CLINICAL PATHWAY

Primary Care & Community Medicine

Type 2 Diabetes Management

CHRISTIANA CARE HEALTH SYSTEM

Type 2 Diabetes Management

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INTRODUCTION

Scope of this Pathway

The Type 2 Diabetes Management Clinical Pathway is the guiding document for Christiana Care Health System's (Christiana Care) comprehensive team-based approach to non-pregnant adult diabetes care in the outpatient setting. 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.

Pathway Contacts

The content of this pathway is developed and maintained by the Primary Care & Community Medicine line of Christiana Care Health System. Questions or feedback about the content may be directed to:

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What is a Clinical Pathway?

A Christiana Care Clinical Pathway is the evolution of the Diabetes Care Management Guideline (CMG). It was developed using an approach that was:

- **MULTIDISCIPLINARY:** We leveraged our wide network of clinical and operational expertise from across the health system and in our community to develop this pathway.
- **OUTCOME ORIENTED:** We took care to ensure our best practices will support our service line metrics and outside metrics like the State Innovation Model Scorecard.
- **EXCEPTIONS & VARIANCE ANALYSIS:** We partnered with Operational Excellence to review and analyze Medical Group of Christiana Care primary care practice metrics to identify areas for targeted improvement.
- **CROSS-CUTTING BOUNDARIES:** We intentionally looked to opportunities where we could employ strategies that encourage collaboration across our traditional silos.
- **PATIENT INVOLVEMENT:** Patient and Family Advisors provided critical input in our overall plan and specifically in the self-management and education development.
- **EVIDENCE-BASED; INTERNAL CONSENSUS:** We continued our support of the American Diabetes Association (ADA) Standards of Care for Diabetes but encouraged open discussion among providers for making those guidelines work here at Christiana Care.

Goal

The goal of this clinical pathway is to assist providers in helping patients reach the treatment goals outlined in Table 1.

CLINICAL PATHWAY

Why Focus on Diabetes?

- DIABETES IS A GROWING PROBLEM. The estimated number of Americans with diabetes increased from 0.93% in 1958 to 7.18% of in 2013.[CDC] The CDC reports that this accounts for 22.3 million U.S. adults, with a continuing annual increase.
- DIABETES IS A DELAWARE PROBLEM. The percent of Delawareans with diabetes more than doubled from 4.4% in 1994 to 9.9% in 2013.[CDC1] Low income adults with lower educational levels are more likely to be obese and have diabetes. In addition another 52,000 Delawareans (8.2%) have reported being told they have pre-diabetes.
- 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.[ADAE] It is estimated that within the next decade, spending will rise to almost $500 billion, or 10% of total health spending.[CDC]
- LATE DIAGNOSIS NEGATIVELY AFFECTS OUTCOMES. Better screening and early diagnosis of diabetes is crucial to improving patient outcomes.
- Many patients with type 2 diabetes develop complications just before or immediately after a diagnosis is made. Approximately one-fourth of type 2 diabetes cases may be currently undiagnosed.[ADA]

- **GOOD MANAGEMENT CAN PRESERVE AND IMPROVE QUALITY OF LIFE.** Uncontrolled diabetes can result in catastrophic health problems including heart disease, stroke, blindness, kidney disease, nervous system disease, amputations, dental disease, and pregnancy complications. Managing diabetes following the recommendations set forth in this care pathway can help delay or prevent these complications.

Treatment Measures, Goals & Frequency

TABLE 1: TREATMENT GOALS

MEASURE	GOAL	FREQUENCY
HbA1C	<7%*	At least every 6 months
Blood pressure	<140/90 mmHg* (lower in some)	At each office visit
Foot exam	Normal	At least yearly & every visit if abnormal
Urine albumin/creatinine ratio	<30 mg albumin/g of creatinine	At least yearly
Serum creatinine	Normal	At least yearly, estimate GFR
Retinal or dilated eye exam	Normal	check every year or every 2 year if diabetes is well controlled
Statin medication	Taking statin medication at appropriate level of intensity	

**Although these blood glucose and blood pressure goals are recommended generally for most people with diabetes, we also recommend individualizing these goals.*

Screening & Diagnosis

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

- **IDENTIFY THOSE AT RISK FOR DIABETES.** Therapeutic lifestyle changes may delay or prevent development of diabetes in people with prediabetes.
- **PREVENT OR DELAY DIABETES COMPLICATIONS.** The length of time between the onset of hyperglycemia and appropriate treatment for the condition can be a significant factor in the development and severity of complications. Type 2 diabetes is often asymptomatic, and at the time of diagnosis a significant number of type 2 patients already have complications such as neuropathy, nephropathy, or retinopathy.
- **IDENTIFY THOSE AT RISK FOR OTHER CAUSES OF HYPERGLYCEMIA.** Hyperglycemia can be chronic, pathogenic, asymptomatic, and can be caused by conditions other than diabetes. Screening for hyperglycemia can also detect patients at risk for complications from vascular, neurological, and renal conditions.

Screening

This Clinical Pathway recommends:

- Routine screening for type 2 diabetes. Note that in addition to testing the patients as specified in Algorithm 1, physicians should consider testing adults older than age 30 every 3 to 5 years. This is a cost-effective strategy; the benefits of early detection of type 2 diabetes include a reduced incidence of myocardial infarction and microvascular complications.[KAH]
- 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 Christiana Care Gestational Diabetes Clinical Pathway.

Diagnosis

Recommended diagnostic tools for type 2 diabetes include:

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

Diagnostic criteria for diabetes are listed in Algorithm 5. Note that in the absence of unequivocal hyperglycemia, repeat testing is required to make a diagnosis of diabetes.[ADA] In an outpatient with new onset of hyperglycemia, causes of hyperglycemia other than diabetes should be considered. The differential diagnosis of hyperglycemia includes type 1 and type 2 diabetes, Cushing's syndrome, electrolyte abnormalities, acromegaly, pheochromocytoma, and pancreatic cancer.

PROFILES: TYPE 2, TYPE 1, LADA

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

TYPE 2

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

TYPE 1

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

LADA (LATENT AUTOIMMUNE DIABETES IN ADULTS)

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

Management Overview

Diabetes care is complex, requiring regular medical care and follow-up. Patients with well controlled diabetes should be seen at least every 6 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 clinical pathway focuses on some important elements of diabetes care and self-management, namely blood glucose monitoring, medical nutrition therapy (MNT), diabetes self-management education (DSME), 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 2 to 3 months and usually reflects overall diabetes control during that period.

HbA1c measurement can validate or call into question a patient's home record of glucose testing or glucose testing performed in the office. In situations where higher home glucose readings do not match in-office HbA1c, consider conditions causing rapid RBC turnover. Sometimes wide fluctuations in blood sugar can be masked by a normal HbA1C so it is important to continue to review the home glucose testing record even in those with controlled HbA1C.

Measuring HbA1c

Preferably HbA1c will be performed in a lab at least 2-3 days before a scheduled office visit; however, we recognize that at times patients will be

unable to arrive with an updated HbA1c value. In those instances we advise using point-of-care HbA1C testing. Christiana Care uses the Alere Afinion™ HbA1c assay tests.

Although our point-of-care testing machines have been CLIA waived, they are known to have some variability compared to standardized lab values.

TABLE 2: APPROXIMATE COMPARISON OF HBA1C AND PLASMA GLUCOSE

HBA1C	PLASMA GLUCOSE
6%	126 mg/dL
7%	154 mg/dL
8%	183 mg/dL
9%	212 mg/dL
10%	240 mg/dL
11%	269 mg/dL
12%	298 mg/dL

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. [INZ, ADA]

- **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,[ACCO] ADVANCE, [ADVA] and VADT [DUC] studies did not show increased cardiovascular benefits from tight control of diabetes. However, tight control has consistently been shown to reduce the HbA1c risk of microvascular and neuropathic complications.

CONSULT OR REFERRAL?

Typically inadequately controlled patients would have been referred for an office visit at the Endocrinology practice. While a visit is still the preferred mechanism for complicate cases, other options are available.

eComm is an embedded communication tool within our electronic medical record which allow primary care providers to curbside consult specialist about care management decisions or for patients where a visit may not be necessary (e.g., specific management question or second opinion about a care decision).

