basal by same amount
- **Adjust:** ↑ dose(s) by 1–2 units or 10–15% once or twice weekly to achieve SMBG target
- **For hypo:** Determine and address cause; if no clear reason for hypo, ↓ corresponding dose by 2–4 units or 10–20%

#### Change to premixed analog insulin 3 times daily (breakfast, lunch, supper)

- **Start:** Add additional injection before lunch
- **Adjust:** ↑ doses by 1–2 units or 10–15% once or twice weekly to achieve SMBG target
- **For hypo:** Determine and address cause; if no clear reason for hypo, ↓ corresponding dose by 2–4 units or 10–20%

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Combination injectable therapy for type 2 diabetes. Adapted with permission from Inzucchi et al. Diabetes Care 2015;38:140–149.
## Medication details

The tables on pages 14–16 give detailed information on oral agents and non-insulin injectables. Insulin for the treatment of adult diabetes is covered on (page 17). Providers should be aware that SelectHealth requires a step-therapy approach or preauthorization for many medications that might be used for diabetes management as a cost-reduction measure. In general, there must be evidence of lack of adequate effect, adverse side effects, or contraindications to at least two medications in the class of sulfonylurea, metformin, or pioglitazone before other non-generic medications may be prescribed. Keep in mind that the choice of non-generic medication is also influenced by the specific SelectHealth plan (SelectMed, SelectMed Advantage, SelectMed Community Health, etc.).

Access SelectHealth’s preauthorization and step-therapy information.

If the patient has chronic kidney disease beyond Stage G2, refer to the Chronic Kidney Disease CPM for necessary dose adjustments.

### TABLE 3. Oral agents and non-insulin injectable medications

<table>
<thead>
<tr>
<th>Class</th>
<th>SelectHealth commercial formulary status</th>
<th>Usual dosing</th>
<th>2017 AWP cost for 30-day supply* (MAC Cost for generics)</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>biguanides</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>metformin</td>
<td>generic (Tier 1)</td>
<td>500 mg twice daily (once daily to start) to 1,000 mg twice daily (max) Most benefit obtained between 1,500 – 1,700 mg/day</td>
<td>Generic: 500 mg twice daily: $6 850 mg twice daily: $7 1000 mg twice daily: $7 Brand name: 500 mg twice daily: $68 850 mg twice daily: $102 1000 mg twice daily: $126</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  • Very cost-effective</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</td>
<td>Glucophage (Tier 3)</td>
<td>500 mg to 1,500 mg once daily at dinner</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>sulfonylureas</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>glipizide XL</td>
<td>Glucotrol XL (Tier 3)</td>
<td>5 mg to 20 mg daily (max) May give dose once or twice daily</td>
<td>Generic: 5 mg once daily: $5 10 mg once daily: $8</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>glimepiride</td>
<td>Amaryl (Tier 3)</td>
<td>1 mg to 8 mg (max) daily May give dose once or twice daily</td>
<td>Generic: 1 mg once daily: $7 4 mg once daily: $11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>thiazolidinediones</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pioglitazone</td>
<td>Actos (Tier 3)</td>
<td>15 mg to 45 mg once daily (dosing at bedtime may decrease edema)</td>
<td>Generic: 15 mg once daily: $11 30 mg once daily: $13 45 mg once daily: $14</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>
</tbody>
</table>

