

MANAGEMENT OF DIABETES

**Federal Bureau of Prisons
Clinical Guidance**

MARCH 2017

Clinical guidance is made available to the public for informational purposes only. The Federal Bureau of Prisons (BOP) does not warrant this guidance for any other purpose, and assumes no responsibility for any injury or damage resulting from the reliance thereof. Proper medical practice necessitates that all cases are evaluated on an individual basis and that treatment decisions are patient-specific. Referenced Program Statement versions within this document are for informational purposes only. Please refer to the most current version of the referenced Program Statement. Consult the BOP Health Management Resources Web page to determine the date of the most recent update to this document:

http://www.bop.gov/resources/health_care_mngmt.jsp

WHAT'S BEEN CHANGED IN THIS DOCUMENT?

This document has been significantly revised since September 2002—in February 2008, April 2009, November 2010, and June 2012. This latest revision in 2017 reflects a change in focus for the Bureau of Prisons Clinical Guidance. Due to the availability of rigorous, comprehensive guidelines from expert organizations such as the American Diabetes Association, this document will primarily offer guidance on the aspects of diabetes management unique to the federal correctional setting.

TABLE OF CONTENTS

| | |
|--|-----------|
| 1. PURPOSE OF THIS DOCUMENT | 1 |
| 2. CLASSIFICATION AND DIAGNOSIS OF DIABETES | 1 |
| Classification | 1 |
| Diagnosis | 2 |
| TABLE 1. ADA Diagnostic Criteria for Diabetes and Pre-Diabetes (in Non-Pregnant Adults) | 3 |
| 3. SCREENING FOR TYPE 2 DIABETES | 4 |
| Preventive Health | 4 |
| Previously Identified IFG or IGT | 5 |
| Pregnancy | 5 |
| 4. BASELINE EVALUATION AND INITIAL TREATMENT PLAN | 5 |
| Intake Blood Glucose Screening of Inmates with Diabetes | 5 |
| Baseline Evaluation | 5 |
| Initial Treatment Plan | 5 |
| 5. TREATMENT OF TYPE 2 DIABETES | 6 |
| Goals and Principles | 6 |
| Interventions for Type 2 Diabetes | 7 |
| TABLE 2. Summary of Antidiabetic Interventions for Type 2 Diabetes | 7 |
| TABLE 3. Metformin in Stable Renal Dysfunction | 10 |
| BOP Treatment Algorithm for Type 2 Diabetes | 13 |
| TABLE 4. Titration of Metformin | 14 |
| 6. TREATMENT OF TYPE 1 DIABETES | 15 |
| 7. INSULIN | 15 |
| Insulin and Insulin Analogues | 15 |
| TABLE 5. Onset and Peak of Commonly Used Insulin Preparations | 16 |
| Intensive vs. Conventional Insulin Therapy | 17 |
| TABLE 6. Examples of Intensive (Multiple-Dose) Insulin Therapy Regimens | 17 |
| Designing a Multiple-Dose Insulin Regimen for New Type 1 Patients | 18 |
| Insulin Administration | 18 |
| Coordination of Insulin and Food Intake in the Correctional Setting | 19 |
| 8. BLOOD GLUCOSE MONITORING | 21 |

| | |
|--|-----------|
| 9. GESTATIONAL DIABETES MELLITUS (GDM) | 21 |
| Detection and Diagnosis of GDM | 21 |
| TABLE 7. Diabetes Screening Recommendations During Pregnancy | 22 |
| TABLE 8. GDM Diagnostic Criteria | 22 |
| Potential Complications of GDM | 22 |
| Monitoring and Treatment of GDM During Pregnancy | 23 |
| Postpartum Monitoring | 23 |
| 10. MEDICAL MANAGEMENT OF DIABETIC COMPLICATIONS | 24 |
| Hypertension | 24 |
| Dyslipidemia | 24 |
| Cardiovascular Events: Aspirin Therapy as Intervention | 25 |
| Diabetic Nephropathy | 25 |
| TABLE 9. Stages of Chronic Kidney Disease | 26 |
| Diabetic Retinopathy | 26 |
| Diabetic Neuropathy | 27 |
| Oral Health and Diabetes | 28 |
| TABLE 10. Cardinal Signs of Periodontitis | 29 |
| Medical Decompensation (Hospitalization Criteria) | 30 |
| 11. PERIODIC EVALUATIONS | 31 |
| Medical History | 31 |
| Physical Examination | 32 |
| Glucose Monitoring | 32 |
| Monitoring for Diabetic Complications | 33 |
| Inmate Education | 33 |
| Documentation | 33 |
| Diabetes Treatment Refusals | 33 |
| 12. HEALTH CARE PROVIDER RESOURCES | 34 |
| DEFINITIONS | 35 |
| REFERENCES | 37 |
| APPENDIX 1: COMPONENTS OF THE COMPREHENSIVE DIABETES EVALUATION | 39 |
| APPENDIX 2: RECOMMENDATIONS FOR DIABETES CHRONIC CARE CLINIC MONITORING | 40 |
| APPENDIX 3. TREATMENT GOALS FOR NON-PREGNANT INMATES WITH DIABETES | 41 |
| APPENDIX 4. INDIVIDUALIZED TREATMENT GOALS FOR OLDER ADULTS WITH DIABETES | 42 |

| | |
|--|-----------|
| APPENDIX 5: BOP TREATMENT ALGORITHM FOR TYPE 2 DIABETES | 43 |
| APPENDIX 6A: INITIATION AND ADJUSTMENT OF INSULIN REGIMENS IN TYPE 2 DIABETES..... | 44 |
| APPENDIX 6B: STRATEGIES TO REPLACE SLIDING SCALE INSULIN (SSI) FOR LONG-TERM CARE SETTINGS | 45 |
| APPENDIX 6C: INSULIN ADMINISTRATION SITES..... | 46 |
| APPENDIX 7: ORAL AGENTS FOR TREATMENT OF TYPE 2 DIABETES | 47 |
| APPENDIX 8: ALTERNATIVE MEDICATIONS FOR TREATMENT OF TYPE 2 DIABETES..... | 51 |
| APPENDIX 9: INFECTION CONTROL FOR DIABETES CARE PROCEDURES | 53 |
| APPENDIX 10: RESOURCES FOR INFORMATION ON DIABETES | 55 |
| APPENDICES 11–13: INMATE HANDOUTS | 56 |
| APPENDIX 11: FACT SHEET ON TYPE 2 DIABETES..... | 57 |
| APPENDIX 12: THE THREE KEYS TO CONTROLLING YOUR DIABETES | 58 |
| APPENDIX 13: EATING TO MANAGE YOUR DIABETES IN THE BUREAU OF PRISONS..... | 59 |

1. PURPOSE OF THIS DOCUMENT

The Federal Bureau of Prisons (BOP) Clinical Guidance for *Management of Diabetes* provides recommendations for the medical management of Federal inmates with diabetes mellitus, as well as inmates at risk for developing diabetes. These recommendations focus on the aspects of diabetes management unique to the correctional setting. For additional guidance, refer to the appropriate guidelines issued by expert organizations, as indicated in the sections below with a star (★).

2. CLASSIFICATION AND DIAGNOSIS OF DIABETES

★ **For up-to-date information on the classification and diagnosis of diabetes**, refer to the American Diabetes Association (ADA) website at http://care.diabetesjournals.org/content/40/Supplement_1s.

CLASSIFICATION

Diabetes is classified into four general categories, as listed below.

→ *Despite the general differences listed below for types 1 and 2, it is sometimes difficult to determine whether an individual has type 1 or type 2 diabetes.*

1. **TYPE 1 DIABETES** is a disease resulting from absolute insulin deficiency, usually caused by autoimmune destruction of pancreatic islet cells. The initial clinical presentation may be diabetic ketoacidosis (DKA) with an acute illness, or a more gradual presentation with symptoms of hyperglycemia. Other autoimmune disorders may also be present—such as Addison’s disease, thyroiditis, and pernicious anemia. A small subset of patients with type 1 diabetes have a non-immune mediated disease process with a waxing and waning clinical course. This form of type 1 diabetes is strongly inherited and most commonly affects persons of African and Asian descent.

The typical patient with type 1 diabetes:

- ▶ Is often diagnosed as a child or young adult (although it can occur at any age).
- ▶ Is lean (i.e., BMI less than 25 kg/m²).
- ▶ Displays normal insulin sensitivity (i.e., insulin requirements do not exceed 0.7 units of insulin/kilogram body weight/24 hours).
- ▶ Displays evidence of anti-beta cell autoimmunity (i.e., anti-GAD, anti-IA-2, and/or anti-insulin antibodies).
- ▶ Is more “ketosis prone” than individuals with type 2 diabetes (i.e., if the individual has a history of repeated bouts of DKA, they are far more likely to have type 1).

2. **TYPE 2 DIABETES** is a disease resulting from a relative, rather than an absolute, insulin deficiency with an underlying insulin resistance. Type 2 diabetes is associated with obesity, age, and physical inactivity. Patients with type 2 diabetes are not prone to ketoacidosis, frequently do not require insulin, and may be asymptomatic, despite being hyperglycemic for many years.

The typical patient with type 2 diabetes:

- ▶ Is more likely to be diagnosed as an adult.
 - ▶ Is overweight or obese (i.e., BMI ≥ 25 kg/m², and often far exceeding that BMI).
 - ▶ Is more likely to have a family history of diabetes (>90% of those with type 2 diabetes will have a first-degree relative with the disease).
 - ▶ If treated with insulin, is more likely to require very large doses to control the blood glucose (e.g., >0.7 units/kg/day) due to insulin resistance. Such individuals frequently have characteristics associated with insulin resistance, including abdominal obesity, hypertension, lipid abnormalities, atherosclerosis, and hyperuricemia.
 - ▶ Does not have evidence of anti-beta cell specific antibodies. Those who do have such circulating antibodies are sometimes referred to as having latent autoimmune diabetes of the adult (LADA). Such individuals seem to have a slowly progressive beta cell destructive process much like that occurring in children with typical type 1 diabetes, but the beta cell destruction occurs more slowly.
 - ▶ Is much less likely to have a history of DKA, but may have a history of hyperosmolar coma.
 - ▶ Is more likely to suffer other consequences of the “metabolic syndrome” (e.g., hypertension, hyperlipidemia).
3. **GESTATIONAL DIABETES (GDM)** is diabetes or any degree of glucose intolerance that is diagnosed during pregnancy. Detection, diagnosis and treatment of gestational diabetes are discussed in [Section 9, Gestational Diabetes](#).
4. **OTHER** causes of diabetes that are not classified as either type 1 or type 2 include: genetic defects of islet cell function; genetic defects in insulin action; endocrinopathies such as Cushing’s disease or syndrome; drug- or chemical-induced hyperglycemia; infections; and insults to the pancreas from a variety of causes such as pancreatic cancer, cystic fibrosis, trauma, and pancreatitis.

DIAGNOSIS

Inmates with any of the following should be evaluated for diabetes:

- Symptoms of hyperglycemia.
- Symptoms that may represent complications of diabetes.
- Clinical presentations that include diabetes in the differential diagnosis.

ADA DIAGNOSTIC CRITERIA

- ➔ *The ADA criteria for the diagnosis of diabetes in non-pregnant adults are shown in **Table 1** below.*
- ➔ *Unless unequivocal symptoms of hyperglycemia are present, diagnosis of diabetes requires that test results be confirmed, preferably by repeating the same test on a subsequent day.*
- **A1C testing:** In 2010, the ADA added the use of A1C testing to diagnose diabetes, with a cut point of 6.5%.
- **Fasting plasma glucose vs. fasting serum testing:** The diagnostic cut-points recommended by the ADA are based on fasting plasma glucose values.
 - ▶ Currently, most BOP laboratories utilize serum for glucose testing. Fasting serum glucose values may vary somewhat from fasting plasma glucose values.

- ▶ A fasting plasma glucose test should be obtained when fasting serum glucose values are borderline high, or if a patient has **impaired glucose tolerance (IGT)** or **impaired fasting glucose (IFG)**.
 - ➔ Please consult with the National Laboratory Administrator if fasting plasma glucose testing is required.
- **The 2-hour plasma glucose following a 75-gram oral glucose tolerance test (OGTT)** is another glucose-based test that may be used to diagnose diabetes. Although it diagnoses more people with diabetes than either the fasting plasma glucose or the A1C, some of the logistical aspects of the test may make it less suitable for use in a correctional environment. However, it may be required when evaluating patients with IFG, or when diabetes is suspected despite a normal fasting plasma/serum glucose test. It is also preferred over A1C for the [postpartum evaluation](#) of women with GDM.
- **Pre-diabetes** is the term that now encompasses IFG and IGT (i.e., hyperglycemia that does not meet the diagnostic criteria for diabetes). Both IFG and IGT, as well as an A1C range of 5.7–6.4%, are associated with a high risk for diabetes and cardiovascular disease.