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, MNT, and physical activity. However, the accuracy of SMBG is dependent on the user and the instrument. Physicians or diabetes educators should teach patients how to do SMBG accurately, and routinely evaluate patients' technique and ability to use the data to adjust their therapy.[ADA]

Providers who manage insulin-treated patients (especially patients using multiple daily injection therapy or insulin pumps) must be able to appropriately analyze patients' SMBG data, including control over specific time intervals, control by time of day (modal day), testing frequency, and glucose variability.

Software for this purpose is provided by device manufacturers at no cost.

Recommendations When Prescribing SMBG

- Ideally practices should maintain a supply of each of the commonly used glucometers (Accucheck, One Touch, Relion and Freestyle) for on-site dispensing during self- management teaching.
- Use the embedded diabetes supply list in the EMR to make ordering additional supplies easier.

  - » In addition to testing strips, be sure to order lancets, alcohol wipes and control solution.

- Insurance coverage of Diabetes DME changes often. Encourage the patient to contract his insurance company for coverage determination. Additional information about SMBG test strip coverage can be found under "COVERAGE FOR SMBG TEST STRIPS."**Error! Reference source not found.Error! Reference source not found.**

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 to 65 years. (Though there is less evidence supporting benefit in children, teens, and young adults; success correlates with consistent use.)

In addition, CGM devices can be a valuable supplemental tools for patients with frequent hypoglycemic episodes and/or hypoglycemic unawareness — and significantly reduce the burden of diabetes by reducing fear of hypoglycemia and the pain of frequent testing.

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

- **Personal CGM** devices belong to the patient and display subcutaneous glucose values to the patient in real time. An alarm feature alerts the patient when his or her subcutaneous glucose value crosses a prespecified threshold. In addition, these monitors have alarms that will warn the patient when glucose values are changing rapidly, potentially averting hypoglycemia. Several short-term studies have demonstrated their efficacy in lowering HbA1c levels and reducing frequency of hypoglycemia.[BEC, TAM] Most commercial

insurance carriers cover CGM; however, the majority of Medicaid and Medicare plans do not cover it.

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

The Role of Continuous Subcutaneous Insulin Infusion (CSII)

CSII (also called insulin pump therapy) is recommended for selected patients with type 1 diabetes and for some patients with insulin-treated type 2 diabetes. **These should only be prescribed by experienced clinicians who have the knowledge, skills, and resources to monitor for failure.** Adequate pump programs should involve a multidisciplinary team of providers — not just the services of industry-employed trainers and salespersons. Most insurance carriers 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.

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 non-sulfonylurea insulin secretagogues 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.
- Pregnant women or patients with hypoglycemic unawareness, test 4 to 8 times per day.
- Patients having sick days.
- Patients modifying therapy.
- Patients having hypoglycemia.
- 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 3 test strips daily for patients with type 1 or type 2 diabetes on any form of insulin therapy. To obtain approval for 4 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 superior products.

Lifestyle Management

All patients with diabetes and prediabetes should be counseled on lifestyle measures. Lifestyle counseling is associated with better control of HbA1c, blood pressure, LDL cholesterol, and weight, as well as improved overall well-being.[MOR]

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

» Exercise Services Flyer (PDF)

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. MOR

Medical Nutrition Therapy (MNT)

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

All patients with prediabetes or diabetes should be referred to a registered dietitian, preferably one specializing in diabetes education, for individualized MNT.

MNT includes an individualized meal plan that accommodates the patient's medications and metabolic needs, as well as their eating habits, lifestyle, and readiness to change. Meal plans are adjusted as needed to help patients comply with needed changes and meet goals.

A meal plan includes the following, at a minimum:

- **Amount and type of carbohydrates consumed.** Both quality and quantity of carbohydrate in foods influence blood glucose levels and glycemic response. However, there is no standard regarding the ideal amount of carbohydrate intake for people with diabetes. 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. For good health, dietary patterns should include carbs from fruits, vegetables, whole grains, legumes, and low-fat milk. Promote fiber intake of 25 g to 35 g per day. BAN

- **Timing of meals and snacks.** Monitoring and maintaining a consistent pattern of carbohydrate use is key to achieving glycemic control. Meals should include a mix of macronutrients (carbohydrate, protein, and fat) individualized to meet the patient's metabolic goals and personal preferences.
- **Caloric restriction combined with physical activity to support any needed weight loss.** Weight loss should be gradual and slow. Aim for a rate of 1 to 2 pounds per week. Mediterranean, low-fat, calorie-restricted, or low-carbohydrate diets may all be effective for weight loss. ADA

» Nutrition Services handout (PDF)

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

- As a temporary guideline, an initial goal is 1200 to 1500 total calories per day for female patients <250 pounds, and 1500 to 1800 calories per day for female patients >250 pounds. An initial goal of 1500-1800 total calories per day for male patients <250 pounds, and 1800-2000 calories per day for male patients >250 pounds.
- Minimum calorie recommendations: 1500 for patients under 250 lbs., 1800 for weight >250 lbs.
- 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 CalorieCount.com can provide nutrition content of foods. Assistance with healthy food choices is available at ChooseMyPlate.gov. Smart phone apps such as MyFitnessPal can also help patients track nutrients.

Medicare will cover 3 hours of initial MNT in first calendar year, plus 2 hours annually. Additional MNT hours are available for change in medical condition, treatment, or diagnosis.

Diabetes Self-Management Education/Training (DSME)

Diabetes self-management education/training and support are critical elements of care of all people with diabetes and is covered by most commercial insurance providers and Medicare. All patients with diabetes should be assessed and referred to DSME and support at four critical times: 1) at diagnosis, 2) annually, 3) when new complicating factors arise, and 4) when transitions in care occur.

DSME includes information on the following:

- Medications
- Monitoring blood glucose
- Physical activity
- Preventing, detecting, and treating acute and chronic conditions
- Nutrition
- Risk reduction
- Emotional health
- Health promotion and behavior change

HOW TO REFER TO METABOLIC SERVICES

DIABETES EDUCATION:

Call 302-661-3050 or fax referral to 302-661-3043 or flag "Nutrition Services" desktop in Centricity

NUTRITION SERVICES:

Call 302-661-3043 or fax referral to 302-661-3043 or flag "Nutrition Services" desktop in Centricity

One-on-one appointments with a registered dietitian for all conditions requiring nutrition education & counseling are available.

» Diabetes Support Services Referral Information (PDF)

WEIGHT MANAGEMENT CENTER:

Call 302-661-3475, Option 2 or fax referral to 302-661-3440

WeightSmart: 10-week group education and coaching sessions led by a registered dietitian.

Fit4Life: 12 weekly one-on-one appointments with a registered dietitian, monthly group support session led by a health psychologist, exercise evaluation, and long-term follow-up. Option to participate with OPTIFAST® Meal Replacement and weight loss medication.

Reference for prior info: Diabetes Self-Management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. This report provides an algorithm and guidance to healthcare providers on when to refer patients to diabetes educators.

Physical Activity

Regular physical activity improves blood glucose control and can prevent or delay type 2 diabetes.[COLB] Regular activity also positively affects cholesterol, blood pressure, cardiovascular risk, mortality rates, and quality of life.

Pre-exercise evaluation. Sedentary patients should be evaluated by a physician before beginning a moderate- to vigorous-intensity exercise program. 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.**[BOD]

Recommendations

Counsel patients to:

- **Increase activity to ≥175 minutes per week** of moderate- to vigorous- intensity aerobic activity — heart beating faster than normal and breathing harder than normal, such as a brisk walk. Spread activity over at least 3 days per week, with no more than 2 consecutive days between bouts of aerobic activity. While the ADA guidelines recommend ≥150 minutes per week, Christiana Care endorses the target of ≥175 minutes used in the Look AHEAD trial based on findings that higher levels of physical activity significantly improve weight loss

maintenance and other health outcomes.[DEL] Casual walking that does not meet at least moderate intensity does not count toward the weekly goal.