*AWP = Average Wholesale Pricing; MAC = Maximum Allowable Cost. Many patients may benefit from manufacturers’ discounts or patient assistance programs. Tier: Tier 1: generic; Tier 2: preferred brand; Tier 3: non-preferred brand
<table>
<thead>
<tr>
<th>Class</th>
<th>SelectHealth commercial formulary status</th>
<th>Usual dosing</th>
<th>2017 AWP cost for 30-day supply* (MAC Cost for generics)</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>DPP-4 inhibitors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| sitagliptin phosphate    | generic Januvia (Not covered)            | 100 mg once daily (as monotherapy or as combination therapy with metformin or glitazones) | 25 mg, 50 mg, or 100 mg once daily: $405 | • Can be taken with or without food | • Increased cost  
|                          |                                          |              |                                                            |                                                                      | • Can be used only for type 2 diabetes  
|                          |                                          |              |                                                            |                                                                      | • Reduce dose with decreasing creatinine clearance < 50 (except linagliptin)  
|                          |                                          |              |                                                            |                                                                      | • Possible acute pancreatitis  
|                          |                                          |              |                                                            |                                                                      | • Possible ↑ heart failure hospitalizations |
| saxagliptin              | generic Onglyza (Not covered)            | 2.5 mg or 5 mg once daily | 2.5 mg or 5 mg once daily: $405 | • No hypoglycemia  
|                          |                                          |              |                                                            |                                                                      | • Weight gain  
|                          |                                          |              |                                                            |                                                                      | • Most PG effect within 1 – 2 weeks of initiation  
|                          |                                          |              |                                                            |                                                                      | • Increased cost  
|                          |                                          |              |                                                            |                                                                      | • Can be used only for type 2 diabetes  
|                          |                                          |              |                                                            |                                                                      | • Reduce dose with decreasing creatinine clearance < 50 (except linagliptin)  
|                          |                                          |              |                                                            |                                                                      | • Possible acute pancreatitis  
|                          |                                          |              |                                                            |                                                                      | • Possible ↑ heart failure hospitalizations |
| linagliptin              | generic Tradjenta (Tier 2, step edit)   | 5 mg once daily | 5 mg once daily: $397 | • Non-insulin dependent; novel MOA | • ↑ female genital mycotic infections, UTIs, and increased urination  
|                          |                                          |              |                                                            |                                                                      | • Low incidence of hypoglycemia  
|                          |                                          |              |                                                            |                                                                      | • ↓ weight  
|                          |                                          |              |                                                            |                                                                      | • Volume depletion; use cautiously in elderly and patients already on diuretic  
|                          |                                          |              |                                                            |                                                                      | • Possible ↑ risk of bladder cancer (dapagliflozin)  
|                          |                                          |              |                                                            |                                                                      | • Requires normal renal function (> 45 ml / min for empagliflozin and canagliflozin and > 60 ml / min for dapagliflozin)  
| alogliptin               | generic Nesina (Not covered)             | 6.25 mg to 25 mg orally once daily | All generic strengths: $205 | • Non-insulin dependent; novel MOA | • ↑ female genital mycotic infections, UTIs, and increased urination  
|                          |                                          |              |                                                            |                                                                      | • Low incidence of hypoglycemia  
|                          |                                          |              |                                                            |                                                                      | • ↓ weight  
|                          |                                          |              |                                                            |                                                                      | • Volume depletion; use cautiously in elderly and patients already on diuretic  
|                          |                                          |              |                                                            |                                                                      | • Possible ↑ risk of bladder cancer (dapagliflozin)  
|                          |                                          |              |                                                            |                                                                      | • Requires normal renal function (> 45 ml / min for empagliflozin and canagliflozin and > 60 ml / min for dapagliflozin)  
| SGLT2 inhibitors         |                                          |              |                                                            |                                                                      |                                                                      |
| canagliflozin            | generic Invokana (Tier 2, step edit)    | 100 mg or 300 mg once daily | All strengths: $437 | • Non-insulin dependent; novel MOA | • ↑ female genital mycotic infections, UTIs, and increased urination  
|                          |                                          |              |                                                            |                                                                      | • Low incidence of hypoglycemia  
|                          |                                          |              |                                                            |                                                                      | • ↓ weight  
|                          |                                          |              |                                                            |                                                                      | • Volume depletion; use cautiously in elderly and patients already on diuretic  
|                          |                                          |              |                                                            |                                                                      | • Possible ↑ risk of bladder cancer (dapagliflozin)  
|                          |                                          |              |                                                            |                                                                      | • Requires normal renal function (> 45 ml / min for empagliflozin and canagliflozin and > 60 ml / min for dapagliflozin)  
| dapagliflozin            | generic Farxiga (Tier 3, prior authorization) | 5 mg or 10 mg once daily | All strengths: $441 | • Non-insulin dependent; novel MOA | • ↑ female genital mycotic infections, UTIs, and increased urination  
|                          |                                          |              |                                                            |                                                                      | • Low incidence of hypoglycemia  
|                          |                                          |              |                                                            |                                                                      | • ↓ weight  
|                          |                                          |              |                                                            |                                                                      | • Volume depletion; use cautiously in elderly and patients already on diuretic  
|                          |                                          |              |                                                            |                                                                      | • Possible ↑ risk of bladder cancer (dapagliflozin)  
|                          |                                          |              |                                                            |                                                                      | • Requires normal renal function (> 45 ml / min for empagliflozin and canagliflozin and > 60 ml / min for dapagliflozin)  
| empagliflozin            | generic Jardiance (Tier 2, step edit)   | 10 mg or 25 mg once daily | All strengths: $441 | • Non-insulin dependent; novel MOA | • ↑ female genital mycotic infections, UTIs, and increased urination  
|                          |                                          |              |                                                            |                                                                      | • Low incidence of hypoglycemia  
|                          |                                          |              |                                                            |                                                                      | • ↓ weight  
|                          |                                          |              |                                                            |                                                                      | • Volume depletion; use cautiously in elderly and patients already on diuretic  
|                          |                                          |              |                                                            |                                                                      | • Possible ↑ risk of bladder cancer (dapagliflozin)  
|                          |                                          |              |                                                            |                                                                      | • Requires normal renal function (> 45 ml / min for empagliflozin and canagliflozin and > 60 ml / min for dapagliflozin)  
| GLP-1 receptor agonists  |                                          |              |                                                            |                                                                      |                                                                      |
| exenatide                | generic Byetta (Not covered)             | 5 mcg twice daily (within 60 minutes before breakfast and dinner) May be increased to 10 mcg twice daily after 1 month | 5 mcg twice daily: $588 | • No hypoglycemia  
|                          |                                          |              |                                                            |                                                                      | • ↓ Weight  
|                          |                                          |              |                                                            |                                                                      | • ↓ Postprandial glycemia  
|                          |                                          |              |                                                            |                                                                      | • Exhibits many of the same glucoregulatory actions of naturally occurring hormones  
|                          |                                          |              |                                                            |                                                                      | • Exenatide: Use caution when initiating or when increasing dose from 5 mcg to 10 mcg in CKD Stage G3  
|                          |                                          |              |                                                            |                                                                      | • All in this class:  
|                          |                                          |              |                                                            |                                                                      | • Gastrointestinal side effects (nausea, vomiting, diarrhea)  
|                          |                                          |              |                                                            |                                                                      | • Training requirements  
|                          |                                          |              |                                                            |                                                                      | • ↑ Heart rate  
|                          |                                          |              |                                                            |                                                                      | • Possible acute pancreatitis  
| exenatide ER             | generic Bydureon (Not covered)           | 2 mg once every 7 days | 2 mg once every 7 days: $570 | • No hypoglycemia  
|                          |                                          |              |                                                            |                                                                      | • ↓ Weight  
|                          |                                          |              |                                                            |                                                                      | • ↓ Postprandial glycemia  
|                          |                                          |              |                                                            |                                                                      | • Exhibits many of the same glucoregulatory actions of naturally occurring hormones  
|                          |                                          |              |                                                            |                                                                      | • Exenatide: Use caution when initiating or when increasing dose from 5 mcg to 10 mcg in CKD Stage G3  
|                          |                                          |              |                                                            |                                                                      | • All in this class:  
|                          |                                          |              |                                                            |                                                                      | • Gastrointestinal side effects (nausea, vomiting, diarrhea)  
|                          |                                          |              |                                                            |                                                                      | • Training requirements  
|                          |                                          |              |                                                            |                                                                      | • ↑ Heart rate  
|                          |                                          |              |                                                            |                                                                      | • Possible acute pancreatitis  
| liraglutide              | generic Victoza (Tier 2, step edit)      | 1.2 mg or 1.8 mg once daily | 1.2 mg once daily:  
|                          |                                          |              |                                                            |                                                                      | (18 mg / 3 mL pen): $564  
|                          |                                          |              |                                                            |                                                                      | 1.8 mg once daily:  
|                          |                                          |              |                                                            |                                                                      | (18 mg / 3 mL pen): $798  
| albiglutide              | generic Tanzeum (Tier 3, step edit)      | 30 mg or 50 mg once every 7 days | 30 mg or 50 mg once every 7 days: $448 | • No hypoglycemia  
|                          |                                          |              |                                                            |                                                                      | • ↓ Weight  
|                          |                                          |              |                                                            |                                                                      | • ↓ Postprandial glycemia  
|                          |                                          |              |                                                            |                                                                      | • Exhibits many of the same glucoregulatory actions of naturally occurring hormones  
| dulaglutide              | generic Trulicity (Tier 2, step edit)    | 0.75 mg or 1.5 mg once every 7 days | 0.75 mg or 1.5 mg once every 7 days: $647 | • No hypoglycemia  
|                          |                                          |              |                                                            |                                                                      | • ↓ Weight  
|                          |                                          |              |                                                            |                                                                      | • ↓ Postprandial glycemia  
|                          |                                          |              |                                                            |                                                                      | • Exhibits many of the same glucoregulatory actions of naturally occurring hormones  