TABLE 1. ADA DIAGNOSTIC CRITERIA FOR DIABETES AND PRE-DIABETES (IN NON-PREGNANT ADULTS)

| NORMAL |
|--|
| 1. A1C < 5.7%. or 2. Fasting plasma glucose <100 mg/dl. or 3. Oral glucose tolerance test (OGTT) 2-hr plasma glucose <140 mg/dl. |
| PRE-DIABETES |
| 1. A1C range of 5.7–6.4%. or 2. Impaired fasting glucose (IFG) = fasting plasma glucose of 100–125 mg/dl. or 3. Impaired glucose tolerance (IGT) = OGTT 2-hr plasma glucose of 140–199 mg/dl. |
| DIABETES |
| 1. A1C ≥6.5%. or 2. Fasting plasma glucose ≥126 mg/dl. or 3. OGTT 2-hr plasma glucose ≥200 mg/dl. or 4. Symptoms of diabetes and a casual plasma glucose ≥200 mg/dl. |
| NOTES ON METHODS OF TESTING: |
| 1. A1C: The test should be performed in a laboratory using a method that is certified by the National Glycohemoglobin Standardization Program (NGSP) and standardized to the Diabetes Control and Complications trial (DCCT) assay. 2. Fasting plasma glucose: “Fasting” is defined as no caloric intake for at least eight hours. 3. OGTT: The test should be performed using a glucose load containing the equivalent of 75-g anhydrous glucose dissolved in water. 4. Casual plasma glucose: “Casual” is defined as any time of day, without regard to the time since the last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss. |
| GENERAL NOTES: |
| <ul style="list-style-type: none"> • Currently, most BOP laboratories utilize serum for glucose testing. When fasting serum glucose values are borderline high, or for patients with IFG or IGT, a fasting plasma glucose should be obtained. Please consult with the National Laboratory Administrator if fasting plasma glucose testing is required. • To diagnose diabetes, lab results must be confirmed, preferably by the same test performed on a subsequent day (unless there are unequivocal symptoms of hyperglycemia). |

3. SCREENING FOR TYPE 2 DIABETES

There is no consensus on the best approach to screening for type 2 diabetes, primarily due to limitations in the available evidence. Many specialty societies, including the ADA and American Society of Clinical Endocrinology, recommend risk-factor based screening in the asymptomatic population.

The United States Preventive Services Task Force (USPSTF) screening recommendations:

- The USPSTF found sufficient evidence to endorse screening of asymptomatic persons who are aged 40 to 70 and are overweight or obese.
- Consideration for earlier screening in asymptomatic persons should be given for those who have a family history of diabetes; have a personal history of gestational diabetes; or are of African, Asian, Hispanic, Native Alaskan, Native American, or Pacific Island descent.
- Rescreening every three years is considered reasonable, but further evidence is needed to support this recommendation.

★ **For up-to-date information on type 2 diabetes screening recommendations, refer to the following:**

- ▶ USPSTF website at: <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/screening-for-abnormal-blood-glucose-and-type-2-diabetes>.
- ▶ ADA website at: http://care.diabetesjournals.org/content/40/Supplement_1.

PREVENTIVE HEALTH

PREVENTION AND DELAY OF TYPE 2 DIABETES

Many studies have demonstrated that diabetes can be delayed, and sometimes prevented, in individuals at high risk for developing diabetes (those with IFG, IGT, or both). All inmates with IFG or IGT should be counseled on the importance of maintaining a healthy diet and a conscious approach to meal planning, as well as the benefits of modest weight loss and regular physical activity. Inmates with IFG, IGT or elevated A1C should be assessed for other cardiovascular disease risk factors (e.g., hypertension and dyslipidemia) and provided treatment as indicated.

Diabetes screening in the BOP is recommended as part of the facility's preventive health care program, in accordance with either the USPSTF or ADA guidelines, as follows:

- Routine universal screening of all patients for type 2 diabetes is recommended at age 45.
- Routine screening for type 2 diabetes should be considered when clinically indicated, based on risk factors for diabetes. Screening should be prioritized for patients who are overweight (BMI ≥ 25 kg/m², or ≥ 23 kg/m² in Asian Americans) with additional risk factors: hypertension, hyperlipidemia, first-degree relative, sedentary lifestyle, high-risk ethnic or racial group, history of gestational diabetes mellitus, polycystic ovary syndrome, history of vascular disease, or other conditions known to be associated with insulin resistance.
- **Screening Tests:** Fasting plasma glucose, A1C, or 2 hour OGTT are all considered appropriate tests to screen for type 2 diabetes. However, the BOP recommends use of either fasting glucose or the A1C for most patients.

- **Screening Intervals:** Testing may be repeated every three years when fasting plasma/serum glucose is ≤ 100 mg/dl or A1C is $\leq 5.7\%$. Follow-up screening for diabetes is recommended annually for inmates with pre-diabetes. When test results are abnormal, repeated testing, preferably using the same test on a different day, is recommended to confirm the diagnosis.

PREVIOUSLY IDENTIFIED IFG OR IGT

Inmates with impaired glucose homeostasis are at increased risk of developing diabetes. Approximately one third of patients with IFG or IGT will develop diabetes within five years. **Annual screening by fasting plasma/serum glucose is recommended for these patients.**

PREGNANCY

Risk-based screening of pregnant women should be conducted in accordance with recommendations outlined in [Section 9](#) of this guidance.

4. BASELINE EVALUATION AND INITIAL TREATMENT PLAN

INTAKE BLOOD GLUCOSE SCREENING OF INMATES WITH DIABETES

It is important to rapidly identify and evaluate insulin-treated inmates at intake to detect those at highest risk for hypo- and hyperglycemia and diabetic ketoacidosis. The BOP recommends obtaining a capillary blood glucose (CBG) at intake on all inmates who report being insulin-dependent.

- ★ *For more in-depth, up-to-date information on the initial evaluation and treatment of, refer to the ADA website at http://care.diabetesjournals.org/content/40/Supplement_1.*

BASELINE EVALUATION

A complete medical evaluation is recommended to classify the patient, detect the presence or absence of diabetes complications, assist in formulating a management plan, and provide a basis for continuing care. If the diagnosis of diabetes has already been made, a review of the previous treatment plan, when available, is recommended to assess past and present degrees of glycemic control. Appropriate laboratory tests are recommended to evaluate the patient's general medical condition.

- ➔ *The components of a comprehensive diabetes baseline evaluation are listed in: [Appendix 1](#), Components of the Comprehensive Diabetes Evaluation, and [Appendix 2](#), Recommendations for Diabetes Chronic Care Clinic Monitoring.*

INITIAL TREATMENT PLAN

The treating physician, with the assistance of other health care providers, should develop and review the initial diabetic treatment plan with the inmate. Involvement of the inmate in the development of the treatment plan is pivotal to its success and should include adequate training to empower the patient to prevent, recognize, and treat hypoglycemia.

The treatment plan should include the following basic components and recommendations:

- Education on diabetes drug treatment options; self-monitoring; recognizing and treating severe hypoglycemic and hyperglycemic episodes; and identifying the signs of diabetic complications such as diseases of the eyes, kidneys, and nervous system.
- A discussion of available treatment options, including the advantages and possible disadvantages. Addressing patient concerns may improve adherence and outcomes.
- Instruction on the inmate's specific drug treatment regimen and methods for monitoring glucose.
- Necessary lifestyle modifications such as improving food selection, increasing physical exercise, and stopping smoking.
- Importance of annual eye exams (funduscopy) by an optometrist or ophthalmologist.
- Need for daily self-examination of the feet.
- Need for daily self-examination of the skin, including insulin injection sites.
- Importance of regular dental examinations and treatment.
- Need for regular screenings: fasting blood glucose, A1C, lipid levels, and kidney monitoring (BUN, creatinine, glomerular filtration rate calculation).
- Consideration of daily aspirin therapy to prevent cardiovascular events in some patients at higher risk.
- Need for annual influenza vaccinations and tuberculosis screening.

5. TREATMENT OF TYPE 2 DIABETES

GOALS AND PRINCIPLES

Based on the results of multiple randomized trials and correctional considerations, a reasonable A1C target for inmates with diabetes is <7.0–7.5%. **It is recognized, however, that glycemic goals should be individualized, as very stringent goals may not be appropriate or practical for some patients.** Clinical judgment, based on the potential benefits and risks of a more intensified regimen, should be applied for every patient. Factors such as life expectancy, history of severe hypoglycemia, presence of advanced micro- or macrovascular complications, and comorbid conditions need to be considered before intensifying a patient's therapeutic regimen.

- Glycemic targets are generally set somewhat higher (e.g., A1C <8%) for older patients and those with comorbidities or a limited life expectancy and little likelihood of benefit from intensive therapy.
- More stringent control (e.g., A1C <6%) may be indicated for individual patients with type 1 diabetes and during pregnancy.
- The National Performance Measure (NPM) for diabetes is intended to catch those patients at the highest risk for complications. The NPM identifies patients with A1C >9%, but this level should not be confused with appropriate A1C targets for patients.

SETTING GOALS AND MONITORING

- ➔ [Appendix 3](#) summarizes treatment goals for non-pregnant diabetic inmates, and [Appendix 4](#) provides guidance on identifying glycemic targets for older inmates.
- Early treatment for diabetes (before blood glucose is significantly elevated) is associated with improved glycemic control and decreased diabetic complications. Further adjustments should be based on glycemic levels, aiming for levels as close to the nondiabetic range as possible.
- Until glycemic goals are achieved, the patient should be seen at least monthly, and more frequently as indicated. Adequate follow-up and care can be achieved utilizing a team of qualified clinicians that might include not only physicians, but also nurse educators, pharmacists with collaborative practice agreements, nurse practitioners, and physician assistants.
- An A1C is recommended every three months for patients with poor glycemic control, or those whose therapy has changed, until patients are at goal. An A1C above the individualized goal indicates the need for further intensification of diet, exercise, and medication management. Medications should be adjusted according to blood glucose data.

INTERVENTIONS FOR TYPE 2 DIABETES

Selection of specific antihyperglycemic agents is based upon their effectiveness in lowering A1C levels, extraglycemic effects (reducing CVD risks), safety profiles, and tolerability. **Table 2** below outlines the advantages and disadvantages of the different antidiabetic interventions.

TABLE 2. SUMMARY OF ANTIDIABETIC INTERVENTIONS FOR TYPE 2 DIABETES

| Interventions* | Expected total decrease in A1C (%)** | Advantages | Disadvantages |
|---|--------------------------------------|---|---|
| STEP 1: LIFESTYLE INTERVENTION AND METFORMIN *** | | | |
| Lifestyle | 1–2 | Low cost, additional health benefits. | Fails as monotherapy for most patients in the first year. |
| Metformin | 1–2 | Weight-neutral, no hypoglycemia, inexpensive, self-carry. | GI side effects, contraindicated in renal impairment, rare lactic acidosis. |
| STEPS 2 AND 3: ADDITIONAL MEDICATION*** | | | |
| Insulin | ≥2.5 | No dose limit, inexpensive formulations available. | Hypoglycemia, weight gain; requires pill line. |
| Sulfonylureas (i.e., Glipizide) | 1–1.5 | Inexpensive. | Hypoglycemia, weight gain, decreased efficacy over time. |
| Thiazolidinediones (i.e., Pioglitazone) | 1–1.3 | Self-carry, improved lipid profile. | Fluid retention, weight gain, bone fractures. |
| ALTERNATIVE MEDICATIONS | | | |
| Alpha-glucosidase inhibitors | 0.5–0.8 | Weight-neutral. | GI side effects, frequent dosing, high cost. |
| DPP4 inhibitors | 0.5–0.7 | Weight-neutral. | Limited efficacy, long-term efficacy not established, high cost. |
| <i>(Table 2 continues on next page.)</i> | | | |

| Interventions* | Expected total decrease in A1C (%)** | Advantages | Disadvantages |
|---|--------------------------------------|--|---|
| <i>(Table 2 continued from previous page.)</i> | | | |
| Glinides | 1–1.5 | Rapid effect. | Weight gain, hypoglycemia, frequent dosing, high cost. |
| GLP-1 agonists (short-acting) | 0.5–1 | Weight loss. | GI side effects, pill line required, long-term safety not established, high cost. |
| GLP-1 agonists (long-acting) | 0.87–1.9 | Weight loss, weekly injection vs. daily with short acting GLP-1 agonist. | GI side effects, pill line required, high cost. |
| Pramlintide | 0.6–0.8 | Weight loss. | Three daily injections, pill line. |
| SGLT-2 inhibitors | 0.5–1.0 | Weight loss. | Candidal infections, urinary tract infections, euglycemic ketoacidosis, long-term safety not established. |
| <p>* INTERVENTIONS: Lifestyle interventions, as well as the classes of medication used to treat type 2 diabetes, are summarized below in this section, <i>Section 5</i>. See Section 7 for a more thorough discussion of insulin. See Appendix 7 for more information on oral agents used in treating type 2 diabetes. See Appendix 8 for more information on the alternative medications listed above. Providers should normally utilize medications on the <i>BOP National Formulary</i> unless contraindicated. Refer to the <i>BOP National Formulary</i> for the formulary status and non-formulary use criteria for specific medications.</p> <p>** The A1C reduction listed is the anticipated decrease if the agent is used as monotherapy.</p> <p>*** STEPS 1–3: For specific recommendations, see the BOP Treatment Algorithm for Type 2 Diabetes below in this section, as well as the flow chart in Appendix 5.</p> | | | |

LIFESTYLE INTERVENTIONS

With rare exceptions, a lifestyle intervention program to increase activity levels, improve dietary choices, and promote weight loss (as indicated) should be included as part of diabetes management. Being overweight and lack of exercise are the most important modifiable risk factors for type 2 diabetes. Losing weight and increasing exercise have been shown to have a beneficial effect on controlling glycemia in both type 1 and type 2 diabetes. Unfortunately, the high rate of weight regain has limited the effectiveness of lifestyle intervention as a long-term means of controlling glycemia.