- **Increase activity gradually.** Patients who are currently sedentary should start with 10 minutes of walking at moderate intensity 3 days per week, gradually increasing to 5 days per week. Once they are walking on most days, patients should add minutes to achieve 20 minutes on most days, and build toward the goal of 30 to 60 minutes on most days of the week.
- Unless contraindicated, **undertake resistance training 2 days per week,** focusing on major muscle groups and core body conditioning.
- **Decrease time sitting and increase daily movement.** All individuals should be encouraged to break up extended amounts of time sitting (>90 minutes).[ADA] 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.[DUN] Individuals can increase daily movement through activities such as taking the stairs, walking rather than riding in a car, etc.
- **At first, monitor blood glucose before, during, and after physical activity.** Once patients have a sense of how exercise works with their medication, food choices, and other factors that affect blood glucose, they won't need to check levels as often.

Behavior Modification and Accountability

Diabetes self-care requires modification to daily behaviors that most patients find challenging. 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 Fit4Life®) or additional contact with a clinician may help.

Intensive Lifestyle Intervention (ILI)

An intensive lifestyle intervention (also referred to as behavioral intervention) can provide the support and follow-up necessary for behavior modification. With passage of the Affordable Care Act (ACA), commercial payers are required to cover an intensive lifestyle intervention at no cost to patients with BMI ≥30 or with BMI ≥25 and one or more cardiovascular disease risk factors.

Christiana Care Weight Management Fit4Life® program is an example of an intensive lifestyle intervention that may be covered by a plan. Christiana Care Weight Management Fit4Life® program consists of:

- 12 individual sessions with a registered dietitian.
- Monthly behavioral health group sessions lead by a psychologist.
- Exercise evaluation and monthly reassessment performed by an exercise physiologist.

Medicare and Medicare Advantage do not cover The Fit4Life® program, but may have coverage for medical nutrition therapy for select patients.

Consider referring patients to Christiana Care's Weight Management program at http://www.christianacare.org/weight. Patient may sign up to attend a free seminar to "Find Your Way to Successful Weight Loss" www.christianacare.org/weightlossseminar.

Bariatric Surgery for People with Type 2 Diabetes

Studies show that bariatric surgery can produce a remission in type 2 diabetes (**normal or near-normal glycemia in approximately** 55% to 95% of patients with type 2, depending on the surgery).[ADA1] 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 response. VET

For further discussion, see Diabetes in Remission

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

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

For primary care providers, we recommend the following:

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

the ASMBS website or the Christiana Care Bariatric Surgery Program website http://www.christianacare.org/bariatrics.

- Postsurgery, ongoing lifestyle support is critical.

LIVING WITH DIABETES

Christiana Care's Living with Diabetes program is an example of a comprehensive diabetes self-management education and support program.

Many commercial payers and Medicare cover this program.

Medicare will allow 10 hours of initial group instruction in a 12-month period, plus 2 hours of follow-up training annually.

Medicaid does not cover group diabetes education but will cover 1:1 diabetes education.

» Living With Diabetes Class handout (PDF)

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. 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%.
- 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.

Diabetes in Remission

In patients who have had gastric bypass surgery or banding or who have implemented lifestyle and weight management changes, glycemia measures may fall below diagnostic thresholds. Because chronic conditions such as

diabetes are never considered to be completely cured, these patients are considered to be in remission. An ADA consensus statement[BUS] defines remission as the following:

- Partial remission.
  - » Hyperglycemia below diagnostic thresholds for at least 1 year, with no active pharmacologic intervention.
- Complete remission.
  - » Normal glycemia measures for at least 1 year, with no active pharmacologic therapy.
- Prolonged remission.
  - » Complete remission for at least 5 years.

Follow-up for patients in remission

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

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

Medication

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

- For type 2 diabetes, oral medication is required for glycemic control if lifestyle modifications don't achieve glycemic control within 2-3 months. Prescribing

considerations include the patient's age, weight, any renal or hepatic impairment, and cardiopulmonary comorbidities. Insulin may be used initially (often temporary) for significant hyperglycemia and is a long-term option for patients on oral agents who still have HbA1c values more than 1% above goal.

Medication Details

This section gives detailed information on medication — oral agents, non-insulin injectables, and insulin — for the treatment of adult diabetes.

TABLE 3: ORAL AGENTS AND NON-INSULIN INJECTABLE MEDICATIONS

CLASS	GENERIC NAME	BRAND NAME	USUAL DOSING	2015 AWP COST FOR 30-DAY SUPPLY* (MAC COST FOR GENERICS)	PROS	CONS
biguanides	metformin	Glucophage	500 mg twice a day (once a day to start) to 1000 mg twice a day (max) Most benefit obtained between 1500–1700 mg/day	*Generic:* 500 mg twice a day: $3 850 mg twice a day: $4 1000 mg twice a day: $4 *Brand name:* 500 mg twice a day: $68 850 mg twice a day: $115 1000 mg twice a day: $139	• 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.	• 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 <30).
	metformin ER	Glucophage XR	500 mg to 1500 mg once a day at dinner	Generic: 500 mg once a day: $2 750 mg once a day: $4 1000 mg (2 × 500 mg): $4 1500 mg (2 × 750 mg): $8 *Brand name:* 500 mg once a day: $35 750 mg once a day: $52		
sulfonylureas	glipizide XL	Glucotrol XL	5 mg to 20 mg once a day (max) [may give dose twice a day]	*Generic:* 5 mg once a day: $5 10 mg once a day: $8	• Extensive experience. • Well tolerated. • Maximum PG effect at 5 to 7 days.	• Hypoglycemia, especially with reduced GFR. • Weight. • Do not use with Prandin, Starlix, or other sulfonylureas. • Limited duration of effect.
	glimepiride	Amaryl	1 mg to 8 mg (max) once a day [may give dose twice a day]	*Generic:* 1 mg once a day: $2 4 mg once a day: $3		
	Glyburide	Diabeta, Glynase	2.5 mg to 20 mg (max) once a day	*Generic:*		

CLASS	GENERIC NAME	BRAND NAME	USUAL DOSING	2015 AWP COST FOR 30-DAY SUPPLY* (MAC COST FOR GENERICS)	PROS	CONS
			[may give dose twice a day]	1.25 mg once a day: $9 2.5 mg once a day: $4 5 mg once a day: $31		

CLASS	GENERIC NAME	BRAND NAME	USUAL DOSING	2015 AWP COST FOR 30-DAY SUPPLY* (MAC COST FOR GENERICS)	• PROS	• CONS
thiazolidinediones	pioglitazone	Actos	15 mg to 45 mg once a day (dosing at bedtime may decrease edema)	*Generic:* 15 mg once a day: $11 30 mg once a day: $13 45 mg once a day: $14	• Option for patients in - tolerant of metformin • No hypoglycemia • ↓Serum insulin • Durability • ↓Triglycerides • Possible ↓ CVD event	• 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 6–12 weeks
	rosiglitazone	Avandia	4 mg to 8 mg daily	*Generic:* 15 mg once a day: $11 30 mg once a day: $13 45 mg once a day: $14		
DPP-4 inhibitors	sitagliptin phosphate	Januvia	100 mg once a day [as monotherapy or as combination therapy with metformin or glitazones]	25 mg, 50 mg, or 100 mg once a day: $397	• Can be taken with or without food. • No hypoglycemia. • No 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.
	saxagliptin	Onglyza	2.5 mg or 5 mg once a day	2.5 mg or 5 mg once a day: $390		
	linagliptin	Tradjenta	5 mg once a day	5 mg once a day: $397		
	Alogliptin	Nesina	25 mg orally once a day	All strengths: $374		
SGLT2 inhibitors	canagliflozin	Invokana (Tier 2, step edit)	100 mg or 300 mg once a day	All strengths: $411	• Non-insulin dependent — novel MOA. • Low incidence of hypoglycemia. • ↓Weight.	• ↑Female genital mycotic infections, UTIs, and increased urination. • 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	Farxiga (Tier 3, step edit)	5 mg or 10 mg once a day	All strengths: $412		
	empagliflozin	Jardiance (Tier 2, step edit)	10 mg or 25 mg once a day	All strengths: $411		