*AWP = Average Wholesale Pricing; MAC = Maximum Allowable Cost. Many patients may benefit from manufacturers’ discounts or patient assistance programs.  
Tier: Tier 1: Generic; Tier 2: Preferred brand; Tier 3: Non-preferred brand
<table>
<thead>
<tr>
<th>Class</th>
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<th>2017 AWP cost for 30-day supply* (MAC Cost for generics)</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amylin mimetic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pramlintide acetate</td>
<td>GENERIC: Symlin (Prior authorization)</td>
<td><strong>See inset</strong></td>
<td>$708</td>
<td>Very positive effect on weight loss</td>
<td>Symlin should only be used by providers with significant knowledge of its properties. Three injections per day bring significant risk of severe nausea and hypoglycemia.</td>
</tr>
<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td>Combinations (examples only)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>sitagliptin + metformin XR</td>
<td>JANUMET XR (Not covered)</td>
<td>Once daily: 100 mg / 1,000 mg, 50 mg / 500 mg, 2 mg / 1,000 mg</td>
<td>$397</td>
<td></td>
<td>See notes for individual components (page 13)</td>
</tr>
<tr>
<td>saxagliptin + metformin XR</td>
<td>KOMBIGLYZE XR (Not covered)</td>
<td>Once daily: 5 mg / 500 mg, 5 mg / 1,000 mg</td>
<td>$390</td>
<td></td>
<td></td>
</tr>
<tr>
<td>linagliptin + metformin</td>
<td>JENTADUETO (Tier 3, step edit)</td>
<td>Twice daily: 2.5 mg / 500 mg, 2.5 mg / 1,000 mg</td>
<td>$397</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alogliptin + metformin (Tier 1, step edit)</td>
<td>KAZANO (Not covered)</td>
<td>Twice daily: 2.5 mg / 500 mg, 2.5 mg / 1,000 mg</td>
<td>$397</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alogliptin + pioglitazone (Tier 1, step edit)</td>
<td>OSENI (Not covered)</td>
<td>Once a day: 25 mg / 45 mg</td>
<td>$200</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin degludec + liraglutide</td>
<td>XULTOPHY (Not covered)</td>
<td>Initial: insulin degludec 16 units + liraglutide 0.58 mg once daily</td>
<td><strong>$1,144</strong></td>
<td>• Single injection of two medications</td>
<td>• Fixed dose combination</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Maximum:</strong> 50 units (insulin degludec 50 units + liraglutide 1.8 mg) once daily</td>
<td></td>
<td>• Consistent coverage of glycemic control</td>
<td>• Limited to 50 units of insulin degludec per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Large potential for HbA1C reduction through combination therapy</td>
<td>• Must be inadequately controlled on insulin or liraglutide prior to initiation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• High expense</td>
<td>• High expense</td>
</tr>
<tr>
<td>Insulin glargine + lixisenatide</td>
<td>SOLIQUA (Not covered)</td>
<td>Initial: 15 units (insulin glargine 15 units + lixisenatide 5 mcg) once daily</td>
<td><strong>$762</strong></td>
<td>• Single injection of two medications</td>
<td>• Fixed dose combination</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Maximum:</strong> 60 units (insulin glargine 60 units + lixisenatide 20 mcg) once daily</td>
<td></td>
<td>• Consistent coverage of glycemic control</td>
<td>• Limited to 60 units of insulin glargine per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Large potential for HbA1C reduction through combination therapy</td>
<td>• Must be inadequately controlled on insulin or liraglutide prior to initiation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• High expense</td>
<td>• High expense</td>
</tr>
</tbody>
</table>

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

Tier: Tier 1: generic; Tier 2: preferred brand; Tier 3: non-preferred brand
TABLE 4. Insulin profiles