NUTRITION

Food Offerings: According to the *ADA Position Statement on Diabetes Management in Correctional Institutions*, the easiest and most cost-effective means of facilitating good nutritional outcomes in patients with diabetes is by offering heart-healthy diet options as part of the master menu. Additionally, there should be consistent carbohydrate content at each meal, and a means for inmates to identify the amount of carbohydrates in each food item. The BOP presently meets these recommendations through its heart-healthy dietary offerings.

Commissary: Commissaries are encouraged to support dietary management by offering healthy options and listing the carbohydrate content of foods. Clinicians should consider offering commissary “healthy choice” counseling to inmates when appropriate.

Nutrition Counseling and Education: Nutrition counseling for patients with diabetes is considered an essential component of diabetes self-management. People with diabetes should receive medical nutrition therapy as needed to achieve treatment goals, preferably from a

registered dietitian. Local clinicians should also provide nutrition counseling regularly as part of the diabetes treatment plan.

Nutrition education, conducted individually or in group settings, should help patients understand how their food choices, carbohydrates in particular, directly affect diabetes control. Inmates with diabetes should be counseled to eat a reduced-calorie, low-sodium, low-fat diet offered through the heart-healthy food options on the BOP National Menu. They should also strive for day-to-day consistency in the times that they eat and in the amount of carbohydrates they consume.

→ This information is available as an Inmate Handout, in [Appendix 13, Eating to Manage Your Diabetes](#), and in the BOP National Carbohydrate Counting Menu available on the Central Office Food Service Branch webpage

PHYSICAL ACTIVITY

Regular exercise can significantly improve glycemic control and contribute to weight reduction. All inmates with diabetes should be counseled on the benefits of increased physical activity, as well as the degree of exercise best suited to them. Sedentary inmates should be medically evaluated prior to undertaking aerobic physical activity that goes beyond the intensity of brisk walking. Institutions may wish to consider implementing structured exercise programs for inmates with diabetes. Ideally, aerobic exercise plans should be developed individually, based on the inmate's interests, co-morbid conditions, and physical limitations. Collaboration between Health Services and Recreation staff may improve inmate participation in physical activity.

METFORMIN

Metformin is the only biguanide available in most of the world. It reduces hepatic glucose production in the presence of insulin and reduces hyperglycemia through other poorly defined mechanisms. Metformin reduces A1C levels by 1–2%. In contrast to sulfonylureas, metformin is associated with weight loss or no weight gain, is risk-neutral for hypoglycemia, and may reduce cardiovascular risk.

- Unless contraindicated, metformin in combination with lifestyle changes is recommended as initial treatment for type 2 diabetes
 - See the treatment algorithm in [Appendix 5](#).
- Metformin can also be used in combination with insulin, sulfonylureas, glitazones, and glinides.
 - See [Appendix 7](#) for general dosing recommendations.
- Metformin therapy should be considered for patients with pre-diabetes, particularly those with BMI > 35 kg/m² and women with a history of GDM.
 - See [Table 4](#) below for recommendations for titrating metformin.

CLINICAL PRECAUTIONS FOR METFORMIN:

- 1) **Metformin should be discontinued during acute illnesses where dehydration is a significant risk or where respiratory acidosis is possible**, since metformin use in these situations may result in life-threatening lactic acidosis. Inmates with acute myocardial infarction, with septicemia, on hunger strikes, on a prolonged fast, or with any significant decrease in caloric intake are at risk of this complication.

- 2) **Metformin is not recommended for individuals with unstable or severe renal dysfunction (eGFR <30 mL/min) or for initiation of therapy when eGFR is 30 to 45 mL/min.**
- 3) **Metformin should be withheld 48 hours before and after surgery or IV contrast radiograph studies;** the inmate should be well-hydrated both before and after these procedures. Discontinue metformin at the time of or before iodinated contrast imaging procedures in patients with an eGFR between 30 to 60 mL/minute/1.73 m², in patients with a history of hepatic disease, alcoholism, or heart failure, and/or in patients who will receive intra-arterial iodinated contrast. Re-evaluate eGFR 48 hours following the imaging procedure; metformin may be reinitiated once renal function is stable.
- 4) **Metformin can cause vitamin B12 deficiency** with an associated anemia and neuropathy. The neuropathy may be misdiagnosed as a diabetic neuropathy.
 - ➔ *Patients who discontinue metformin are often switched to agents with increased risk for hypoglycemia, making continuation of metformin therapy advantageous when possible.*
 - ➔ *Metformin-associated lactic acidosis is rare, and clinicians may choose to continue metformin therapy for patients with diabetes who are well-controlled, but have creatinine levels above the threshold, closely monitoring renal function as described in **Table 3** below.*

TABLE 3. METFORMIN IN STABLE RENAL DYSFUNCTION

| eGFR (mL/min) | MAXIMUM DAILY DOSE | MONITORING |
|---------------|--------------------|---|
| >60 | 2550 mg | Monitor renal function at least annually. |
| 45 to 59 | 2000 mg | Monitor renal function at every 3 to 6 months. |
| 30 to 44 | 1000 mg | Monitor renal function every 3 months. Do NOT initiate metformin therapy, although metformin may be continued in patients already taking it. |
| <30 | Do NOT use. | N/A |

Adapted from: PL Detail-Document, Clinical Use of Metformin in Special Populations. Pharmacist's Letter/Prescriber's Letter. March 2015.

INSULIN

Insulin is the oldest of the currently available medications and, thereby, the one with the most clinical experience. Although initially developed to treat insulin-deficient type 1 diabetes, it has long been used to treat insulin-resistant type 2 diabetes. It is the most effective drug to decrease glycemia. In adequate doses, insulin can decrease any level of elevated A1C to meet a therapeutic goal.

- Unlike the other blood glucose-lowering medications, there is no maximum dose of insulin beyond which there is no therapeutic effect. To overcome the insulin resistance of type 2 diabetes and lower the A1C to goal, relatively large doses of insulin (>1 unit/kg) may be required.
- **Initial therapy is aimed at increasing basal insulin supply.** Patients may require pre-meal, regular insulin, as well.

- Insulin therapy has beneficial effects on triglyceride and HDL cholesterol levels, but is associated with weight gain of about 2–4 kg that may have an adverse effect on cardiovascular risk.
- Insulin therapy is also associated with hypoglycemia.
- See [Section 8](#) for a more thorough discussion of insulin, including conventional vs. intensive insulin therapy, as well as insulin and insulin analogue.
- See [Appendix 6a](#) for a recommended approach to insulin management in type 2 diabetes.

SULFONYLUREAS

Sulfonylureas stimulate insulin secretion and require endogenous insulin production. The various sulfonylureas have equivalent efficacy, reducing A1C by 1–1.5%. Second-generation sulfonylureas such as glipizide, glyburide, and glimepiride have more favorable side effect profiles and fewer drug interactions than first-generation sulfonylureas such as chlorpropamide, tolazamide, and tolbutamide. **Glipizide is the only formulary sulfonylurea.**

- **In patients for whom metformin is contraindicated, sulfonylureas can be prescribed as monotherapy, or they can be combined with other oral agents.** The combination of insulin and sulfonylureas may increase the risk of hypoglycemia, and caution is advised if these therapies are used concurrently. Sulfonylureas should **not** be used in combination with the non-sulfonylurea secretagogues (repaglinide and nateglinide), due to the similarity in their mechanisms of action.
- Hypoglycemia (particularly in the elderly and patients with renal insufficiency) and weight gain are the two most common adverse effects of sulfonylurea therapy. As with insulin, the weight gain may have an adverse effect on cardiovascular risk.
- All sulfonylureas are metabolized by the liver and excreted in the urine; therefore, they should be used with caution in patients who suffer from either renal or hepatic insufficiency. Glipizide has less renal toxicity than the other sulfonylureas and can be used in patients with renal insufficiency if the creatinine clearance is ≥ 10 mL/min.
- Sulfonylureas have a relatively high secondary failure rate (5–10% per year), most likely due to the gradual decline of endogenous insulin production over time. Therefore, clinicians should expect eventual loss of glycemic control with sulfonylureas and should counsel the inmate about the eventual need to add another oral agent or insulin to the treatment regimen.
- See [Appendix 7](#) for general dosing recommendations for sulfonylureas.

CLINICAL PRECAUTION FOR SULFONYLUREAS:

- 1) **Hypoglycemia caused by sulfonylureas can be prolonged or recurrent**, due to the drugs' long duration of action. Symptomatic hypoglycemia that cannot be managed with frequent feedings over a 24-hour period should be treated in a hospital setting.
- 2) **The combination of insulin and sulfonylureas may increase risk of hypoglycemia.**

THIAZOLIDINEDIONES

Thiazolidinediones (TZDs) increase the insulin sensitivity of target cells without increasing pancreatic insulin secretion, and may lower the A1C by up to 1.3%. **Pioglitazone is the only formulary TZD (see CLINICAL PRECAUTION below on rosiglitazone).**

- TZDs may cause weight gain (due to fluid retention), but do not increase the risk of hypoglycemia.
- The TZDs are associated with added benefits: slight reductions in blood pressure, increases in HDL cholesterol, and decreases in triglycerides.

CLINICAL PRECAUTION FOR TZDs:

- 1) TZDs may precipitate heart failure and peripheral edema. Initiation of TZDs in New York Heart Association Class III or IV heart failure is contraindicated, and TZDs are not recommended for use with any degree of symptomatic heart failure.
- 2) Increased risks of myocardial infarction and death have been associated with rosiglitazone.
- 3) Due to potential for drug-induced liver injury, serum liver function tests should be obtained at baseline. Liver function studies should be monitored every two months for one year, and then periodically thereafter.

→ See [Appendix 7](#) for general dosing recommendations for pioglitazone.

ALTERNATIVE MEDICATIONS

→ [Appendix 7](#) and [Appendix 8](#) provide an overview of alternative medications for treating type 2 diabetes, including dosing information. In the BOP, their use should generally only be considered under special circumstances, e.g., drug intolerance or contraindications. Reference BOP National Formulary for non-formulary use criteria where available. Some of the newer alternative therapies are described below.

DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS

The DPP-4 inhibitors reduce the breakdown of endogenous GLP-1, resulting in increased glucose-dependent insulin secretion and decreased glucagon secretion. These oral agents are better tolerated than the GLP-1 agonists, but they only reduce the A1C by about 0.7%.

- Benefits are tolerability and no risk of hypoglycemia.
- Disadvantages are limited A1C reduction, cost, and some drug-drug interactions.

GLUCAGON-LIKE PEPTIDE 1 (GLP-1) AGONISTS

The GLP-1 agonists activate receptors that enhance glucose-dependent insulin secretion, slow gastric emptying, promote satiety, and decrease hepatic glucose production. These injectable medications have a glucose-dependent mechanism of action and can decrease the A1C up to 1.5% or more.

- Benefits of GLP-1 agonists include weight reduction, reduced postprandial glucose levels and no risk of hypoglycemia.
- Disadvantages are necessity of pill line administration, high cost, and gastrointestinal side effects.

SODIUM-GLUCOSE COTRANSPORTER-2 (SGLT-2) INHIBITORS

The SGLT-2 inhibitors block glucose reabsorption in the kidney, increasing the amount of glucose excreted in the urine. These oral agents can reduce the A1C up to 1% and can be used in combination with other oral therapies.

- Benefits of SGLT-2 inhibitors are weight loss, blood pressure lowering, no risk of hypoglycemia, and efficacy at all stages of type 2 diabetes.
- Cost is a disadvantage for these therapies, and side effects include genitourinary infections, frequent urination, and dizziness/hypotension. Euglycemic ketoacidosis is also possible on these medications.

BOP TREATMENT ALGORITHM FOR TYPE 2 DIABETES

Initiation of medication is generally recommended when the A1C is ≥ 7.0 –7.5%, or above the individualized goal. Patients should be seen as necessary during titration; except in rare circumstances, hospitalization is not required to initiate or adjust therapy for type 2 diabetes.