CLASS	GENERIC NAME	BRAND NAME	USUAL DOSING	2015 AWP COST FOR 30-DAY SUPPLY* (MAC COST FOR GENERICS)	• PROS	• CONS
amylin mimetic	pramlintide acetate	Symlin (Tier 2, step edit)	**See below	60 injection pen (1.5 mL): $708	Very positive effect on weight loss	• Symlin should only be used by providers with significant knowledge of its properties. 3 injections per day brings significant risk of severe nausea and hypoglycemia
	**Dosing instructions for Symlin: • Type 1: 15 mcg immediately prior to major meals; increase at 15 mcg increments to a maintenance dose of 60 mcg or as tolerated. • Type 2: 60 mcg immediately prior to major meals; increase to 120 mcg as tolerated. • When initiating Symlin, reduce insulin dosages, including premixed insulins (70/30).					
combinations (examples only)	sitagliptin + metformin XR	Janumet XR (Tier 3, step edit)	Once a day: 100 mg/1000 mg 50 mg/500 mg two 50 mg/1000 mg	All strengths: $397	All strengths: $397 See notes for individual components	
	saxagliptin + metformin XR	Kombiglyze XR (Tier 3, step edit)	Once a day: 5 mg/500 mg 5 mg/1000 mg 2.5 mg/1000 mg	All strengths: $390		
	linagliptin + metformin	Jentadueto (Tier 3)	Twice a day: 2.5 mg/500 mg 2.5 mg/1000 mg	All strengths: $397		
*AWP = Average Wholesale Pricing; MAC = Maximum Allowable Cost. Many patients may benefit from manufacturers' discounts or patient assistance programs.						

Additional notes:

For Liraglutide- Add 0.6 mg once daily for 1 week then, 1.25 mg or 1.8 mg once a day For Sitagliptin + Metformin XR

a. Add 2.5/850 mg.

b. If listing combination products with Metformin, then need to add the following for completion:

i. Canagliflozin + Metformin.

ii. Dapagliflozin + Metformin.

iii. Empagliflozin +Metformin.

iv. Other combo products available:

1. Empagliflozin + Linagliptin.

There are also other glucose lowering agents-Meglitinides (Nateglinide, Repaglinide), Alphaglucosidase inhibitors (Acarbose, Miglitol), Dopamine Agonist (Bromocriptine) and Bile Acid Sequestrant (Colesevelam).

Insulin Therapy

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

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

TABLE 4: INSULIN PROFILES

INSULIN TYPE	GENERIC (BRAND) NAME	DESCRIPTION	ONSET	PEAK	USUAL EFFECTIVE DURATION	2015 30-DAY AWP
Rapid-acting	aspart (NovoLog)	Clear	10 to 20 minutes	1 to 2 hours	3 to 5 hours	10 mL: $244 FlexPen 15 mL: $471
	glulisine (Apidra)	Clear	10 to 20 minutes	1 to 2hours	3 to 5 hours	10 mL: $243 SoloSTAR pen 15 mL: $471
	lispro (Humalog)	Clear	10 to 20 minutes	1 to 2 hours	3 to 5 hours	10 mL: $243 KwikPen 15 mL: $470
	human (Afrezza)	Inhalation powder	10 to 15 minutes	1 hour	2 to 3 hours	equivalent to 1000 units: $630
Regular (short-acting)	Novolin R Humulin R ReliOn R	Clear	30 to 60 minutes	2 to 4 hours	4 to 8 hours	10 mL: $132 ReliOn R 10 mL: $28
Intermediate-acting	NPH (Novolin N) NPH (Humulin N) ReliOn N	15 mg once a day: Cloudy	1 to 3 hours	4 to 10 hours	10 to 18 hours	10 mL: $132 ReliOn N 10 mL: $28
Peakless	detemir (Levemir)	Clear	1 hour	peakless	18 to 24 hours	10 mL: $298 FlexPen 15 mL: $447
	glargine (Lantus)	Clear	2 to 3 hours	peakless	24 + hours	10 mL: $298 SoloSTAR pen 15 mL: $447
	argine U-300 (Toujeo)	Clear	develops over 6 hours	peakless	24 + hours	SoloSTAR pen 14 .5
Mixes	70/30 (NovoLog Mix) 75/25 (Humalog Mix) 50/50 (HumalogMix) 70/30 (ReliOn Mix)					10 mL: $253; pen: $471 10 mL: $252; pen: $470 10 mL: $252; pen: $470 10 mL: $28

Insulin Conversion

There are times when a provider may need to convert a patient from one type of insulin to another. The following links below as examples of insulin conversion that may be useful:

http://www.hopkinsmedicine.org/endocrinology_diabetes_metabolism/_documents/Total_Daily_Insulin_Dose_and_JHH_Formulary_Insulins.pdf (scroll to the bottom for conversions)

http://portal.mah.harvard.edu/cms/content/B7ACBE692D3340DD9CD308883BC9750B/48BE034147324F50A4FFD277C40B3DE1.pdf

Physiologic Insulin Regimen: Peakless + Rapid-Acting Insulins

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

- Use peakless insulin to control blood glucose when not eating. The period between bedtime and breakfast is the best reflection of how this method is working — pre-breakfast blood glucose should approximate bedtime blood glucose. A bedtime snack is not required; if desirable, match its carb content with a rapid-acting insulin dose.
- Add rapid-acting insulin prior to each meal and planned snack.
  - » Adjust this insulin to prevent post-meal hyperglycemia or hypoglycemia. Blood glucose levels 4 hours after a meal should approximate premeal levels.

  - » Determine premeal rapid-insulin doses by counting carbohydrates and using an insulin-carbohydrate ratio. Alternatively, base premeal insulin dose on a fixed meal plan (budgeted carbohydrates).
  - » Train patients in MNT and insulin use; support with referral to diabetes educator/registered dietitian.
  - » Train patients in use of correction dose to treat hyperglycemia. (At bedtime, the correction dose may be reduced to as much as 50% of the usual correction dose.)
- Teach patients how to modify insulin doses when exercising, on sick days, to combat significant premeal hypoglycemia, or to prevent delayed post-meal hyperglycemia due to higher fat meals. Support with referral to diabetes educator/registered dietitian.

Basic (Nonphysiologic) Regimen: NPH + Rapid-Acting Insulin

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

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

Sample Basic Insulin Regimens

Following are some sample basic insulin regimens.

- **Premixed insulins:** These insulins are all given twice a day (before breakfast and before the evening meal).
  - » 70% aspart protamine suspension /30% aspart injection (NovoLog Mix 70/30).

» 70% NPH /30% regular (Novolin 70/30).

- **Split-mixed insulins:** NPH is given twice a day (either morning and before the evening meal, or morning and bedtime) with:

» Regular insulin before breakfast and before the evening meal.

OR

» Rapid-acting insulin before breakfast and before the evening meal.

EXAMPLE OF WEEKLY TITRATION SCHEDULE

(TREAT-TO-TARGET TRIAL)[RID]

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

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

TABLE 5: FORCED WEEKLY INSULIN TITRATION SCHEDULE (FOR TREAT-TO-TARGET FBG OF <120 MG/DL)

MEAN OF FBG VALUES OVER 3 DAYS	INCREASE OF INSULIN DOSAGE (IU/DAY)
>180 mg/dL	+8
160–180 mg/dL	+6
140–159 mg/dL	+4
120–139 mg/dL	+2

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

USING THE 1700 RULE

THE 1700 RULE CAN BE USED TO CALCULATE:

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

To calculate either of these doses:

- Determine the current total daily dose (TDD): Add up ALL the insulin (rapid and long-acting) the patient takes in a 24-hour period.
- Divide 1700 by the TDD. This is the predicted amount (mg/dL) the PG will decrease for each unit of rapid-acting insulin added (correction factor).