<table>
<thead>
<tr>
<th>Insulin type</th>
<th>Generic (Brand) name</th>
<th>Onset (min. or hrs.)</th>
<th>Peak (hours)</th>
<th>Usual effective duration (hours)</th>
<th>2017 30-Day AWP</th>
<th>SelectHealth commercial formulary status**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid acting (clear, except Afrezza)</td>
<td>aspart (NovoLog)</td>
<td>10 to 20 min.</td>
<td>1 to 2</td>
<td>3 to 5</td>
<td>10 mL: $244, FlexPen 15 mL: $471</td>
<td>Tier 2</td>
</tr>
<tr>
<td></td>
<td>glulisine (Apidra)</td>
<td>10 to 20 min.</td>
<td>1 to 2</td>
<td>3 to 5</td>
<td>10 mL: $243, SoloSTAR pen 15 mL: $471</td>
<td>Not covered</td>
</tr>
<tr>
<td></td>
<td>lispro (Humalog)</td>
<td>10 to 20 min.</td>
<td>1 to 2</td>
<td>3 to 5</td>
<td>10 mL: $243, KwikPen 15 mL: $470</td>
<td>Not covered</td>
</tr>
<tr>
<td></td>
<td>human (Afrezza)* (inhalation powder)</td>
<td>10 to 15 min.</td>
<td>1</td>
<td>2 to 3</td>
<td>equivalent to 1000 units: $630</td>
<td>Not covered</td>
</tr>
<tr>
<td>Regular (rapid acting) (clear)</td>
<td>Novolin R</td>
<td>30 to 60 min.</td>
<td>2 to 4</td>
<td>4 to 8</td>
<td>10 mL: $132, ReliOn R 10 mL: $28</td>
<td>Novolin R: Tier 2, Humulin R: Not covered, ReliOn R: Not covered†</td>
</tr>
<tr>
<td></td>
<td>Humulin R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ReliOn R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intermediate acting (cloudy)</td>
<td>NPH (Novolin N)</td>
<td>1 to 3 hrs</td>
<td>4 to 10</td>
<td>10 to 18</td>
<td>10 mL: $132, ReliOn N 10 mL: $28</td>
<td>Novolin N: Tier 2, Humulin N: not covered, ReliOn N: Not covered†</td>
</tr>
<tr>
<td></td>
<td>NPH (Humulin N)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ReliOn N</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peakless (clear)</td>
<td>detemir (Levemir)‡</td>
<td>1 hr</td>
<td>18 to 24</td>
<td></td>
<td>10 mL: $333, FlexTouch 15 mL: $485</td>
<td>Tier 2</td>
</tr>
<tr>
<td></td>
<td>glargine U-100 (Lantus)‡</td>
<td>2 to 3 hrs</td>
<td>24 +</td>
<td></td>
<td>10 mL: $298, SoloSTAR pen 15 mL: $447</td>
<td>Tier 2</td>
</tr>
<tr>
<td></td>
<td>glargine U-100 (Basaglar)</td>
<td>2 to 3 hrs</td>
<td>24 +</td>
<td></td>
<td>Kwikpen 15 mL: $380</td>
<td>Not covered</td>
</tr>
<tr>
<td></td>
<td>glargine U-300 (Toujeo)</td>
<td>develops over 6 hrs</td>
<td>24 +</td>
<td></td>
<td>SoloSTAR pen 14.5 mL: $403</td>
<td>Tier 2</td>
</tr>
<tr>
<td></td>
<td>degludec U-100, U-200 (Tresiba)</td>
<td>~ 1 hr</td>
<td>24 to 48</td>
<td></td>
<td>FlexTouch 15 mL: $533</td>
<td>Not covered</td>
</tr>
<tr>
<td></td>
<td>Insulin mixes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>70/30 (NovoLog Mix)</td>
<td></td>
<td></td>
<td></td>
<td>10 mL: $253, pen: $471</td>
<td>70/30 NovoLog mix: Tier 2, Humalog mixes: Not covered, ReliOn mix: Not covered†</td>
</tr>
<tr>
<td></td>
<td>75/25 (Humalog Mix)</td>
<td></td>
<td></td>
<td></td>
<td>10 mL: $252, pen: $470</td>
<td></td>
</tr>
<tr>
<td></td>
<td>50/50 (Humalog Mix)</td>
<td></td>
<td></td>
<td></td>
<td>10 mL: $252, pen: $470</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70/30 (ReliOn Mix)</td>
<td></td>
<td></td>
<td></td>
<td>10 mL: $28</td>
<td></td>
</tr>
</tbody>
</table>

* Afrezza contraindications: Asthma, COPD, smoking. Requires PFT monitoring at baseline, 6 months, and then yearly. Supplied in 4-unit and 8-unit, single-dose cartridges. Dose adjustments are made in 4-unit increments.

** Tier: Tier 1: generic; Tier 2: preferred brand; Tier 3: non-preferred brand

† 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, glargine, and degludec). Administer as follows:
- **Detemir** insulin twice a day for type 1 diabetes and at bedtime for type 2 diabetes.
- **Glargine** insulin once a day at the same time for type 1 and type 2 diabetics who require long-acting insulin for control of hyperglycemia.
- **Degludec** for type 1 and type 2 diabetics who require long-acting insulin once a day at any time.
- Peakless insulin cannot be diluted or mixed with other types of insulin or solutions.
- Administer peakless insulin subcutaneously only — DO NOT give it intravenously.

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. Recommendations are as follows:

- **Before surgery:** Optimize glycemic control, and temporarily stop metformin and sulfonylureas if appropriate.

- **When patient receives a steroid (injection or oral):** Patients often experience a elevation of plasma glucose. Advise more frequent SMBG, and either increase medication doses or initiate low-dose insulin as needed.

- **When patient is fasting prior to a test or procedure.** Temporarily stop metformin and sulfonylureas if appropriate.

- **Illness.** Consider increasing frequency of blood glucose monitoring. Metformin may need to be held if the patient is at risk for dehydration.
Insulin therapy for type 2 diabetes

To treat patients with type 2 diabetes, keep these general principles in mind when using oral agents with insulin:

- **Use starting dose for patients with type 2.** A total daily dose (TDD) is approximately 0.5 U/kg to 0.7 U/kg. See table 4 on page 17 for insulin profiles.
- **Follow basal insulin regimen (bedtime dose of peakless insulin) as the recommended first choice** when adding insulin to treatment with oral agents.
- **Consider the timing of the patient’s hyperglycemia** when adding or adjusting insulin.
  - Control morning FPG with peakless insulin at bedtime.
  - Control daytime PPG with sulfonylureas, DPP-4 inhibitors, and GLP-1 agonists. When morning FPG is controlled with peakless insulin, daytime PPG readings frequently come under control with an oral agent and dietary modification.
  - Consider physiologic insulin regimen generally while continuing metformin if two-hour postprandial PG is still above goal with FBG > 100 mg/dL.

Example of a weekly titration schedule (Treat-to-Target Trial)

<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 a peakless insulin with this titration schedule to significantly reduce nocturnal hypoglycemia. This can help achieve recommended standards of diabetes care more quickly.

**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 either have been unsuccessful with oral medication combinations or are unable 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 MNT plan. The following are examples of basic insulin regimens:

- **Premixed insulins.** These insulins are 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 or rapid-acting insulin before breakfast and before the evening meal.
**Using the 1,700 Rule**

The 1,700 Rule can be used to calculate a correction dose of rapid-acting insulin for either a high plasma glucose (PG) reading or an insulin-to-carbohydrate ratio to approximate the rapid-acting insulin needed to cover a meal’s carbohydrate content.

- **Determine the current total daily dose (TDD).** Add up all the insulin (rapid and long-acting) the patient takes in a 24-hour period. If the patient is not yet on a stable insulin dose, then use 0.5 U/kg to calculate a TDD.