- In order to achieve glycemic goals as soon as possible, medications should be adjusted as frequently as titration allows (i.e., as often as every 3 days for insulin and every week for metformin).
 - Until glycemic goals are achieved, the patient should be seen at least monthly to adjust medications, based on plasma/serum glucose data, and to counsel the inmate on diet and exercise.
 - The A1C should be obtained every three months until the patient has reached the individualized goal. (There is no benefit in ordering the A1C at less than three-month intervals.) An A1C above the individualized goal (usually 7–7.5%) suggests the need for further intensification of diet, exercise, and medication management.
- [Appendix 5](#), *BOP Treatment Algorithm for Type 2 Diabetes*, presents a flow chart of recommended steps in the management of type 2 diabetes.

INDICATIONS FOR USING INSULIN AS INITIAL THERAPY IN SEVERELY UNCONTROLLED DIABETES

In many cases, management of type 2 diabetes can follow Steps 1–3 described below. However, insulin therapy in combination with lifestyle interventions is the initial treatment of choice for severely uncontrolled diabetes (i.e., plasma/serum glucose levels >250 mg/dl, random glucose levels consistently >300 mg/dl, A1C $>10\%$, or the presence of ketonuria or symptomatic diabetes with polyuria, polydipsia, and weight loss). Some patients with these characteristics have unrecognized type 1 diabetes; others have type 2 diabetes with severe insulin deficiency.

Insulin can be titrated often and is the drug most likely to rapidly bring glucose down to target levels. After symptoms are relieved, oral agents can often be added, and it may be possible to withdraw insulin. In addition, patients with type 2 diabetes and significant renal or liver dysfunction often require insulin because they cannot take most oral agents.

STEP 1: USE LIFESTYLE INTERVENTION AND METFORMIN.

Throughout management of type 2 diabetes, [lifestyle intervention](#) (outlined in **Section 5** above) should be an underlying theme. However, lifestyle interventions alone rarely result in long-term achievement of glycemic goals. Therefore it is recommended that drug treatment be initiated along with lifestyle intervention at the time of type 2 diabetes diagnosis.

- **Presuming there are no contraindications, metformin is the initial drug of choice** for the following reasons: effective glycemic control, absence of weight gain, absence of hypoglycemia, low level of side effects, and high level of acceptance.
 - ➔ See box above for [indications for using insulin as initial therapy](#).
- **An eGFR should be obtained prior to initiating metformin.** Metformin is contraindicated in patients with eGFR <30 mL/min, and should not be initiated in patients with eGFR <45 mL/min. If metformin is contraindicated, then insulin, glipizide, or pioglitazone may be used as the initial therapy.
- **Titration of metformin** is used to minimize gastrointestinal side effects, as shown in **Table 4**.

TABLE 4. TITRATION OF METFORMIN

1. Begin with low-dose metformin (500 mg) once or twice daily with meals (breakfast and/or dinner).
2. After 5–7 days (if GI side effects have not occurred), advance dose to 850 or 1,000 mg before breakfast and dinner.
3. If GI side effects appear as doses are increased, decrease to previous lower dose and try to advance dose at a later time.
4. Generally, clinically significant responses are not seen at doses <1,500 mg daily. Modest improvements in effectiveness can be achieved with doses up to a maximum daily dose of 2550 mg (administered 850 mg, three times a day or other combination). GI side effects are dose-related and may limit therapy.

Adapted from: Nathan DM, Buse JB, Davidson MB, et al. Management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy. *Diabetes Care* 2006;29(8):1969.

STEP 2: ADD INSULIN, GLIPIZIDE, OR PIOGLITAZONE.

- ➔ Refer to the *National BOP Formulary* for the most current insulin, sulfonylurea, and TZD options.

If lifestyle interventions plus a maximally tolerated dose of metformin fail to achieve or sustain glycemic goals within two to three months, another medication should be added. Addition of insulin, glipizide, or pioglitazone is generally recommended. The A1C level will determine, in part, which agent should be selected next.

Insulin should be added or initiated for inmates with A1C >8.5%, or who have symptoms of hyperglycemia. Insulin is considered a fundamental tool for treating type 2 diabetes; initiation of insulin should not be delayed in patients who fail to meet glycemic goals.

- ➔ See [Appendix 6a](#) for suggested initial insulin regimens.

STEP 3: ADD OR INTENSIFY INSULIN.

If lifestyle interventions plus metformin and a second medication fail to achieve glycemic goals, the next step is to start or intensify insulin therapy. Usually, there is no benefit to prescribing three oral agents. If plasma/serum glucose and A1C goals are not met in a compliant patient on two oral agents, e.g., metformin and glipizide, the most effective next step is to add NPH insulin. Intensification of insulin therapy usually consists of additional injections, often including regular insulin prior to selected meals to reduce postprandial glucose excursions.

- ➔ In general, once insulin has been started, sulfonylureas are discontinued due to concern for sustained, severe hypoglycemia.

RATIONALE IN SELECTING SPECIFIC COMBINATIONS

- **The majority of patients with type 2 diabetes will require multiple medications over time.** This is because patients with type 2 diabetes have both insulin resistance at the tissue level and declining pancreatic insulin production.
 - **The first-line oral agents utilized within the BOP are metformin, glipizide, and pioglitazone.** If these oral agents are contraindicated or not tolerated, the use of other oral antihyperglycemic agents should be considered on a case-by-case basis. Consult the *National BOP Formulary* for non-formulary use criteria.
 - ▶ **Drug selection should be based on** glucose-lowering effectiveness, mechanism of action, side effect profile, and other factors that may reduce diabetes complications, e.g., weight loss or improvement in lipid profile.
 - ▶ **When adding antihyperglycemic medications,** the synergy of particular combinations and other interactions should be considered. As a rule, antihyperglycemic drugs with different mechanisms of action will have the greatest synergy.
- See [Appendix 7](#) for more information on oral agents used in treating type 2 diabetes.

6. TREATMENT OF TYPE 1 DIABETES

Patients with type 1 diabetes generally present with acute diabetes symptoms, as well as significantly elevated blood glucose levels. Given the acute onset of symptoms, type 1 diabetes is usually detected soon after symptoms develop.

→ *Treatment goals for type 1 diabetes are the same as those for type 2 (see [Appendix 3](#)).*

Insulin therapy is the cornerstone of medication management, and oral antihyperglycemic agents are not indicated in patients with type 1 diabetes. Furthermore, it has been clearly demonstrated that intensive insulin therapy results in improved glycemic control and reduction in diabetes-related complications (including nephropathy, retinopathy, neuropathy, and cardiovascular morbidity and mortality.)

→ *For information on intensive insulin therapy, see **Section 7** below.*

7. INSULIN

INSULIN AND INSULIN ANALOGUES

The recent introduction of insulin analogues has expanded options for management of diabetes. The long-acting and rapid-acting insulin analogues are reviewed below.

- **LONG-ACTING INSULINS** (insulin glargine and insulin detemir) are frequently utilized in the community (i.e., outside the correctional setting) in place of intermediate-acting insulin (NPH).
 - ▶ **Insulin glargine (Lantus)** has virtually no peak and can often be administered once daily. A disadvantage of insulin glargine is that it cannot be mixed with other insulins and thus requires a separate injection.

- ▶ **Insulin detemir** has a shorter duration of action than that of insulin glargine, but longer than that of NPH. Detemir is generally administered twice daily.

Studies comparing glargine and detemir with NPH have shown that the two longer-acting agents have no superiority over NPH in terms of glycemic control; A1C values are no lower with long-acting insulins than they are with NPH insulin. It is important to note that evening doses of NPH insulin should be given at bedtime or as close to bedtime as feasible.

- **RAPID-ACTING INSULINS** are often utilized in the community in place of short-acting (regular) insulin.
 - ➔ ***In general, rapid-acting insulin is not utilized in the BOP. If used, rapid acting insulins must be carefully timed to avoid the risk of hypoglycemia.***
 - ▶ The advantages of rapid-acting insulin over regular insulin include a reduction in the postprandial rise in blood glucose concentration and modest reductions in hypoglycemia. Rapid-acting insulin can be especially useful in situations where unexpectedly high blood glucose levels are encountered, i.e., in stressful situations or between meals, because it quickly lowers glucose levels without a prolonged effect.
 - ▶ Rapid-acting insulin must be injected immediately before or after meals (a potential advantage in the community, but a disadvantage in the correctional setting).
 - ▶ It may be necessary to increase the dose of basal insulin when a patient is switched from regular to rapid-acting insulin.

Recognizing that many inmates with diabetes may have used insulin analogues prior to incarceration, the action profiles of commonly utilized insulin analogues are outlined in Table 5.

TABLE 5. ONSET AND PEAK OF COMMONLY USED INSULIN PREPARATIONS

| Insulin or Insulin Analogue | Action Profile | |
|---|----------------|--|
| | Onset | Peak |
| ULTRA-RAPID-ACTING | | |
| Insulin lispro (Humalog) | 10–20 min | 30 min–90 min |
| Insulin aspart (Novolog) | 10–20 min | 30 min–90 min |
| Insulin glulisine (Apidra) | 10–20 min | 30 min–90 min |
| Inhaled Insulin (Afrezza) | 10–20 min | 12 min–15 min |
| SHORT-ACTING | | |
| Regular (human) Humulin R/Novolin R | 30 min–1 hr | 2–4 hrs |
| INTERMEDIATE-ACTING | | |
| NPH (human) Humulin N/Novolin N | 1–3 hrs | 4–10 hrs (~8 hrs) |
| LONG-ACTING | | |
| Insulin glargine (Lantus) | 1–3 hrs | No peak, ~24hr duration |
| Insulin detemir (Levemir) | 1–3 hrs | 9 hrs–unknown |
| Insulin degludec | 1–2 hrs | No peak, 42+ hr duration |
| ULTRA-CONCENTRATED | | |
| U-500 Regular Insulin | <30 minutes | 4–8 hrs |
| U-300 Insulin glargine (Toujeo) | ~6 hours | No peak, maximum effect seen at 5 days therapy |
| Source: McCulloch, DK. Insulin therapy in type 2 diabetes mellitus. In: <i>UpToDate</i> , Nathan DM (Ed), UpToDate, Waltham, MA. | | |

INTENSIVE VS. CONVENTIONAL INSULIN THERAPY

➔ When NPH is used as part of either a conventional or an intensive insulin regimen, evening doses should be administered at bedtime or as close to bedtime as feasible.

CONVENTIONAL INSULIN THERAPY involves single daily injections, or two injections per day—usually twice-daily administration of a combination of short-acting (regular) and intermediate-acting (NPH) insulins.

INTENSIVE INSULIN THERAPY describes treatment with three or more insulin injections per day, including basal and pre-meal. Intensive insulin therapy aims to provide a more physiologic profile of insulin. **Intensive insulin therapy—either as a multiple-dose insulin regimen or by means of an insulin pump—is recommended for patients with type 1 diabetes and some patients with type 2 diabetes.**

Intensive therapy can also be accomplished with continuous infusion of insulin via a pump. See **Table 6** for examples of non-continuous, intensive insulin therapy regimens.

TABLE 6. EXAMPLES OF INTENSIVE (MULTIPLE-DOSE) INSULIN THERAPY REGIMENS

| Regimen | Pre-Breakfast | Pre-Lunch | Pre-Dinner | Pre-Bedtime |
|---------|----------------|-----------|------------|-------------|
| 1 | Reg | Reg | Reg | NPH |
| 2 | Reg + NPH | — | Reg | NPH |
| 3 | Reg + Glargine | Reg | Reg | — |
| 4 | Reg | Reg | Reg | Glargine |

Although research findings strongly support the use of intensive insulin therapy, there are associated drawbacks:

- Greater effort is required on the part of the inmate to coordinate diet, activity, insulin administration, and glucose monitoring.
- Greater effort is required to assure that insulin and mealtimes are coordinated.
- There is up to a three-fold increase in the incidence of hypoglycemia (a significant concern for correctional facilities).
- Weight gain is more likely, sometimes limiting patient compliance.

SLIDING SCALE INSULIN THERAPY refers to the use of varying doses of regular insulin in response to hyperglycemia. Sliding scale insulin therapy is not a recommended strategy for long-term management of patients with diabetes.

➔ See [Appendix 6b](#) for information on replacing sliding scale insulin therapy for inmates in long-term care situations.

DESIGNING A MULTIPLE-DOSE INSULIN REGIMEN FOR NEW TYPE 1 PATIENTS

Patients who are newly diagnosed with type 1 diabetes ordinarily can be started on a total daily dose of 0.2 to 0.4 units of insulin per kg per day; most will eventually require 0.6 to 0.7 units per kg per day.