To calculate a correction dose:

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

Correction dose example:

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

To calculate an insulin-to-carb ratio:

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

Insulin-to-carb ratio example:

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

HIGHER DIETARY FAT AND POSTMEAL HYPERGLYCEMIA

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

Glucose Management in Special Circumstances

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

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

SGAs and Metabolic Abnormalities

Although the second-generation antipsychotic medications (SGAs) have many notable benefits compared with their earlier counterparts, their use has been associated with reports of significant weight gain, diabetes (even DKA), and a worsened lipid profile (increased LDL and triglyceride levels and decreased HDL cholesterol).[ADAP,NEW]

This has led to growing concern about a possible link between these metabolic effects and therapy with SGAs. There are also data that suggest these agents elevate the risk for sudden cardiac death. The table below shows the metabolic abnormalities associated with various SGAs.

Given these findings and the increased use of SGAs, we recommend the following:

- **Monitor patients regularly (perhaps monthly) after SGA therapy is initiated.** Measure weight, glucose, blood pressure, and lipids.
- **Consider switching the SGA if a patient gains ≥5% of his or her initial weight at any time during therapy.** Note that abruptly discontinuing clozapine has the potential for serious psychiatric sequelae.

TABLE 6: SGAS AND METABOLIC ABNORMALITIES [NEW]

GENERIC (BRAND) NAME	WEIGHT GAIN	RISK FOR DIABETES	WORSENING LIPID PROFILE
clozapine (Clozaril)	+++	+	+
olanzapine (Zyprexa)	+++	+	+
risperidone (Risperdal)	++	+	+
quetiapine (Seroquel)	++	+	+
aripiprazole (Abilify)*	+/−	−	−
ziprasidone (Geodon)*	+/−	−	−

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

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 clinical pathway recommends the following vaccinations for patients with diabetes:

- Annual influenza vaccination for all patients over 6 months of age. Patients with diabetes show an increased rate of hospitalization for influenza. The influenza vaccine can reduce hospital admissions for these patients by as much at 79% during flu epidemics.[COLQ]
- 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%.[SMI] Patients with diabetes need the following pneumococcal vaccines:
  - 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, given at least one year apart.

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

Data and Reports

The IT Department in collaboration with the PCCM Service line and Medical Group of Christiana Care use data to create reports for primary care physicians and endocrinologists to identify patients who may not have had testing done, or who have test results outside standards of good diabetes management. Data for the reports is obtained from insurance claims, billing records, lab results, and the electronic medical record (EMR). Physicians can review their data and make corrections (as needed).

The Diabetes Bundle

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

The PCCM Service Line metric is % of the population achieving 7/9 of the following:

- HgbA1C <8.
- % Non-smoker.
- % HgbA1C 6 months.
- % Foot exam annually.
- %LDL annually.
- % Eye exam annually.
- % BP <140/90.
- % on statin (adjusted).
- % Influenza vaccination given annually.

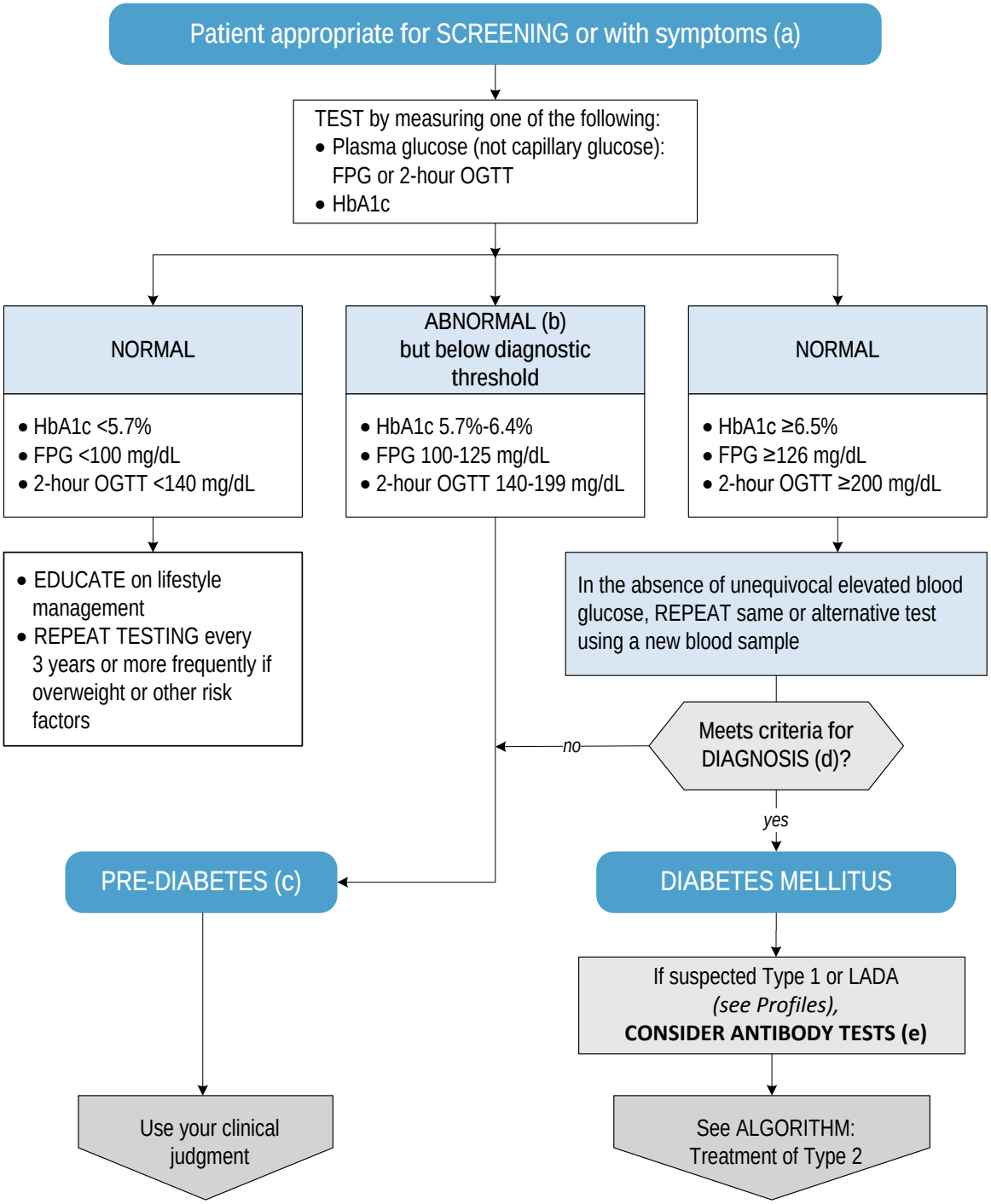
CHRISTIANA CARE CARE LINK

Care Link at Christiana Care is an interdisciplinary care coordination team comprised of nurses, case managers, social workers, pharmacists and support staff who using information-technology and predictive analytics support physician practices in providing improved care.

- RN Care Manager.
- Certified Diabetes Educators.
- Christiana Care VNA Diabetes Home Visits.

PATHWAY ALGORITHMS

ALGORITHM 1: SCREENING & DIAGNOSIS



Algorithm Notes

ALGORITHM 2: (A) DIABETES SCREENING

(a) DIABETES SCREENING
SCREEN THESE PATIENTS AT LEAST EVERY 3 YEARS OR MORE FREQUENTLY DEPENDING ON INITIAL RESULTS AND RISK STATUS:
• Adults ≥45 years. • Adults of any age who are overweight or obese (BMI ≥ 25 kg/m2 or ≥23 kg/m2 in Asian Americans) and have any of these additional risk factors: – Hypertension >140/90 mm Hg or on therapy for hypertension. – Family history: first-degree relative with diabetes. – Habitual physical inactivity. – High-risk ethnicity (African American, Latino, Native American, Asian American, Pacific Islander). – Previous GDM or delivery of baby >9 pounds. – Dyslipidemia (HDL-cholesterol <35 mg/dL and/or triglycerides >250 mg/dL). – Polycystic ovary syndrome (PCOS). – History of vascular disease. – Other clinical conditions associated with insulin resistance, e.g., acanthosis nigricans, sleep apnea, multiple skin tags, peripheral neuropathy, and gout. – Use of second-generation antipsychotic medication (SGAs); see Table 6.
SCREEN THESE PATIENTS ANNUALLY
• History of elevated HbA1c ≥5.7%, impaired fasting glucose (≥100mg/dL), or impaired glucose tolerance (≥140mg/dL).