- **Divide 1,700 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.
- 1,700 ÷ 50 = 34 (Round to 35, which means that one unit of insulin will lower PG by 35 points — a correction factor of 35).
- If the goal is 130, and PG is 165, use one extra unit of insulin to drop PG to about 130. If PG is 200, use two units, and so on.

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

**Insulin-to-carbohydrate ratio example:**
- Patient takes 50 units of insulin per day: TDD = 50.
- 1,700 ÷ 50 = 34 (Round to 35, which means that one unit of insulin will lower PG by 35 points).
- 35 × 0.33 = 12, which means that one unit of insulin is needed for every 12 grams of carbohydrate anticipated in a meal.

**Insulin therapy for type 1 diabetes**

**Algorithm 4: 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.
- **Teach injection technique.**
- **Divide dose as follows:** One-half of total daily dose as peakless “basal” insulin dose and one-half as rapid-acting, “bolus” insulin (The rapid-acting insulin dose is divided through the day). Use carbohydrate ratio and correction factor to calculate premeal and bedtime rapid-acting insulin doses. See table 4 on page 17 for insulin profiles.
- **Instruct patient to carefully record SMBG** (before meals, at bedtime).

**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.

- **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 the carb content of the snack with a rapid-acting insulin dose.
- **Add rapid-acting insulin prior to each meal and planned snack.**
  - Adjust to prevent post-meal hyperglycemia or hypoglycemia. Blood glucose levels four hours after a meal should approximate premeal levels.
  - Determine premeal rapid-insulin doses by counting carbohydrates and using an insulin-carbohydrate ratio. Alternatively, base premeal insulin dose on a fixed-meal plan (budgeted carbohydrates).
  - Train patients in MNT and insulin use; refer to diabetes educator/RDN.
  - 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 18). Support with referral to diabetes educator/RDN.
PREVENTION AND MANAGEMENT OF RELATED CONDITIONS

Cardiovascular disease
Diabetes is considered a cardiovascular disease equivalent, and patients with diabetes have a two to eight 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.

ALGORITHM 5: RISK ASSESSMENT & SCREENING FOR CARDIOVASCULAR DISEASE

PERFORM cardiovascular risk assessment with any cardiovascular symptoms and at least annually
MONITOR for symptoms at every clinic visit

Asymptomatic with no history of CAD or PVD

Asymptomatic with history of CAD or PVD

Typical or atypical symptoms suggestive of CAD

REDUCE risk factors aggressively, following guidelines on page 21 and these additional recommendations for secondary prevention:
• USE a beta blocker if previous MI
• PRESCRIBE antiplatelet therapy for secondary prevention
• CONSIDER ACE inhibitor, especially for patients older than 55 years

CONDUCT surveillance and RESCREEN
Examine and watch for progression of new symptoms, and repeat CV risk assessment annually

RELATED CONDITIONS
Patients with diabetes are likely to have related conditions that often accompany or result from diabetes, such as:
• Cardiovascular disease (page 20)
• High cholesterol (page 22)
• High blood pressure (page 24)
• Kidney disease (page 26)
• Retinopathy (page 27)
• Diabetic nephropathy (page 27)
• Foot problems (page 28)
• Obstructive sleep apnea (page 30)
• Low testosterone in men (page 30)
• Conditions associated with type 1 diabetes (page 30)
The pages that follow highlight the risks, goals, and management options for these related conditions.

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 patients with diabetes may benefit to an even greater extent. This CPM recommends helping patients lower their cardiovascular risk by promoting lifestyle modifications as needed (smoking cessation, weight loss, etc.) and following the guidelines for good management of glucose, lipids, and blood pressure. Also consider using proven medications in appropriate patients; see discussion on page 21.
**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 recommend the new Risk Calculator to evaluate 10-year risk and lifetime risk of ASCVD. This calculator is available at: [tools.acc.org/ascvd-risk-estimator/](http://tools.acc.org/ascvd-risk-estimator/)

### TABLE 5. Aspirin guidelines

<table>
<thead>
<tr>
<th>Recommended for:</th>
<th>May be considered for:</th>
<th>NOT recommended 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 blood pressure</td>
<td>Albuminuria</td>
</tr>
<tr>
<td>High cholesterol</td>
<td>Family history of premature CVD</td>
<td></td>
</tr>
</tbody>
</table>

**Medications for CV risk reduction**

**Empagliflozin, liraglutide, and canagliflozin.** The ADA and the AACE support prescribing one of these three medications as second-line therapy for all patients with type 2 diabetes and cardiovascular disease to reduce major cardiovascular events and mortality.\(^{GAR, ADA}\)

- **Empagliflozin:** The EMPA-REG OUTCOME trial demonstrated a reduction in overall cardiovascular mortality that started within three months of taking empagliflozin, which continued to strengthen over a three-year period. The final outcome revealed a 14% reduction in nonfatal myocardial infarction, nonfatal stroke, and cardiovascular death. Hospitalizations for congestive heart failure also decreased with use of this medication.\(^{ZIN}\)

- **Liraglutide:** The LEADER Trial found liraglutide extended the first occurrence of cardiovascular death (as compared to a placebo). While nonfatal myocardial infarction, nonfatal stroke, and hospitalization for congestive heart failure were not statistically significant, the death rate was significantly less.\(^{MAR}\)

- **Canagliflozin:** The CANVAS study proved that the composite of cardiovascular death, nonfatal MI, and nonfatal stroke was reduced with canagliflozin therapy. Heart failure hospitalizations also decreased significantly. The study also reports an increased risk of toe and foot amputation.\(^{NEA}\)

**ACE inhibitors (ACEIs).** Several studies have shown ACEIs 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 ACEI 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 two years.

**Aspirin therapy.**\(^{ADA}\) 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 CVD prevention 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 resource noted in the sidebar at left.