Initially, the total daily dose should be composed as follows:

- **NPH: Approximately half the total dose should be NPH insulin, administered twice daily.** In general, two-thirds of the total NPH dose should be given in the morning and one-third at bedtime (or as close to bedtime as feasible).
- **REGULAR: The other half of the total daily insulin dose should usually consist of pre-meal, regular insulin.** The dosing of pre-meal insulin is based upon the usual meal size and calorie count. Nutritional consistency is critical for maintaining adequate glycemic control.
 - ➔ *When NPH insulin is utilized as part of the regimen, a pre-lunch bolus of regular insulin may not be necessary.*

CLINICAL PRECAUTION FOR MULTIPLE-DOSE INSULIN REGIMENS:

- 1) **A disadvantage of insulin glargine (Lantus)** is that it cannot be mixed with any other insulins.
- 2) **Fixed-dose insulin combinations (e.g., 70/30 insulin preparations)** are generally not suitable for insulin-dependent patients who need to achieve target A1C levels. Fixed-dose insulin formulations are not flexible enough to match changes in caloric intake with appropriate doses of short-acting and long-acting insulin.
- 3) **For patients with type 1 diabetes, and any patients with type 2 diabetes who require short-acting insulin,** a process must be in place to ensure that patients have access to glucose monitoring on an as-needed basis in order to achieve optimal control and to avoid hypoglycemia.
- 4) **Rapid-acting insulin should be avoided in most circumstances;** the benefit versus risk of using these agents within the correctional environment needs to be carefully assessed and appropriately justified on a case-by-case basis. Anything that keeps the inmate from eating within 20–30 minutes after a rapid-acting insulin injection is very likely to induce symptomatic hypoglycemia.
 - ➔ *If the rapid- or short-acting insulin dose is not high enough to cause at least some symptoms of hypoglycemia in the absence of food, then it is also not high enough to provide adequate glucose control.*

INSULIN ADMINISTRATION

Inmates who require insulin should be educated on the appropriate and safe administration of insulin:

- **ADMINISTRATION:** Directly observed self-administration of insulin is recommended whenever feasible. Insulin should be administered subcutaneously at a 45-to-90 degree angle at a clean injection site, using clean hands. Absorption is fastest from injections into the abdominal wall (>2 inches from the umbilicus), making this site preferable for pre-meal (regular) insulin therapy. Injections into the leg or buttock result in slower absorption and are thereby

appropriate for the evening dose of intermediate-acting (NPH) insulin. Rotating injection sites is recommended to prevent lipodystrophy.

→ See [Appendix 6c](#) for a visual reference.

- **PROCEDURE FOR MIXING REGULAR AND NPH INSULIN:** Regular insulin should be drawn up first, followed by the NPH (being careful not to inject the regular insulin into the NPH vial). Administer the mixture of regular/NPH insulin within 15 minutes of drawing them up.
- **INFECTION CONTROL ISSUES: Insulin syringes should be used only once; they should never be used on more than one patient or reused in the same patient.** Infection control procedures should be established to prevent the recapping of insulin needles following injection, or the handling of contaminated syringes by other inmates or health care providers. Used insulin syringes should be promptly disposed of in puncture-resistant containers. Measures should be taken to avoid contamination of insulin solution when using multi-dose vials. Individual (single-person) use of multi-dose vials can be considered when inmates are permitted to draw up their own insulin. Multi-dose vials should be discarded if their sterility has been compromised.
→ See a more complete list of infection control recommendations outlined in [Appendix 9](#).
- **INSULIN PUMPS are rarely necessary for patients with type 2 diabetes.** Newly incarcerated patients with type 1 diabetes who are already on insulin pumps should usually be maintained on the pump. A physician with expertise in treating diabetes should be consulted before initiating long-term use of an insulin pump.
- **INHALED INSULIN (Afrezza)** was approved by the FDA in 2014 as an alternative to subcutaneous rapid-acting insulin. The clinical indications are being evaluated. Inhaled insulin is not indicated as a first-line treatment, given its higher cost, constraints in dosage flexibility, questionable efficacy in achieving tight glycemic control, and concerns for sudden bronchospasm in patients with asthma, COPD, or chronic lung disease.

COORDINATION OF INSULIN AND FOOD INTAKE IN THE CORRECTIONAL SETTING

The correctional environment poses challenges for coordinating insulin administration with food intake, particularly for inmates on short-acting (regular) insulin. The consequences of insulin/food mismatch are, at best, suboptimal control of hyperglycemia; at worst, the result of insulin/food mismatch is frequent and potentially severe hypoglycemic episodes. Because of the many factors in a correctional environment that can interfere with the optimal timing of insulin and food, the insulin regimen should be as “forgiving” as possible. The shorter the onset and peak of the insulin, the more critical it is to coordinate food intake with insulin administration.

→ *Consequently, rapid-acting insulin is generally not utilized within the BOP.*

TIMING OF SHORT-ACTING (REGULAR) INSULIN: Short-acting insulin is typically administered two-to-three times per day; ideally, it should be administered prior to a meal to allow some absorption of insulin prior to the rise in blood glucose that occurs during a meal.

However, if the timing of meals is uncertain, regular insulin can be administered immediately after eating (rather than before). Although the inmate will have a short period of postprandial hyperglycemia, this approach causes fewer long-term consequences and good diabetic control can still be achieved.

PLANNING FOR INSULIN/FOOD COORDINATION: Institutions should consider developing local processes to ensure that insulin dosing is timed appropriately and that the proper precautions have been implemented should dosing times be interrupted.

Consider these questions when planning for optimal insulin/food coordination in BOP facilities:

- Is the pill line open during the entire meal period to administer insulin? Depending on the size of the dining hall, the size of the inmate population, and the type of meal being served, it may take anywhere from one-to-three hours to serve a meal.
- Do inmates have free movement to go to the pill line before they go to the dining hall?
- If insulin is given prior to a meal, and then an institution recall occurs (lockdown, emergency count, fog line, severe weather incident, etc.), would the recall prevent inmates from eating?
- How quickly could a sack lunch or snack be provided to inmates who had received their insulin, but were then prevented from eating their usual meal?
- Are correctional staff trained to appropriately identify and respond to hypoglycemic episodes in insulin-dependent inmates?

DIABETIC SNACKS: In most patients with diabetes, the use of diabetic snacks is not routinely recommended or required; patients may be overweight/obese and/or have uncontrolled glucose levels or hypertension—thereby not in need of additional calories, carbohydrates, or sodium.

- **Short-term issues:** However, initiation or adjustment of insulin or oral medication may lead to short-term issues with hypoglycemia and necessitate the need for a **temporary** diabetic snack in order to avoid hypoglycemia. After patients have been monitored, and insulin or medication adjustments have been made to avoid hypoglycemia, diabetic snacks should be discontinued.
 - **Long-term orders:** In isolated cases of chronic documented issues of hypoglycemia, long-term orders for diabetic snacks may be indicated. These snacks are a part of the medical treatment plans for these patients and should be prescribed by medical staff **only as needed, on an individual basis**—and after assessment, counseling, and education have been conducted by a registered dietitian at all non-MRCs. According to the *Food Service Manual*, the preferred diabetic snack is one cup of skim milk and one serving of non-sugar-coated dry cereal.
- *Additional information on diabetic snacks, including alternative snacks, can be found in the Food Service Manual.*

8. BLOOD GLUCOSE MONITORING

- ★ **For up-to-date recommendations on blood glucose monitoring**, refer to the latest ADA guidance at http://care.diabetesjournals.org/content/40/Supplement_1

In the correctional setting, the methods and frequency of glucose monitoring must be determined with consideration of the institution's security concerns, as well as the relevant patient factors.

- While both self-monitored blood glucose checks and those at Health Services permit adequate monitoring of blood or plasma/serum glucose in inmates with diabetes, self-monitoring of blood glucose (SMBG) is the preferred method for assessing day-to-day glycemic control for inmates with **type 1 diabetes**.
- Glucose monitoring via SMBG is also considered appropriate for most inmates with **type 2 diabetes who require insulin**. However, in such cases, SMBG has not been shown to improve clinically significant outcomes or quality of life, and it is unclear whether it improves glycemic control.

Glucometers should be provided to inmates in accordance with the periodic guidance from the Medical Director that addresses security, logistical, and infection control concerns. **In addition, the following criteria should be used to determine if an inmate should be issued a glucometer:**

- The inmate requires insulin on a chronic basis.
 - The inmate has arrived at his or her designated facility.
 - The inmate is highly motivated to monitor his or her blood glucose values.
 - The inmate has no cognitive or sensory impairments that would prevent accurate and safe self-monitoring.
- ➔ *Periodic finger sticks at Health Services are still recommended so that reliable data can be collected to monitor the patient's response to treatment.*

INFECTION CONTROL: Outbreaks of hepatitis B have been reported related to sharing of finger stick devices and glucose monitors. Finger stick devices must be issued for individual use only. Glucometers generally should be issued for individual use, as well. However, if a glucometer must be used by more than one patient, it should be cleaned and disinfected after each use.

- ➔ *See infection control recommendations outlined in [Appendix 9](#).*

9. GESTATIONAL DIABETES MELLITUS (GDM)

DETECTION AND DIAGNOSIS OF GDM

- **GDM RISK FACTORS:** All pregnant inmates should be assessed for GDM risk factors at the first prenatal visit.
 - ▶ Ethnicity with high prevalence of diabetes (African-American, Native American, Southeast Asian, or Pacific Islander).
 - ▶ Pre-pregnancy weight in the obese range (BMI > 30 kg/m²), or significant or excessive weight gain as an adult.
 - ▶ Personal history of GDM, IFG, or IGT.

- ▶ Medical conditions associated with diabetes or insulin resistance (glucocorticoid treatment, hypertension, metabolic syndrome, polycystic ovary syndrome).
 - ▶ Factors related to the current pregnancy (age > 25 years, glycosuria at first prenatal visit, multiple gestation).
 - ▶ Family history of diabetes in a first-degree relative.
- **SCREENING FOR GDM:** Because more than 90% of all pregnant women have at least one risk factor for GDM, universal screening for GDM is recommended between 24 and 28 weeks of gestation in asymptomatic pregnant women with no current diagnosis of diabetes.
 - ➔ See **Tables 7 and 8** below.
 - **SCREENING FOR PRE-EXISTING DIABETES:** Data do not support earlier screening for GDM, but screening for pre-existing diabetes using standard criteria and screening tests is recommended at the first prenatal visit.
 - ➔ See **Table 7** below.

TABLE 7. DIABETES SCREENING RECOMMENDATIONS DURING PREGNANCY

| SCREENING RECOMMENDATIONS FOR ALL PREGNANT WOMEN | |
|--|---|
| AT FIRST PRENATAL VISIT | AT 24–28 WEEKS GESTATION |
| <ul style="list-style-type: none"> • Test for Pre-Existing Diabetes: Use the same screening criteria and tests used for non-pregnant patients. ➔ See Section 3, <i>Screening for Type 2 Diabetes</i>. • Assess for <i>GDM Risk Factors</i>. Regardless of risk factors, universal screening for GDM is recommended at 24–28 weeks. | <ul style="list-style-type: none"> • Test for GDM: Perform one-step test (75-gm OGTT) or two-step test (50-gm OGTT, followed by 100-gm OGTT if 50-gm test is abnormal) for women not diagnosed with diabetes earlier in the pregnancy. ➔ See Table 8 below for diagnostic criteria. |

TABLE 8. GDM DIAGNOSTIC CRITERIA

| 75-GRAM OGTT* | 100-GRAM OGTT* |
|---|---|
| <ul style="list-style-type: none"> > 92 mg/dl fasting > 180 mg/dl at 1 hour > 153 mg/dl at 2 hours | <ul style="list-style-type: none"> > 95 mg/dl fasting > 180 mg/dl at 1 hour > 155 mg/dl at 2 hours > 140 mg/dl at 3 hours |
| <p>* Two or more of the plasma/serum glucose values must be exceeded for a positive diagnosis. Repeat testing is not necessary for diagnosis.</p> | |

POTENTIAL COMPLICATIONS OF GDM

It is crucial that women with GDM be monitored closely because the fetuses of mothers with hyperglycemia are at greater risk for intrauterine death or neonatal mortality. GDM is also associated with fetal macrosomia, as well as neonatal hypoglycemia, hypocalcemia, polycythemia, and hyperbilirubinemia.

MONITORING AND TREATMENT OF GDM DURING PREGNANCY

The following guidelines should be considered when managing inmates with GDM:

- Close surveillance of the mother and fetus must be maintained throughout the pregnancy. Self-monitoring of blood glucose should be done on a frequent (daily) basis. Use of postprandial monitoring is preferred.
 - ➔ *Monitoring of urinary glucose is not an adequate measure.*
- Screening for hypertension should include measurement of blood pressure and urine protein.
- Clinical estimation of fetal size and asymmetric growth via serial ultrasounds—especially early in the third trimester—may identify large infants who would benefit from maternal insulin therapy.
- All inmates with GDM should receive dietary counseling and be provided with adequate calories and nutrients during pregnancy.
- Metformin or insulin therapy should be considered if dietary management does not result in:
 - ▶ Fasting whole blood glucose ≤ 95 mg/dL **OR** fasting plasma/serum glucose ≤ 105 mg/dL
 - AND**
 - ▶ Two-hour postprandial whole blood glucose ≤ 120 mg/dL **OR** two-hour postprandial plasma/serum glucose ≤ 130 mg/dL.
- Oral antihyperglycemic agents other than metformin may be considered as alternatives to insulin or metformin on a case-by-case basis, but only after careful consultation with an obstetrician; their efficacy and safety are still being investigated.
- Breast feeding may improve maternal glucose levels, but a long-term reduction in incidence of type 2 diabetes has not been proven conclusively. Challenges inherent to the correctional environment may make breast feeding infeasible, but it should be encouraged in women with GDM when it is authorized.
- Whenever possible, care should be coordinated with an obstetrician experienced in the treatment of women with GDM.