ALGORITHM 3: (B) INVESTIGATING ABNORMAL VALUES

(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-9 code 790.6 Abnormal Chemistry to order follow-up test. DO NOT use ICD-9code 250.xx or your patient will be labeled a diabetic regardless of the test result. • Hemoglobinopathy. If patient has hemoglobinopathy and diabetes is suspected based on blood glucose or symptoms, measure two FPG values for confirmation.

Algorithm Notes (continued)

ALGORITHM 4: (C) PREDIABETES

(c) PREDIABETES

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

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

ALGORITHM 5: (D) CRITERIA FOR DIABETES DIAGNOSIS

(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.

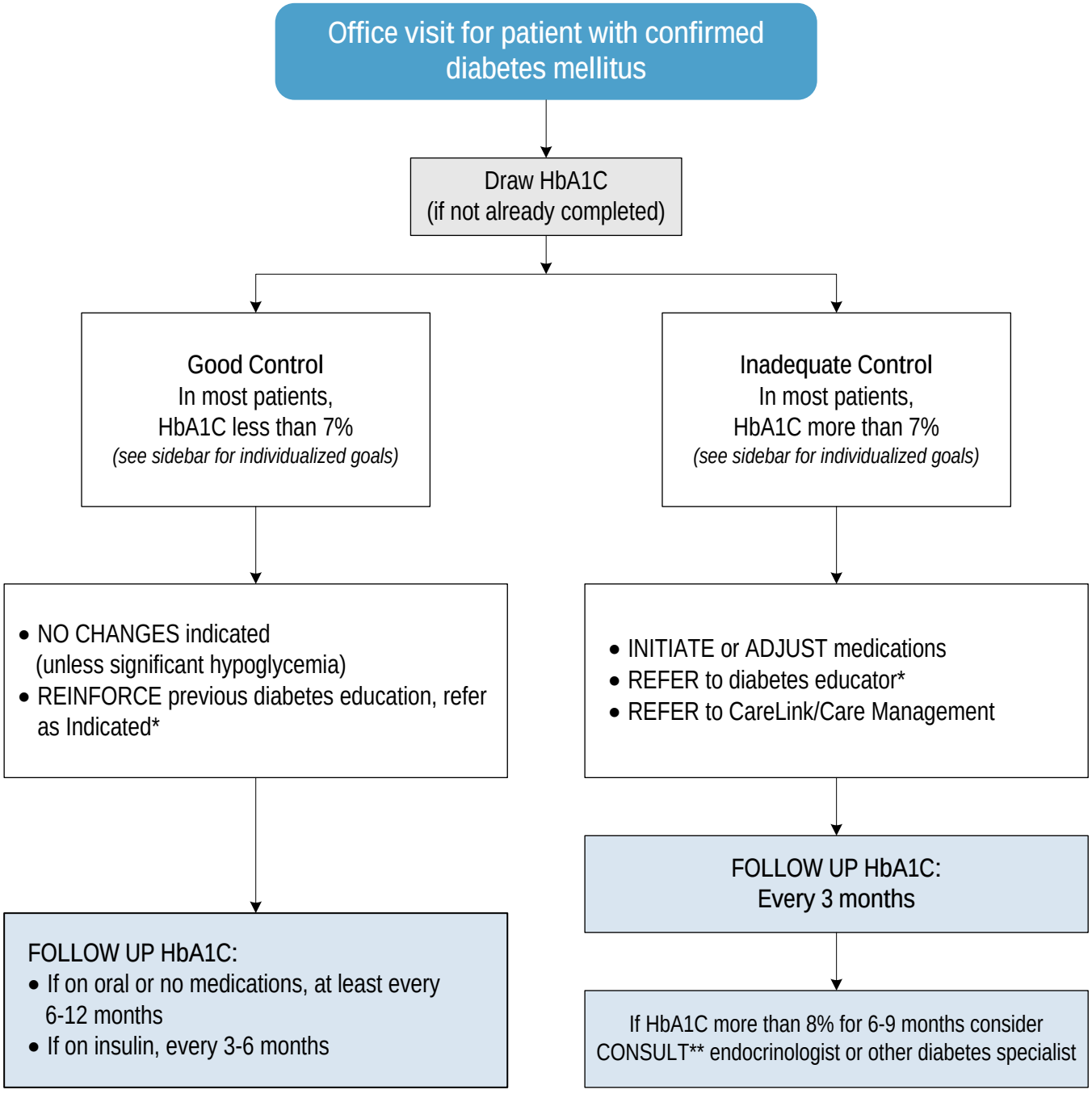
Remember: Plasma glucose values must NOT come from a finger stick.

ALGORITHM 6: (E) ANTIBODY TESTING

(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 page 8 for further discussion of LADA and information on ordering tests.

ALGORITHM 7: MONITORING HBA1C



* At least annually, reinforce/update patients' diabetes knowledge and skills. Consider using diabetes educators who are registered dietitians and can provide Individualized Medical Nutrition Therapy (MNT). Education can be provided in person, via-telehealth or using a group visit model.

** See below for example and Consult or Referral options including eComm on page 11.

EXAMPLES OF REASONS TO CONSIDER ENDOCRINOLOGY CONSULT

- **Excessive glycemic variability.**
- **Hyperglycemia unresponsive to management strategies.**
- **Recurrent severe hypoglycemia.**
- **Advancing diabetes complications despite adequate A1C control.**
- **A1C consistently above 8%.**
- **Type 1 Diabetes.**
- **Continuous subcutaneous insulin infusion or complicated insulin regimen (eg. U500).**

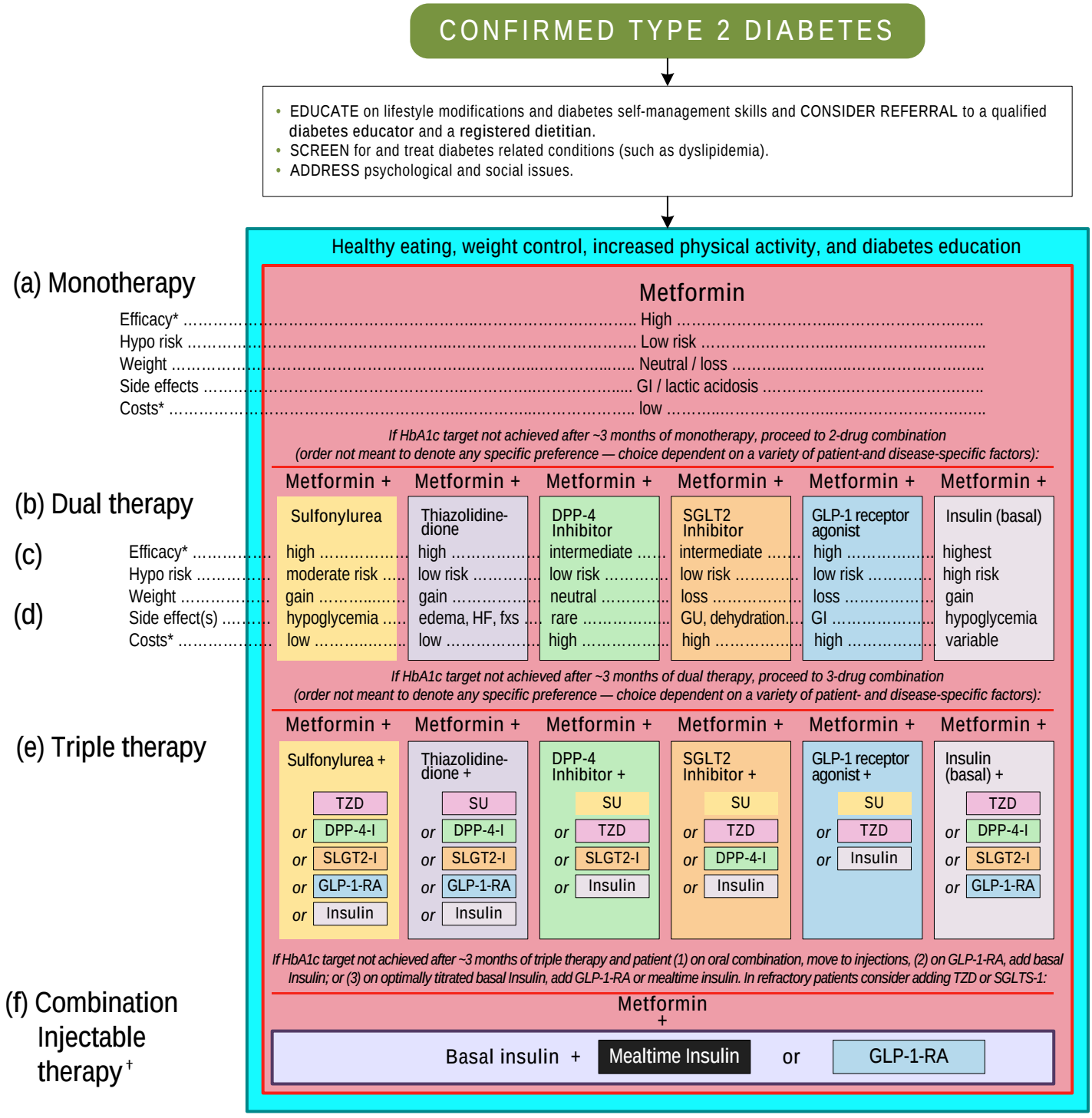
ALGORITHM 8: DIABETES SELF-MANAGEMENT EDUCATION & SUPPORT FOR ADULTS WITH TYPE 2 DIABETES