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 162mg/day following the guidelines in table 5 at right.
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. **HEA, SEV**

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 2017 ADA Standards recommend following this guideline for diabetes treatment. **ADA**

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**.
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. Fenofibrate 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 colesevelam 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. 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 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 7: MANAGEMENT OF HYPERTENSION

General approach for most patients under 80 years old

CHECK BP at each office visit (a)

- Systolic ≥ 140 or diastolic ≥ 90?
  - Yes
    - RECHECK to confirm high BP (b)
      - Follow-up office visit
      - Home BP readings
      - High BP confirmed?
        - Yes
          - TREAT high BP to management target: < 140 / < 90 (c)
        - No
          - 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. (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 1 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 (e)

ACEI (or ARB): Lisinopril (or losartan) (f)

- Lisinopril titration: 10 mg daily → 20 mg daily
- For patients who require additional medications to manage high blood pressure, refer to the High Blood Pressure CPM.

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**ALGORITHM NOTES**

(a) Check BP at each office visit

Best practices for consistent BP readings:
- Seat patient with feet on the floor, back supported, and arm supported at heart level.
- Allow patient to rest for 5 minutes. Empty air bladder if necessary. Ensure reading is at least 30 minutes after last heavy meal, heavy exercise, or intake of caffeine, alcohol, or nicotine.
- Use appropriate-size cuff (not too small).
- Avoid talking with the patient or asking questions while taking BP. See the High Blood Pressure CPM for more detail.

(b) Confirming high BP

Methods

Follow-up office visit
- High BP can be confirmed through two office visits total, with two BP checks in each visit.

Home BP monitoring
- Train patient on checking BP at home, and make sure patient has appropriate home BP monitor.
- Patient takes at least 6–10 home BP readings over two weeks or more. Make sure patient brings monitor to office visit to verify consistency of readings.

(c) Blood pressure targets

Most patients
- The 2015 ADA standards recommend management to <140/<90 for most patients with diabetes, but allow for individualized targets for patients with chronic kidney disease or other risk factors.

Younger or at risk for stroke
- Consider a target of <130/<80 for some patients, including younger patients, if the burden of more aggressive therapy is not excessive.

Elderly
- In elderly patients, avoid reducing diastolic BP below an average of 60. Lower diastolic BP may cause symptoms of hypotension and increase risk of myocardial infarction and stroke.

(d) Therapeutic lifestyle changes (TLC)

TLC elements include weight reduction, the DASH eating plan, sodium reduction, regular physical activity, limiting alcohol, and smoking cessation. For more information on the effects of TLC on blood pressure, see page 10 of the High Blood Pressure CPM.

(e) Secondary causes of uncontrolled BP

If a patient is on multiple medications and still not meeting BP goals, explore these possible secondary causes: Primary aldosteronism, sleep apnea, chronic kidney disease, coartation of aorta, Cushing’s syndrome or steroid therapy, drug-induced hypertension, pheochromocytoma, renovascular disease, thyroid/parathyroid disease, alcohol use.

(f) Medication notes

- Consider nonadherence. Ask how many doses were missed since the last visit.
- Consider interfering agents, such as NSAIDs.

Medications in the algorithm

- lisinopril/losartan
  - Use either drug as a first-line choice.
  - Switch to losartan if dry cough with lisinopril.
  - Avoid all ACEI or ARB medications in pregnancy.
  - Do NOT combine an ACEI or an ARB.
  - Avoid the direct renin inhibitor aliskiren.

Other preferred blood pressure medications

- amlodipine
  - Monitor for peripheral edema.
  - Consider alternative statin due to drug interaction if patient is on simvastatin >20 mg daily.
  - Consider starting with 2.5 mg daily in elderly patients. Maximum therapeutic effect can take up to three weeks.

- HCTZ
  - Prescribe as single combination with an ACEI/ARB.

- carvedilol
  - Monitor for bradycardia (keep HR >55 BPM).

(g) 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 amlodipine and then a diuretic.
  - Heart failure
    - Prescribe ACEI / ARB, plus carvedilol (preferred) or metoprolol succinate, plus spironolactone (if not contraindicated) if ejection fraction <1/4 to40%.
  - Chronic kidney disease
    - Treat to <140/<90; consider <130/80 if ACR >300. Monitor K+ and creatinine with ACEI/ARBs.
  - 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.
  - Confirmed 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.\(^\text{2}\)

**Screening and management recommendations\(^\text{ADA, HAN, NKF}\)**

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, this CPM recommends 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:
- **Optimize blood glucose control** (HbA1c less than 7%).
- **Optimize blood pressure control**. In patients with increased urinary albumin excretion or nephropathy, treat to a blood pressure goal of 130/80 or lower.
- **Use 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.
- **Restrict 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.

For patients with increased urinary albumin excretion, nonsteroidal inflammatory medications are discouraged. Note also that in this population, *intravenous contrast dyes* may precipitate renal failure.

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**ALGORITHM 8: NEPHROPATHY SCREENING**

TEST ANNUALLY: urine albumin/creatinine ratio (ACR) AND serum creatinine + eGFR

1. **ACR < 30?**
   - **yes**
   - **no**
     - **REPEAT ACR, and DO urinalysis**
     - **ACR < 30?**
       - **yes**
       - **no**
         - **CONSIDER** secondary causes of nephropathy
           - **CONFIRM** diabetic nephropathy
             - **REFER to Chronic Kidney Disease**

\(^\text{2}\) Indicates an Intermountain measure
### 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. This CPM recommends the following practices:

- **Screening.** Early signs of retinopathy frequently go unnoticed by patients but can be seen with retinal photography (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 screening schedule below:

- **For type 2 diabetes, initial screening should occur at diagnosis.** Repeat dilated eye exam every one to two years if under good control and no retinopathy; every two years in those with good blood pressure, blood glucose, and lipid levels.

- **For type 1, initial screening should occur within five years of diagnosis.** Repeat dilated eye exam every year or every one to two 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 three months thereafter or as recommended by the ophthalmologist.

- **Referral.** Refer to an ophthalmologist experienced in managing diabetic retinopathy for patients with diabetes and:
  - **Become pregnant.** (Women who develop gestational diabetes are not at increased risk.)
  - **Have macular edema or any retinopathy.**

### Diabetic Neuropathy

Neuropathies are among the most-common chronic complications of both type 1 and type 2 diabetes. They are asymptomatic up to 50% of the time, and early recognition is important. Early control of glucose may help to prevent or delay the development of peripheral neuropathy in both type 1 and type 2 diabetes and development of autonomic neuropathy in type 1 diabetes.