POSTPARTUM MONITORING

- Women with GDM are at an increased risk for developing diabetes later in life and should be educated on the importance of maintaining normal body weight, good nutrition, and physical activity. Inmates should be taught to recognize symptoms of hyperglycemia so that they readily seek medical attention at the onset of diabetes.
 - ➔ *A 75-gram OGTT is recommended 4 to 12 weeks after delivery.*
- Inmates with IFG or IGT (“pre-diabetes”) should be screened annually for diabetes with a fasting plasma/serum glucose test; at that time, they should also be counseled regarding diet and a plan for aerobic exercise or increased physical activity. Metformin therapy should be considered in patients with pre-diabetes.
- If postpartum glucose levels are normal, a fasting plasma/serum glucose screening should be obtained every three years in asymptomatic inmates.

10. MEDICAL MANAGEMENT OF DIABETIC COMPLICATIONS

Ongoing research continues to shape recommendations for the treatment of co-morbidities and complications of diabetes.

- ★ **For up-to-date information on management of diabetic complications**, refer to the ADA website at http://care.diabetesjournals.org/content/40/Supplement_1.

HYPERTENSION

Patients with diabetes and hypertension should have their blood pressure (BP) lowered to targeted levels, since serious microvascular and macrovascular diabetic complications are strongly linked to hypertension.

- **The treatment goal for non-pregnant patients with diabetes over age 18 is a systolic BP of <140 and a diastolic <90 mmHg**, although some patients may be safely treated to a BP of 130/80 mmHg. The optimal treatment goals for non-pregnant patients with diabetes continue to be investigated.
- **Patients with a systolic BP >140 or a diastolic BP >90 mmHg should receive drug therapy in addition to recommended lifestyle interventions.** All patients with diabetes and hypertension should ordinarily be treated with an ACE inhibitor **or** an Angiotensin II receptor blocker (ARB), **but not both**. If one class is not tolerated, the other should be substituted. Multiple drug therapy is often required to achieve blood pressure goals. ACE inhibitor therapy may also be considered for inmates with diabetes who have other cardiovascular risk factors, with or without hypertension.

DYSLIPIDEMIA

Clinical trials have demonstrated significant benefits of statin use in patients with diabetes, without regard for specific LDL goals; this evidence has resulted in new recommendations for the treatment of dyslipidemia in diabetic patients.

- **All patients with diabetes and overt cardiovascular disease** (previous cardiovascular events or Acute Coronary Syndrome) should be treated with a high-intensity statin and lifestyle changes.
- **For all patients with diabetes aged 40–75 years** without cardiovascular risk factors, a moderate-intensity statin is recommended; those in the same age group, with additional cardiovascular risk factors, should be considered for high-intensity statin therapy.
- **In patients who are less than 40 or greater than 75 years of age** with diabetes and additional cardiovascular risk factors, consider using a moderate- or high-intensity statin. Clinicians may choose to monitor individual patient response and adjust statin therapy based on patient response, but it is not necessary to treat to a specific LDL level.

CARDIOVASCULAR EVENTS: ASPIRIN THERAPY AS INTERVENTION

Clinical trials have demonstrated that aspirin therapy is a cheap and effective intervention for preventing serious cardiovascular events such as myocardial infarctions and stroke among people with diabetes.

The following recommendations are adapted from the ADA's 2017 Standards of Medical Care in Diabetes, Summary of Revisions (see [References](#)):

HIGH-RISK PATIENTS: Consider aspirin therapy with enteric coated aspirin (75–162 mg/day) as a **primary prevention** strategy in patients with type 1 or type 2 diabetes who are at increased cardiovascular risk (10-year risk >10%). This includes men and women ≥ 50 years of age who have at least one additional major risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). Use aspirin therapy (75–162 mg/day) as a **secondary prevention** strategy in patients with diabetes who also have a history of CVD.

- ▶ The **USPSTF** has similar recommendations on aspirin for primary prevention in persons 50 to 59 years old, but recommends more individualized decisions for those 60 to 69 years old. There is insufficient evidence to make recommendations for those younger than 50, or 70 years old or older.
- ▶ **Other antiplatelet agents** may offer reasonable alternatives for patients who are high-risk, but have conditions that contraindicate aspirin therapy such as an aspirin allergy, undergoing anticoagulant therapy, a bleeding tendency, recent gastrointestinal bleeding, or clinically active hepatic disease. For patients with CVD and documented aspirin allergy, clopidogrel (75 mg/day) should be used.
- ▶ **Combination therapy** with aspirin (75–162 mg/day) and clopidogrel (75 mg/day) is reasonable for up to a year after an acute coronary syndrome.
- **LOW-RISK PATIENTS:** There is not sufficient evidence to recommend aspirin for primary prevention in lower-risk individuals, such as patients <50 years of age who do not have other major risk factors. For patients in these age-groups who have multiple other risk factors, clinical judgment is required.

CLINICAL PRECAUTION FOR ASPIRIN THERAPY:

Do not routinely use aspirin in inmates <21 years of age, due to the increased risk of Reye's syndrome.

DIABETIC NEPHROPATHY

Microalbuminuria (30–300 mg/24 hour), the earliest stage of kidney disease associated with diabetes, often progresses to clinical albuminuria (>300 mg/24 hours), with a subsequent decline in renal function over a period of years. Hypertension usually develops during the onset of microalbuminuria and, if left untreated, can hasten the progression of renal disease.

Prevention and treatment recommendations for diabetic nephropathy include:

- **Maximize glycemic control** to delay onset of microalbuminuria.
- **Annually screen for microalbuminuria** in all inmates with type 2 diabetes, in inmates with type 1 diabetes (beginning five years after diagnosis), and in those with GDM. The recommended method for screening for microalbuminuria in the BOP is by measurement of

the albumin-to-creatinine ratio in a random spot collection. Clinical microalbuminuria is defined as the occurrence of elevated albumin-to-creatinine ratio for two of three tests within a six-month period. Measurement of spot urine for albumin only is **not** recommended.

- **Measure serum creatinine annually to calculate a glomerular filtration rate (GFR).** Serum creatinine alone is not an adequate measure of kidney function. Studies have found a decreased GFR in the absence of increased urine albumin excretion in a substantial percentage of adults with diabetes.
 - ▶ **All inmates with diabetes should have a GFR calculated at baseline and annually.** The GFR can be calculated utilizing an internet calculator from the National Kidney Foundation: http://www.kidney.org/professionals/kdoqi/gfr_calculator.cfm.
 - ▶ **The stages of chronic kidney disease based on GFR are outlined in Table 9 below.** A nephrologist should be consulted if the GFR is <30 mL/min per 1.73 m².

TABLE 9. STAGES OF CHRONIC KIDNEY DISEASE

| STAGE | DESCRIPTION | GFR (mL/min/1.73 m ²) |
|-------|---|-----------------------------------|
| 1 | Kidney damage with normal or elevated GFR | ≥90 |
| 2 | Kidney damage with mildly decreased GFR | 60–89 |
| 3 | Moderately decreased GFR | 30–59 |
| 4 | Severely decreased GFR | 15–29 |
| 5 | Kidney failure | <15 (or dialysis) |

KIDNEY DAMAGE is defined as pathologic abnormalities or markers of damage, including abnormalities in the composition of blood or urine tests, or abnormalities in imaging tests.

CHRONIC KIDNEY DISEASE is defined as either kidney damage or GFR <60 mL/min/1.73 m² for 3 months or more.

- **Regardless of blood pressure status, treat patients with diabetes and microalbuminuria with ACE inhibitors** (unless medically contraindicated). An ARB should be considered if ACE inhibitors cannot be tolerated or are contraindicated. Monitor for hyperkalemia and test renal function 7 to 10 days after starting treatment.
- **Lower blood pressure to <140/90 mmHg**, using multi-drug therapy if necessary. In patients with albuminuria, consider blood pressure target of <130/80 mmHg.
- **Restrict protein intake for inmates with diabetes at the onset of nephropathy.**
- **Avoid metformin in patients with reduced creatinine clearance or unstable renal dysfunction** (creatinine clearance <30 mL/min, reduced doses <60 mL/min), and do not start metformin when eGFR is 30 to 45 because of increased risk of lactic acidosis.

DIABETIC RETINOPATHY

Patients with type 1 diabetes do not usually have vision-threatening retinopathy in the first five years of their disease. Over the next 20 years, however, nearly all patients with type 1 diabetes develop some retinopathy. A significant percentage of patients with type 2 diabetes have retinopathy at the time of diagnosis, and many will develop some degree of retinopathy over subsequent years.

Retinopathy progresses in a predictable manner, advancing from mild background abnormalities to pre-proliferative retinopathy, and then to proliferative retinopathy. Vision loss occurs when macular edema or capillary non-perfusion cause the loss of central vision, or when proliferative retinopathy leads to retinal detachment and irreversible vision loss. The proliferative vessels may also bleed, leading to pre-retinal or vitreous hemorrhage.

Prevention and treatment recommendations for diabetic retinopathy include the following:

- **Maximize glycemic control**, which reduces the risk of progression to clinically significant retinopathy.
- **Maximize blood pressure control.**
- **Provide annual funduscopy eye exams.** Screen all patients with diabetes for retinopathy, since proliferative retinopathy and macular edema may occur in completely asymptomatic patients.
- **Monitor pregnant patients with diabetes closely**, since pregnancy may aggravate retinopathy.
- **Continue aspirin therapy.** It neither prevents retinopathy nor increases the risk of retinal hemorrhage.
- **Refer patients with retinopathy for laser photocoagulation surgery when indicated.** Photocoagulation reduces the risk of further vision loss in patients with retinopathy, but does not ordinarily reverse established vision loss.

DIABETIC NEUROPATHY

Peripheral diabetic neuropathy may result in pain, loss of sensation, and muscle weakness. Autonomic diabetic neuropathy may affect the gastrointestinal, cardiovascular, and genitourinary systems. Diabetic neuropathy is treated by maximizing glycemic control and addressing the related symptoms.

PAIN: Pain related to diabetic neuropathy can be treated with first line agents, tricyclic amines (nortriptyline or desipramine) and SNRIs (venlafaxine and duloxetine). Second line agents are antiepileptic drug (AED) sodium channel blockers like oxcarbazepine, and third line agents are AED calcium channel blockers (gabapentin) or newer agents such as pregabalin.

- Opioid therapy is **not** recommended for the treatment of diabetic neuropathies.
- NSAIDs are generally **not** recommended due to potential for acute kidney injury.
- Caution should be exercised when prescribing multiple medications affecting serotonin; due to the risks of serotonin syndrome and therapeutic duplication, combining SSRIs and SNRIs should be avoided.

SENSORY LOSS AND OTHER SYMPTOMS OF DIABETIC NEUROPATHY: Although the pain associated with diabetic neuropathy can be relieved with pharmacologic intervention, other neuropathic symptoms such as sensory loss are generally permanent and not alleviated by medication.

- **Foot ulcers and amputations are complications of diabetes that are frequently related to neuropathy.** The risk of amputation is associated with the following conditions: peripheral neuropathy with a loss of sensation, evidence of increased pressure (erythema, hemorrhage under a callus), peripheral vascular disease (absent distal pulses), severe nail disease, and a history of foot ulcers.

- **Screening for diabetic neuropathy should include monofilament testing** at least annually upon making a diagnosis of type 2 diabetes, or five years after the diagnosis of type 1 diabetes. For a thorough description of how to conduct a diabetes foot screen, including monofilament testing and LEAP categories, consult the following website: Department of Health and Human Services, Health Resources and Services Administration, Lower Extremity Amputation Prevention (LEAP) Program at <http://www.hrsa.gov/leap/>.
- **Footwear recommendations for inmates with diabetes should consider the following:**
 - ▶ The current version of the BOP standard-issue work shoe addresses most concerns of inmates without diabetes, as well as inmates with diabetes who are Category 0 or 1 based on the LEAP diabetic foot screen.
 - ▶ The institution is required to provide an inmate with a properly fitting work shoe. Tennis shoes and other recreational footwear are solely the responsibility of the inmate.
 - ▶ **Inmates with diabetes shall receive a foot screen in accordance with the LEAP screening form, and are categorized into category levels 0–3, based on the exam:**
 - **CATEGORY 0** patients have full protective sensation as determined by a five-gram monofilament. In the absence of other risk factors, category 0 patients may be issued a standard-issue work shoe.
 - **CATEGORY 1** patients have lost part or all of their protective sensation and have no other complicating factors. Category 1 patients may be issued a standard-issue work shoe.
 - **CATEGORY 2** patients have loss of protective sensation, in addition to other factors leading to greater risk of foot ulceration such as peripheral artery disease, poor circulation, foot deformities, or impaired vision. Category 2 patients should be issued an extra-depth diabetic shoe.
 - **CATEGORY 3** patients have all the risk factors associated with category 2, as well as a previous history of neuropathic ulceration, neuropathic fracture (Charcot foot), or amputation. Category 3 patients should be issued an extra-depth diabetic shoe unless the risk of ulceration cannot be adequately managed with a standard extra-depth diabetic shoe. In this case, custom or semi-custom orthotics/shoes may be considered to help manage the higher risk for these patients.