1. AT DIAGNOSIS	2. ANNUAL ASSESSMENT OF EDUCATION, NUTRITION AND EMOTIONAL NEED	3. WHEN NEW COMPLICATING FACTORS INFLUENCE SELF-MANAGEMENT	4. WHEN TRANSITIONS OCCUR
A primary care provider or specialist should consider referral:			
• Newly diagnosed. All newly diagnosed individuals with type 2 diabetes should receive DMSE. • Ensure that both nutrition and emotional health are appropriately addressed in education or make separate referrals.	• Needs review of knowledge, skills and behaviors. • Long-standing diabetes with limited prior education. • Change in medication, activity or nutritional intake. • HbA1c out of target. • Maintain positive health outcomes. • Unexplained hypoglycemia or hyperglycemia. • Planning pregnancy or pregnant. • For support to attain and sustain behavior changes.	Change in: • Health conditions such as renal disease and stroke, need for steroids or complicated medication regimen. • Physical limitations such as visual impairment, dexterity issues, movement restrictions. • Emotional factors such as anxiety and clinical depression.	Change in: • Living situation such as inpatient or outpatient rehabilitation or now living alone. • Medical care team. • Insurance coverage that results in treatment change. • Age-related changes affecting cognition, self-care, etc.

1. AT DIAGNOSIS	2. ANNUAL ASSESSMENT OF EDUCATION, NUTRITION AND EMOTIONAL NEED	3. WHEN NEW COMPLICATING FACTORS INFLUENCE SELF-MANAGEMENT	4. WHEN TRANSITIONS OCCUR
	• Weight or other nutrition concerns. • New life situations and competing demands.	• Basic living needs such as access to food, financial limitations.	
FOUR CRITICAL TIMES TO ASSESS, PROVIDE AND ADJUST DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT			
Primary care provider/endocrinologist/clinical care team: areas of focus and action steps			
• Answer questions and provide emotional support regarding diagnosis. • Provide overview of treatment and treatment goals. • Teach survival skills to address immediate requirements (safe use of medication, hypoglycemia treatment if needed, introduction of eating guidelines). • Identify and discuss resources for education and ongoing support. • Make referral for DSME/S and MNT.	• Assess all areas of self-management. • Review problem-solving skills. • Identify strengths and challenges of living with diabetes.	• Identify presence if factors that affect diabetes self-management and attain treatment and behavioral goals. • Discuss effect of complications and successes with treatment and self-management.	• Develop diabetes transition plan. • Communicate transition plan to new health care team members. • Establish DSME/regular follow-up care.
Diabetes education: areas of focus and action steps			
Assess cultural influences, health beliefs, current knowledge, physical limitations, family support, financial status, medical history, literacy, numeracy to determine content to provide and how:	• Review and reinforce treatment goals and self-management needs. • Emphasize preventing complications and promoting quality of life. • Discuss how to adapt diabetes treatment and self-management to new life situations and competing demands.	• Provide support for the provision of self-care skills in an effort to delay progression of the disease and prevent new complications. • Provide/refer for emotional support for	• Identify needed adaptions in diabetes self-management. • Provide support for independent self-management skills and self-efficacy. • Identify level of significant other

1. AT DIAGNOSIS	2. ANNUAL ASSESSMENT OF EDUCATION, NUTRITION AND EMOTIONAL NEED	3. WHEN NEW COMPLICATING FACTORS INFLUENCE SELF-MANAGEMENT	4. WHEN TRANSITIONS OCCUR
• Medications- choices, action, titration, side effects. • Monitoring blood glucose– when to test, interpreting and using glucose pattern management for feedback. • Physical activity– safety, short-term vs. long-term goals/recommendations . • Preventing, detecting and treating acute and chronic complications. • Nutrition– food plan, planning meals, purchasing food, preparing meals, portioning food. • Risk reduction– smoking cessation, foot care. • Developing personal strategies to address psychosocial issues and concerns. • Developing personal strategies to promote health and behavior change.	• Support efforts to sustain initial behavior changes and cope with the ongoing burden of diabetes.	diabetes-related distress and depression. • Develop and support personal strategies for behavior change and health coping. • Develop personal strategies to accommodate sensory or physical limitations, adapting to new self-management demands, promote health and behavior change.	involvement and facilitate education and support. • Assist with facing challenges affecting usual level of activity, ability to function, health beliefs, and feelings of well-being. • Maximize quality of life and emotional support for the patient (and family members). • Provide education for others now involved in care. • Establish communication and follow-up plans with the provider, family and others.

ALGORITHM 9: TREATMENT OF TYPE 2 DIABETES — A PATIENT-CENTERED APPROACH[INZ]



See Lifestyle Modifications on page 14.