**Peripheral polyneuropathy** is generally symmetrical and is felt first in the lower extremities, but it may affect the upper extremities as well. It can cause pain, numbness, or both. It can also affect position sense and increase the risk of falls. The pain associated with neuropathy can be treated with medication. Peripheral neuropathy is generally a clinical diagnosis, and nerve conduction tests are usually not needed except in complicated cases. Once the diagnosis is made, it may be worth considering other causes for neuropathy, such as vitamin B12 deficiency, liver, kidney, or thyroid disease, in selected patients.

**Autonomic neuropathy** is also common and may cause symptoms in multiple organ systems, such as tachycardia, orthostatic hypotension, gastroparesis, sexual dysfunction, and bladder dysfunction.

Although loss of sensation from neuropathy cannot be reversed, the medications listed in table 6 at left could be considered for treatment of discomfort due to peripheral polyneuropathy.

---

### Table 6: Medication options for peripheral polyneuropathy

<table>
<thead>
<tr>
<th>Class</th>
<th>Examples</th>
<th>Typical Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tricyclic drugs</strong></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><strong>Anticonvulsants</strong></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><strong>5-hydroxytryptamine and norepinephrine uptake inhibitor</strong></td>
<td>Duloxetine 60–120 mg a day</td>
<td></td>
</tr>
<tr>
<td><strong>Substance P inhibitor</strong></td>
<td>Capsaicin cream 0.025–0.075 % applied 3 to 4 times a day</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** Peripheral polyneuropathy has been associated with vitamin B12 deficiency, a potential side-effect of metformin use.
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. \(^1\) 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%. \(^2\)

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.

**Preventive foot care: Three major components**

1. **Perform routine foot exams.** For patients with insensate feet, foot deformities, or a history of foot ulcers, examine feet every visit.

   See page 29 for foot exam guidelines. Note that no single test of sensation is 100% sensitive in detecting sensory deficits. Testing should include a combination of monofilament fiber plus any one of the following:

   - Vibratory sensation testing using a 128-Hz tuning fork (see page 29 for instructions)
   - Pinprick sensation testing
   - Ankle reflex testing

   Vibratory sensation testing may be the most sensitive test. An abnormal monofilament fiber test result most accurately predicts ulcer risk.

2. **Educate patients on daily foot care,** which includes the following:

   - Check feet daily for problems.
   - Wear white socks to help identify drainage from an unknown ulcer.
   - Use a hand, rather than a foot, to check bathtub and other water temperatures.
   - Avoid going barefoot.
   - Avoid medicated corn pads as well as cutting corns and calluses with a blade. Use a pumice stone or nail file.
   - Trim nails straight across.

3. **Emphasize the importance of appropriate footwear.**

   Patients should select soft-fitting, extra-depth shoes. They should not expect shoes to stretch out and should break in new shoes slowly.

   Medicare covers diabetic shoes for patients with previous ulcers, foot deformities, or neuropathy. Diabetic shoes are easier to put on and have softer insoles (to accommodate foot deformities) and higher toe boxes (to avoid rubbing).
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 six 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. 1

- **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%. 2

  - Age 19 to 64: One dose PPSV23.
  
  - Age 65 or older: One dose PPSV23. If patient has not previously received PCV13 as an adult, give also one dose PCV13 (preferably before PPSV23). Doses need to be separated by one year.

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

- **Hepatitis B vaccination for unvaccinated adults with diabetes under 60.** In 2013, the Advisory Committee on Immunization Practices of the CDC recommended the following: 3

  - Age 19 – 59: Vaccinate with three doses of hepatitis B vaccine.
  
  - Aged ≥ 60 years: Consider vaccination after assessing risk and likelihood of an adequate immune response.

There is an increased risk of hepatitis B in institutionalized (e.g., nursing home, prison) patients.

**TABLE 7: Routine foot exams**

<table>
<thead>
<tr>
<th>Exam</th>
<th>Action</th>
<th>Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular</td>
<td>• Edema</td>
<td>Whether pulses are palpable and the degree of edema</td>
</tr>
<tr>
<td></td>
<td>• Dorsalis pedis and posterior tibial pulses</td>
<td></td>
</tr>
<tr>
<td>Neurologic</td>
<td>Sensory exam using monofilament test (see description below)</td>
<td>Protective threshold present or absent</td>
</tr>
<tr>
<td></td>
<td>Vibratory exam using 128-Hz tuning fork (see description below)</td>
<td>Number of seconds until the patient no longer feels the vibration</td>
</tr>
<tr>
<td>Dermatological</td>
<td>• Open lesions</td>
<td>Any positive findings</td>
</tr>
<tr>
<td></td>
<td>• Thickened or deformed nails</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Callus formation on bony prominences on the ball of the foot</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Hyperkeratosis or corns, including between the toes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Dry skin and cracks on heels</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Evidence of venous stasis</td>
<td></td>
</tr>
<tr>
<td>Skeletal</td>
<td>Musculoskeletal abnormalities, such as bunions, hammer toes, etc.</td>
<td>Any positive findings</td>
</tr>
</tbody>
</table>

**HOW TO PERFORM A 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. 4

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

**HOW TO PERFORM A 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 is as follows:

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

Individuals with diabetes or insulin resistance have a two- to four-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. Follow these guidelines:

- **Screening.** All patients with diabetes should be screened for OSA, particularly those patients with waist circumference above normal. Intermountain recommends using the OSA 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 a patient will have moderate or severe OSA.

- **Referral.** For patients with three or more STOP-BANG risk factors (see below), consider referral to a sleep specialist.

- **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.

Low testosterone in men

Type 2 diabetes is a known risk factor for low testosterone levels in men. Consider evaluating male patients who have diabetes and symptoms of hypogonadism. Refer to the Intermountain clinical guideline Testosterone Therapy for Men for guidance on diagnosis and treatment. The guideline can be accessed from within the Intermountain Healthcare firewall at intermountainphysician.org.

Conditions associated with type 1 diabetes

An adult diagnosed with autoimmune diabetes (type 1) has an increased risk for other autoimmune disorders, most commonly celiac disease and thyroid disease. Since both of these can be silent early on, routine screening is recommended.

- **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.
THE DIABETES LIST

Patients are included on the list if they have:

- One abnormal HbA1c
- Two outpatient visits with diabetes as the diagnosis
- One acute inpatient or ED visit with diabetes as the diagnosis
- 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 Stephen Smith, Primary Care Clinical Program Data Manager.