ORAL HEALTH AND DIABETES

Patients with diabetes are at greater risk of developing oral health problems. The most common oral health problems associated with diabetes are gum disease, fungal infections, infection, salivary gland dysfunction, tooth decay, inflammatory conditions, and delayed healing. **Clinical collaboration between medical providers and dental providers is an important component of successful treatment of patients with diabetes.** Just as patients are advised about retinopathy, neuropathy, nephropathy, macrovascular disease, and altered wound healing, they need to be made aware of the oral health complications (periodontal disease) associated with diabetes. Diabetes care providers should determine if patients are experiencing symptoms of periodontal disease or other oral health complications and refer them to the oral health care team. Long-term treatment often includes patient education, routine hygiene appointments, and antibiotic therapy. It is important that patients with diabetes be strongly encouraged to maintain excellent oral hygiene and seek preventive dental treatment. **In addition to preventive care, patients should be encouraged to seek dental treatment for bleeding, swelling, burning mouth, decayed teeth, and white patches.**

DIABETIC PERIODONTITIS

Periodontal disease is a very common oral health complication associated with diabetes, with research suggesting that periodontal disease is more frequent and severe in patients with diabetes. An infective and inflammatory disease such as periodontitis can have pronounced adverse effects for individuals with diabetes, due to patient's altered immune system and reparative processes.

In periodontal disease, biofilms containing gram-negative anaerobes initiate an immune response that results in the local and systemic release of a cascade of mediators and factors. An oral evaluation may reveal the periodontium (teeth and supporting gums and bone) as a possible focus of infection and a contributing factor in poor glycemic control. Healthcare providers should examine the oral cavity for **cardinal signs** of overt periodontal disease (see **Table 10** below). Incipient changes to gingival tissue may present as gingivitis (gum inflammation). Advanced periodontitis will present as gum inflammation, bone loss, and tooth mobility.

TABLE 10. CARDINAL SIGNS OF PERIODONTITIS

| | | |
|---|--|--|
| 1 | Bleeding gums | Patients report frequent bleeding, even though they brush and floss consistently; the bleeding is related to inflammatory changes in the gums. |
| 2 | Red swollen gums | Gums are inflamed, and may be stippled. (Healthy gum tissue is pink and well-adapted to the underlying osseous architecture.) |
| 3 | Gums that have pulled away from the teeth | Root surfaces are exposed, giving the appearance that the teeth are actually longer. |
| 4 | Infection or abscesses | Exudate (pus) can be expressed at the gingival crevice by slightly pressing on the tissue. |
| 5 | Fetid odor | Bad breath often accompanies active oral infection. |
| 6 | Mobile teeth | Teeth are loose. Patients also may complain of gaps and spaces, which have resulted from bone loss and the teeth moving away from each other. |
| 7 | Occlusal changes | Patients complain that their bite has changed, a result of bone loss and inflammatory changes. |
| 8 | Changes in the fit of prosthetics | Dentures no longer fit or feel comfortable, due to unstable periodontium. |
| 9 | Tooth loss | Teeth are lost as a result of progressive bone loss around teeth. |

Dentists should consider the following when treating inmates with diabetes and periodontitis:

- Informing the inmate's physician about the presence of periodontal infection and the proposed treatment.
- Providing periodontal therapy and motivating the inmate to establish and maintain periodontal health.
- Determining a recall interval specifically for each patient, based on his or her needs according to a risk assessment.
- Prescribing systemic antibiotics in conjunction with mechanical therapy.
- Educating the inmate regarding the possible impact of periodontal infection on glycemic control.

CONSIDERATIONS IN PROVIDING DENTAL PROCEDURES FOR DIABETIC PATIENTS

Dental providers should prepare for appointments with diabetic patients by becoming aware of the patient's condition as it relates to diabetes. The provider should review the patient's EMR to determine the type and severity of diabetes, the level of diabetic control, medications, and recent labs—hemoglobin A1C values, in particular.

- **Appointments should be scheduled in the morning when possible**, and the provider should verify that the patient has taken medication and food as usual.
- **Finger stick monitoring of blood glucose levels** should be reviewed by dental provider prior to invasive procedures. (Elective treatment should be deferred if blood glucose >200 mg/dL.)
- **Vital signs also should be taken** and recorded prior to invasive procedures. High blood pressure (>180/100) may indicate a potential medical issue; elective dental treatment should be deferred, and the patient referred for medical assessment.
- **Prior to performing invasive procedures** (e.g., surgery or exodontia), dentists should consider antibiotic coverage for patients with poorly controlled diabetes. Patients with uncontrolled hyperglycemia are susceptible to post-operative infections and associated sequelae. The administration of antibiotics may improve post-operative healing. Antibiotics should be considered for patients with uncontrolled diabetes (blood glucose > 200mg/dL) who are at increased risk for infection.
- **After all dental procedures**, patients with diabetes should be screened carefully for occult dental infections. Special attention should be given to the post-surgery dietary needs of patients undergoing extensive periodontal or oral surgical procedures. The inmate's primary physician should be consulted for dietary recommendations.

MEDICAL DECOMPENSATION (HOSPITALIZATION CRITERIA)

The decision to admit inmates to an inpatient hospital unit should be made on a case-by-case basis, but the following indications generally warrant hospitalization for inmates with diabetes:

- **Diabetic ketoacidosis** that is characterized by a plasma/serum glucose >300 mg/dL with an arterial pH <7.30, an increased anion gap, and serum bicarbonate level <15 mEq/L, along with moderate ketones in the urine or blood. Low sodium, elevated potassium, and elevated BUN may also occur. Total body intracellular potassium may be significantly depleted, regardless of serum potassium levels.
- **Hyperglycemic hyperosmolar state** that is characterized by an elevated serum osmolality (>320 mOsm/kg), usually with severe hyperglycemia (plasma/serum glucose >600 mg/dL) and associated with an altered mental status that may progress to coma.
- **Severe hypoglycemia** with a blood glucose <50 mg/dL and an altered mental status that does not readily improve with treatment or is associated with neurologic deficits. Hypoglycemia caused by sulfonylureas can be prolonged or recurrent due to the drugs' long duration of action. Symptomatic hypoglycemia that cannot be managed with frequent feedings over a 24-hour period should be treated in a hospital setting.
- **Uncontrolled hyperglycemia diagnosed during pregnancy.**
- **Moderate to severe hyperglycemia** that is unresponsive to standard therapies or is associated with an acute illness.
- **Severe complications of diabetes** that warrant inpatient evaluation and treatment.

11. PERIODIC EVALUATIONS

OVERVIEW

Diabetes management requires the expertise of a variety of clinicians, including physicians, pharmacists, nurses, optometrists or ophthalmologists, dentists, dieticians, physical therapists, and recreation specialists. Inmate treatment plans should be individualized, have measurable goals, and emphasize self-management. Regularly scheduled evaluations help maximize glycemic control, reduce diabetic complications, and enhance educational efforts.

→ A one-page summary of recommended periodic evaluations is attached in [Appendix 2](#).

The frequency of chronic care clinic visits for inmates with diabetes should be individualized, depending on a number of factors:

- Degree of glycemic control
- Complexity of the medication regimen
- Frequency of changes to the regimen
- Presence of complications of diabetes and co-morbid conditions
- Inmate's understanding of the disease and his or her self-motivation

Inmates with uncomplicated type 2 diabetes that is controlled by diet and exercise alone can be monitored predominantly by mid-level providers. Inmates with poorly controlled diabetes or with other serious complications such as heart or kidney disease should be monitored closely by a physician, along with the patient's mid-level provider(s). Weekly or monthly clinician evaluations may be necessary for patients with diabetes that is difficult to manage. Utilization of appropriately credential pharmacists can provide for intensive follow-up when necessary.

Inmates with IFG or IGT ("pre-diabetes") should be monitored annually for the development of diabetes with fasting plasma/serum glucose measurements. One-third of these patients will be diagnosed with diabetes within five years.

MEDICAL HISTORY

The periodic patient interview should target the following concerns:

- Results of glucose monitoring and review of medication and/or insulin compliance.
- Frequency, causes, and severity of any hypoglycemic symptoms or other medication side effects experienced since the last visit.
- Changes in the treatment regimen or any lifestyle changes made by the inmate between clinic visits (including level of participation in exercise, diet, and smoking cessation programs).
- Symptoms of concurrent illnesses such as untreated infections (e.g., tinea pedis, tinea cruris, ear infections, and urinary tract infections).
- Symptoms that suggest evolving complications such as paresthesias, weakness, angina, visual disturbances, skin infections, or foot problems.

PHYSICAL EXAMINATION

The periodic examination should target the following:

- Vital signs and weight.
 - Foot exam (inspection, palpation of pulses, and an annual sensory exam, using a monofilament and documented on Diabetes Foot Screen form from <http://www.hrsa.gov/leap/>).
 - Focused exam of organ systems, triggered by positive responses to questions on the interim history or the presence of diabetic complications.
- ➔ A more comprehensive physical should be conducted annually and whenever clinically necessary.
- ➔ See [Appendix 1](#) for additional information on the physical exam.

GLUCOSE MONITORING

- **GLUCOSE MONITORING:** Inmates with diabetes should have their fasting or random glucose (by finger stick or venipuncture) evaluated frequently by the clinicians, nurses, and pharmacists they encounter, with notation as to the number of hours postprandially the sample is obtained. (If recent laboratory data are not available, at the very minimum, a random finger stick glucose should be measured as an indication of the degree of glucose control.)

The frequency of blood glucose monitoring by the clinic should be based on factors that affect glycemic control:

- ▶ For patients on intensive insulin regimens, consider glucose checks before each meal and bedtime. Self-monitoring may be a reasonable option, and patients should bring their glucometers to their appointment
 - ▶ For challenging patients (those requiring frequent adjustments or with history of hypoglycemia), consider monitoring two to three times daily with finger stick glucose checks performed by medical staff.
 - ▶ Patients on hypoglycemia-inducing therapies may need closer monitoring than those who are not.
 - ▶ Patients managed with oral therapies and basal insulin alone may not require blood glucose monitoring outside of periodic laboratory assessments.
- **A1C LEVELS:** Periodic measurement of A1C levels is essential for assessing glucose control and compliance with therapy. Quarterly measurements are recommended if treatment changes are made or if glucose goals are not met; otherwise, measurements two times per year are ordinarily adequate.
 - ▶ A1C measurements should be obtained just prior to a scheduled appointment to review glycemic control.
 - ▶ A1C results outside of goal range indicate the need for therapeutic adjustment.
 - ➔ See [Appendix 5](#), *BOP Treatment Algorithm for Type 2 Diabetes*, and [Appendix 6a](#), *Initiation/Adjustment of Insulin Regimens in Type 2 Diabetes*.
 - **URINE GLUCOSE:** Urine glucose monitoring has limited value; it should only be considered as an alternative assessment of glucose control if inmates are unable or unwilling to perform blood glucose testing.

MONITORING FOR DIABETIC COMPLICATIONS

Inmates should receive the following evaluations to screen for diabetic complications:

- Annual serum electrolytes.
- Annual creatinine used to calculate a GFR.
- Annual screening test for microalbuminuria, usually with urine albumin-to-creatinine ratio (for inmates who have had type 1 diabetes for more than five years and all inmates with type 2 diabetes), unless proteinuria has already developed).
- Annual fasting lipid profile to screen for hypercholesterolemia.
- Annual, comprehensive, dilated-eye and vision examination, by an ophthalmologist or optometrist (for inmates who have had type 1 diabetes for more than five years and all inmates with type 2 diabetes). If an optometrist identifies ocular complications of diabetes or other serious problems, the inmate should be referred to an ophthalmologist.
- At each periodic visit, a foot examination (inspection and palpation) to identify risk factors for amputation. Assess sensory loss through monofilament testing annually.

INMATE EDUCATION

All inmates with diabetes should receive education from a health care provider at the time of diagnosis, and then periodically during subsequent evaluations and treatments. Inmates should be counseled on a range of issues related to their disease: **(1)** the symptoms of hyperglycemia and hypoglycemia, **(2)** how complications of diabetes progress, **(3)** the importance of glycemic control, **(4)** the benefits of healthy dietary selections and regular exercise, **(5)** the importance of modifying heart disease risk factors, and **(6)** the benefits and side effects of different medications. Inmates with poor glycemic control require more intensive educational efforts, either one-on-one or in groups.