(a) Initial drug monotherapy

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

(b) Two-drug combinations

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

(c) Medication Alternatives

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

(d) Insulin

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

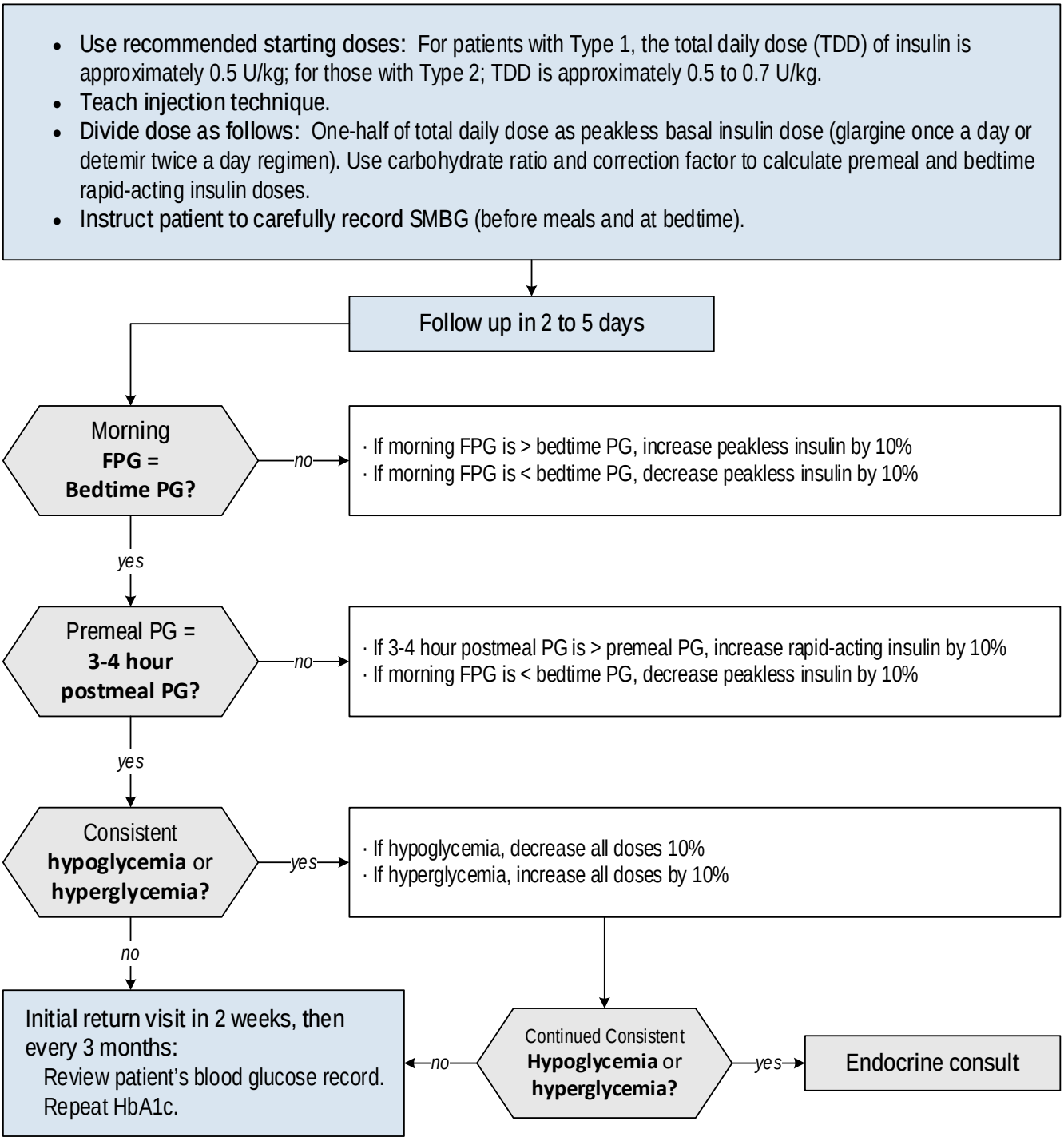
(e) An effective triple therapy

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

(f) Progression to multiple daily doses of insulin

Consider a more rapid progression from a two-drug combination directly to multiple daily insulin doses – or consider beginning at this stage – in patients with severe hyperglycemia (e.g., HbA1c≥10% to 12%).

ALGORITHM 10: INITIAL PHYSIOLOGIC INSULIN REGIMEN



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

Office Practice Team Roles

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

Algorithm: Patient Visit

PRIOR TO VISIT
• CARE LINK and RN Health Coach/CDE.

ALGORITHM 11: PATIENT ROOMING (MEDICAL ASSISTANT OR PATIENT CARE TECH)

Patient check-in	
PATIENT ROOMING (MEDICAL ASSISTANT OR PATIENT CARE TECH)	
Data • Record vital signs, including height, weight, BMI, BP. • Record data from glucose meter, if applicable. • Record smoking status and provide cessation handout if necessary. • Update preventive services (mammogram, colonoscopy) using the Care Gap Rooming Tool. • Update ophthalmology/eye exam date using the Care Gap Rooming Tool. • Document reason for visit.	Orders and tests • Propose orders as prompted by Care Gap Rooming Tool. • Perform A1C test as ordered. • Administer PHQ-2 to patients who have not had one in the last 12 months. • If PHQ-2 is positive, administer PHQ-9. • Conduct fall risk assessment and provide education handout if necessary. • Perform and document diabetic monofilament foot screening if due. • Administer due immunizations via standing orders.
Medications and allergies • Update medications. • Verify and document allergies.	Patient Preparation • Notify provider of outstanding orders. • Notify RN care coordinator for patients requesting any additional information. • Notify Behavioral health Consultant of any positive PHQ screening.

ALGORITHM 12: PATIENT VISIT (PRIMARY CARE PROVIDER)

PATIENT VISIT (PRIMARY CARE PROVIDER)	
Data • Review responses to care gap tool, PHQ screens and medication reconciliation. • Document diabetes in the problem list (if not already done), including date of onset - may enter approximate date. • Document associated conditions (eg. tobacco dependence, obesity, CKD etc.) if not already done.	Management • Manage diabetes according to Clinical pathway guidelines. • Collaborate with clinical pharmacist as needed. • Identify patients whose comorbid conditions or age may be a contraindication to pursing treatment goals. • Review compliance with diet and exercise recommendations. • Determine need for vaccinations.
Orders and tests • Review and sign all proposed orders. • Consider pre-ordering labs for next visit.	Follow-up • Schedule follow-up for patients who are not a goal per clinical pathway. • Send follow-up to Carelink and encourage patient to continue plan. • Encourage BHC follow-up if necessary. • Alert CDE or RN health coach of outstanding items for follow-up. • Refer for Diabetes Home visit for patients who are not at goal.

HEALTH DISPARITIES

We know that some communities including Latinos/Hispanics, African Americans, Asian Americans, Native Hawaiians and Pacific Islanders, and American Indian/Alaskan Natives are more severely affected by diabetes. Racial and ethnic minority populations often have a higher risk of diabetic complications, such as lower limb amputations, retinopathy and kidney failure, than non-Hispanic Whites.

The Delaware Division of Public Health (DPH), the University of Delaware's School of Public Policy & Administration, and other partners created the Health Equity Guide for Public Health Practitioners and Partners to help Delawareans better understand tools and strategies that promote health equity and support upstream population health approaches. It can be found here:

http://www.dhss.delaware.gov/dhss/dph/mh/files/healthequityguideforpublichealthpractitionersandpartners.pdf

At Christiana Care we are committed to ensuring our community has access to cost-effective, high quality care. We believe everyone deserves an exceptional experience and can achieve optimal health outcomes regardless of their background. We are actively striving to improve health equity through a wide range of programs and initiatives including community outreach, medical-legal partnerships, patient-centered medical homes and providing Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS).

PATIENT EDUCATION MATERIALS

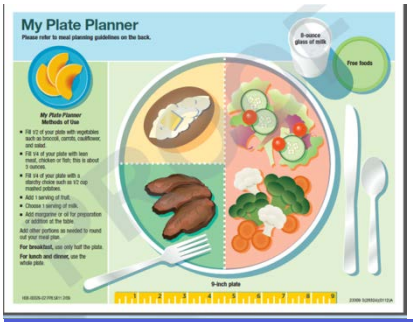
Diabetes Exercise Plan:

- Exercise Services Flyer (PDF)

Diabetes Meal Plan:

Diabetes Support Services Referral Information (PDF)

SmartWorks users may order the plate handout pictured below (item #23309) for an approximate cost of $57 per 100 via this link.



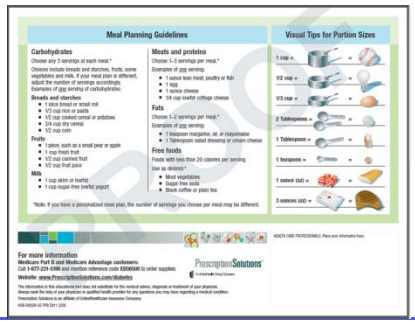


Plate handout

Living With Diabetes:

Living with Diabetes class handout (PDF)

Living with Diabetes class handout (v. 2 PDF)

CLINICAL EDUCATION MATERIALS

The PCCM Service line in collaboration with the Medical Group of Christiana Care and the Learning Institute are developing a wide range of diabetes-focused clinician education tools.

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Subcommittees

- Patient Education
- Clinician Education

The Christiana Care Way

We serve our neighbors as respectful, expert, caring partners in their health. We do this by creating innovative, effective, affordable systems of care that our neighbors value.

CHRISTIANA CARE
HEALTH SYSTEM