801-442-5269
Stephen.C.Smith@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, click on the links or enter either PCCPCT or CorrectionTool in your browser to go directly to the correction tool.
- Affiliated providers can fax their corrections along with documentation to SelectHealth Quality Improvement (801-442-0920).

DATA AND REPORTS

The Intermountain Primary Care Clinical Program maintains a database of 130,000 patients with diabetes who have been seen within the Intermountain system (see sidebar at left 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 either 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 left).

The diabetes bundle

Good management of diabetes is key to delaying and preventing complications, which improves patient satisfaction, medical outcomes, and appropriate healthcare resource utilization. The “diabetes bundle” is a set of four elements that together represent a measure of an individual’s 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 ages 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 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 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.
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
The medical assistant should propose orders for the following tests as the appropriate advisories fire in iCentra:
- HbA1c (every six months, or every three months if HbA1c is > 9).
- eGFR and serum potassium if patient is taking an ACE / ARB or diuretic (yearly, or as needed).
- Creatinine blood test (yearly).
- Urine ACR (yearly).
- B12 (yearly for patients taking metformin).
- Two-year exam scheduled with ophthalmologist, or date of last eye exam entered.

Consider prescribing:
- ACE / ARB
- Statin (if not on allergy list)

*It’s important that visits be scheduled with the appropriate diagnosis.

ADDITIONAL SUPPORT FROM THE CARE MANAGEMENT TEAM
The role of the care management team is to provide support by:
- Collaborating with providers on:
  - Managing patients and providing education
  - Identifying and referring patients who need specialty care
  - Utilizing the diabetes bundle reports
- Counseling patients via face-to-face visits or phone calls to help them achieve their lifestyle management goals

CARE TEAM ROLES
A clinic visit for a patient with diabetes requires the support of the entire team to assure comprehensive care. Algorithm 9 below suggests general responsibilities to help a clinic team share accountability for diabetes management.

ALGORITHM 9: PATIENT VISIT

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

Patient check in

Patient rooming (MA)
Data
- ENTER responses from patient worksheet
- RECORD vital signs, including height, weight, BP, and PAVIS
- DOWNLOAD data from glucose meter, if applicable
- DOCUMENT problems as directed by provider

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
- ADMINISTER PHQ-9 if PHQ-2 is positive

Patient preparation
- HAVE patient remove shoes and socks in preparation for foot exam
- ASK patient if they need additional education and notify care manager if requested

Medications and allergies
- RECONCILE medications
- VERIFY and document allergies
- PROVIDE any additional education

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

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)

Abbreviations:
CMT = care management team
MA = medical assistant
PCP = primary care provider
PSR = patient service representative

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- DOCUMENT problems as directed by provider

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
- ADMINISTER PHQ-9 if PHQ-2 is positive

Patient preparation
- HAVE patient remove shoes and socks in preparation for foot exam
- ASK patient if they need additional education and notify care manager if requested

Medications and allergies
- RECONCILE medications
- VERIFY and document allergies
- PROVIDE any additional education

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

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)

Abbreviations:
CMT = care management team
MA = medical assistant
PCP = primary care provider
PSR = patient service representative
TRANSITIONS OF CARE

To ensure the coordination and continuity of care as patients transfer between locations or levels of care, follow these guidelines:

- **Review the problem list**, and look for diabetes diagnosis.
- **Review the provider note** for most current dosing of medications.
  - Changes in insulin dosing may appear in the comments rather than in the medication list on the order information.
  - The most up-to-date information is likely to be located in the notes from the primary care provider (PCP), endocrinologist, or Certified Diabetes Educator (CDE).
- If admission or evaluation at a hospital is caused by or related to a diabetes diagnosis, **message the PCP and schedule a follow-up appointment** within an appropriate time frame.
- **Ensure admissions and discharge information is sent to the PCP** with each hospitalization.

PROVIDER RESOURCES

Go to: [IntermountainPhysician.org/ClinicalPrograms](http://IntermountainPhysician.org/ClinicalPrograms), and select “Diabetes” from the topic list. See the tab titled “Clinical Guidelines & CPMs” for the following:

- Outpatient Management of Adult Diabetes Mellitus (this care process model)
- Prediabetes CPM
- Gestational Diabetes CPM
- Lifestyle and Weight Management CPM

Related condition care process models and clinical guidelines include the following:

- Metabolic and Bariatric Surgery for the Treatment of Obesity CPM
- Chronic Kidney Disease CPM
- Cardiovascular Risk and Cholesterol CPM
- High Blood Pressure CPM
- Obstructive Sleep Apnea CPM
- Testosterone Therapy for Men Clinical Guideline
LOCATING PATIENT EDUCATION MATERIALS

Intermountain education materials are designed to support your efforts to educate and engage patients and families. They complement and reinforce diabetes team interventions by providing a means for patients to reflect and learn in another mode and at their own pace. To access these materials:

- **Search for Intermountain items in iCentra.** Look for items tagged with "_Title (IH)" in the patient education module.
- **Log in to Intermountain physician.org,** and search for the patient education library under A–Z. Then, search item number and title in the appropriate area.

- **Use iprintstore.org** for one-stop access and ordering for all Intermountain-approved education, such as fact sheets, booklets, and trackers.

DIABETES EDUCATION RESOURCES

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

Intermountain-approved patient education materials

The following Intermountain-approved patient education resources can be accessed and ordered online at minimal cost. See access and ordering information at left.

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

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

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

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

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

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

FACT SHEETS from Intermountain (All available in English and Spanish):

- **Diabetes Medications: What you should know**
- **Diabetes: First steps after diagnosis**
- **Weight-loss Surgery: A Decision Tool**
- **Diabetes Resources**
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 the numbers listed below.

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REFERENCES


References (continued)


REY Reynolds AN, Mann JJ, Williams S, Venn BJ. Advice to walk after meals is more effective for lowering postprandial glycaemia in type 2 diabetes mellitus than advice that does not specify timing: A randomised crossover study. Diabetologia. 2016;59(12):2572-2578.


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 Christopher Jones, MD, Intermountain Healthcare, (Christopher.Jones@imail.org).