- *Inmate handouts are attached in:*
[Appendix 11](#), *Fact Sheet on Type 2 Diabetes*,
[Appendix 12](#), *The Three Keys to Controlling Your Diabetes*, and
[Appendix 13](#), *Eating to Manage Your Diabetes in the Bureau of Prisons*.

DOCUMENTATION

Periodic clinician evaluations should be documented in the inmate's medical record.

DIABETES TREATMENT REFUSALS

Every refusal increases risks for complications from diabetes and its associated conditions. The cost of medical care increases. Utilize the BEMR medical treatment refusal form and add an entry in the inmate medical record if the inmate:

- Is a frequent no-show at insulin line.
- Admits and demonstrates refusal to change lifestyle.
- Admits and demonstrates (has poor medication refill history) lack of medication adherence.
- Is a no-show for clinic visits.

Document the specific refused encounter, test, procedure, medication, etc. Include the potential consequences of the inmate's refusal such as amputation, blindness, heart attack, kidney failure, pain, stroke, or death.

A call out appointment may be needed to perform the appropriate counseling about refused diabetes care. In some cases, refusal of care will generate an incident report. Refer to custody staff for guidance.

12. HEALTH CARE PROVIDER RESOURCES

Informational resources for managing diabetes are listed in [Appendix 10](#).

DEFINITIONS

CLINICIAN is a physician, mid-level provider, or an appropriately credentialed pharmacist.

CONVENTIONAL INSULIN THERAPY describes the more simple insulin regimens such as single injections of regular insulin given once daily, or two injections per day of regular and NPH insulin mixed together in fixed amounts in the same syringe (see [INTENSIVE INSULIN THERAPY](#) below).

DIABETES MELLITUS (DM) is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both.

FASTING PLASMA GLUCOSE is a blood glucose that is obtained after no caloric intake for at least eight hours. It should be collected in a grey-top tube with glycolytic inhibitor and submitted for no other testing. Consult with the National Laboratory Administrator for further guidance.

A1C (GLYCATED HEMOGLOBIN) reflects the mean glycemia occurring over the preceding two to three months. Values are free of day-to-day glucose fluctuations and are unaffected by exercise or recent food ingestion. The interpretation of this test depends on the red blood cells having a normal life span, the average being 120 days. Persons with hemolytic disease, or other conditions with a shortened red blood cell survival, exhibit a significant reduction in A1C. A1C can still be used to monitor inmates with such conditions, but the values must be compared with previous values from the same inmate, not from published reference values. High A1C levels have been reported in iron deficiency anemia, probably due to the high proportion of old, circulating erythrocytes.

GESTATIONAL DIABETES MELLITUS (GDM) is any degree of glucose intolerance identified during pregnancy.

IMPAIRED GLUCOSE TOLERANCE (IGT) AND IMPAIRED FASTING GLUCOSE (IFG) are intermediate stages between normal glucose homeostasis and diabetes, and have recently been termed [PRE-DIABETES](#). Persons with either IGT or IFG are at risk for future diabetes and cardiovascular disease.

INTENSIVE INSULIN THERAPY describes more complex regimens than [CONVENTIONAL INSULIN THERAPY](#). Intensive insulin therapy provides basal insulin delivery (given as one or two daily injections of intermediate- or long-acting insulin) together with superimposed doses of short-, rapid-, or very rapid-acting insulin, three or more times daily.

LOWER EXTREMITY AMPUTATION PREVENTION (LEAP) PROGRAM is a screening tool for peripheral neuropathy designed by the Hansen's Disease Center; it uses a 10-gram monofilament to assess sensation of the soles of the feet. Refer to: <http://www.hrsa.gov/leap/>.

ORAL GLUCOSE TOLERANCE TEST (OGTT) is a supplemental test for diagnosing diabetes in certain patients. It involves an overnight fast after consuming an unrestricted diet for three days; then, an oral glucose load is given, followed by serial measurements of plasma/serum glucose concentrations.

PRE-DIABETES is a term applied to both impaired fasting glucose (IFG) and impaired glucose tolerance (IGT). IFG and IGT are each risk factors for future diabetes and cardiovascular disease.

TYPE 1 DIABETES is caused by a deficiency of insulin secretion that is due to pancreatic islet β -cell destruction, which is frequently associated with pancreatic autoantibodies. Individuals with type 1 diabetes are usually dependent on exogenous insulin and are at risk for ketoacidosis.

TYPE 2 DIABETES is caused by insulin resistance with a relative, but not absolute, deficiency of insulin. The etiology of type 2 diabetes is uncertain. Individuals with type 2 diabetes are not prone to ketoacidosis and may be asymptomatic.

REFERENCES

Academy of Nutrition and Dietetics (formerly the American Dietetic Association), Diabetes Care and Education Practice Group. *Carbohydrate Counting: Focus on Consistency for People Who Use Diabetes Pills and Basic Insulin Regimens* [patient handout]. 2008. Available at: https://dpg-storage.s3.amazonaws.com/dce/resources/carb_counting_focus_consistency.pdf

Academy of Nutrition and Dietetics (formerly the American Dietetic Association). Carbohydrate counting for people with diabetes. *Nutrition Care Manual*. Available at: <http://nutritioncaremanual.org/download.cfm?path=/editor/Docs/CarbohydrateCounting.pdf>

American Diabetes Association. Diabetes management in correctional institutions. *Diabetes Care*. 2007;30(suppl 1):S77–S84. Available at: http://care.diabetesjournals.org/content/30/suppl_1/S77.full

American Diabetes Association. 2017 Standards of medical care in diabetes. *Diabetes Care*. 2017;40(suppl 1):S1–S135. Available at: http://care.diabetesjournals.org/content/40/Supplement_1

American Diabetes Association. Oral Health and Hygiene – Warning Signs. ADA website. Available at: <http://www.diabetes.org/living-with-diabetes/treatment-and-care/oral-health-and-hygiene/warning-signs.html>. Accessed February 2012.

Bassim C, Ward T, Nucci D. Diabetes and oral health. *Federal Practitioner*. 2007;24(7):64–71.

Centers for Disease Control and Prevention. National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011. Available at: http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf

Centers for Disease Control and Prevention. Transmission of hepatitis B virus among persons undergoing blood glucose monitoring in long-term-care facilities—Mississippi, North Carolina, and Los Angeles County, California, 2003–2004. *MMWR*. 2005;54:220–223. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5409a2.htm>

Health Resources & Services Administration (HRSA). Lower Extremity Amputation Prevention Program [homepage on the internet]. Available at: <http://www.hrsa.gov/leap/>. Accessed February 25, 2009.

Lalla E, Papapanou PN. Diabetes mellitus and periodontitis: A tale of two common interrelated diseases. *Nat Rev Endocrinol*. 2011 Jun 28;7(12):738–48.

Lipska, KJ, Bailey, CJ, Inzucchi, SE. Use of metformin in the setting of mild-to-moderate renal insufficiency. *Diabetes Care*. 2011;34(6):1431–1437. Available at: <http://care.diabetesjournals.org/content/34/6/1431.long>

Mattson JS, Cerutis RD. Diabetes mellitus: a review of the literature and dental implications. *Compendium of Continuing Education in Dentistry*. 2001;22(9):757–770.

Mokdad, AH. The continuing epidemics of obesity and diabetes in the United States. *JAMA*. 2001;286:1195–1200.

McCulloch, DK. Insulin therapy in type 2 diabetes mellitus. In: UpToDate, Nathan DM (Ed), UpToDate, Waltham, MA. Accessed on March 29, 2016.

Nathan DM, Buse JB, Davidson MB, et al. Management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy. *Diabetes Care*. 2006;29(8): 1963–1972. Available at: <http://care.diabetesjournals.org/cgi/content/full/29/8/1963>

Stone, NJ, et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Available at: <http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a>

APPENDIX 1: COMPONENTS OF THE COMPREHENSIVE DIABETES EVALUATION

| MEDICAL HISTORY | |
|---|---|
| <ul style="list-style-type: none"> • Age and characteristics of onset of diabetes (e.g., diabetes ketoacidosis, routine screening) • Prior A1C records • Symptom review • Eating patterns, nutritional status, weight history; exercise history • Diabetes education history • Review of previous diabetes treatment • Current treatment of diabetes: medications, meal plan, results of glucose monitoring • Hypoglycemic episodes (any severe hypoglycemia – frequency, severity, cause) • History of diabetes-related complications: <ul style="list-style-type: none"> • Microvascular (eye, kidney, nerve) • Macrovascular (CHD, PAD) • Other (sexual dysfunction, gastroparesis) | <ul style="list-style-type: none"> • Diabetic ketoacidosis: frequency, severity, cause • Risk factors for atherosclerosis, i.e., smoking, hypertension, obesity, dyslipidemia, family history • Review of concurrent medications that may affect blood glucose levels or precipitate diabetes, i.e., HIV protease inhibitors, atypical antipsychotic agents, corticosteroids, pentamidine, high-dose thiazide diuretics • Review of prior/current infections, particularly of the skin, feet, dentition, genitourinary system • Female patients: gestational history including hyperglycemia, delivery of infant weighing more than 9 lbs., toxemia, stillbirth, polyhydramnios, or otherwise complicated pregnancy • Tuberculin (TST) skin test history and history of treatment of latent TB infection (LTBI) |
| IMMUNIZATION HISTORY | |
| <ul style="list-style-type: none"> • Influenza vaccine (indicated annually for inmates with diabetes, unless contraindicated) • Pneumococcal vaccine (at diagnosis; or at age 65, one-time revaccination if ≥ 5 yrs since initial vaccine) | |
| PHYSICAL EXAMINATION | |
| <ul style="list-style-type: none"> • Vital signs: height, weight, blood pressure (including orthostatic) • Funduscopic examination (preferably with pupillary dilation) • Thyroid palpation (Type I diabetes) • Skin examination (insulin injection site) • Oral exam • Hand and finger examination • Abdominal examination to rule out hepatomegaly, bruits, or enlargement of the abdominal aorta • Examination of the feet for infections or skin breakdown; testing for neuropathy | <ul style="list-style-type: none"> • Cardiac exam; auscultation/palpation of DP and PT pulses • Presence/absence of patellar and Achilles reflexes • Determination of proprioception, vibration, and monofilament sensation • Signs of other conditions that can cause secondary diabetes: bronzed skin color with hemochromatosis; GI malignancy (acanthosis nigricans); and endocrine disorders such as acromegaly, Addison's disease, pheochromocytoma, and Cushing's syndrome |
| LABORATORY EXAMINATION | |
| <ul style="list-style-type: none"> • Fasting plasma or serum glucose (if not already obtained) • Hemoglobin A1C • Fasting lipid profile (including total, LDL, and HDL cholesterol, triglycerides) • Liver function tests • Urinalysis, as clinically warranted • Serum creatinine and calculated glomerular filtration rate (GFR) • Thyroid stimulating hormone • Screening for celiac disease in type 1 diabetes and as indicated in type 2 diabetes | <ul style="list-style-type: none"> • Testing for microalbuminuria in inmates who have had type 1 diabetes for at least five years, and in all inmates with type 2 diabetes. (If routine urinalysis on two or more occasions detects protein, and other causes such as infection and menses are ruled out, then microalbumin determinations are <i>not</i> necessary because the nephropathy has already progressed to overt proteinuria.) • Urine culture, if symptoms of a urinary tract infection are present • Electrocardiogram (ECG) – baseline • TST (if not previously tested) |
| REFERRALS | |
| <ul style="list-style-type: none"> • Baseline optometry or ophthalmology exam • Dental care (including hard/soft tissue exam, periodontal assessment, and follow-up exam if indicated) • Diabetes education and medical nutrition therapy | |
| <p>Adapted from: American Diabetes Association. 2017 Standards of medical care in diabetes. <i>Diabetes Care</i>. 2017;40(suppl 1):S1–S135.</p> | |

APPENDIX 2: RECOMMENDATIONS FOR DIABETES CHRONIC CARE CLINIC MONITORING

| PATIENT EVALUATION / ROUTINE EXAM – SOAP FORMAT | | | | |
|---|--|---|---------------------------------|--------------|
| SUBJECTIVE | <ul style="list-style-type: none"> • Observations and patient complaints • Compliance with lifestyle changes and medications • Side effects of medications • Symptoms of diabetic complications | | | |
| OBJECTIVE | <ul style="list-style-type: none"> • Vital signs: blood pressure, pulse, respiration rate, temperature, weight, height • HEENT (include funduscopic exam and neck evaluation) • Lungs/heart • Abdomen • Extremities / peripheral pulses / neuropathy / visual foot examination • Labs, x-rays, other studies | | | |
| ASSESSMENT | <ul style="list-style-type: none"> • Assessment, analysis of data, diagnosis, degree to which glycemic goals are met | | | |
| PLAN | <ul style="list-style-type: none"> • Therapeutic regimen • Diagnostic studies • Education: adherence to all self-care aspects, exercise evaluation, follow-up of referrals, smoking cessation | | | |
| PROCEDURE, TEST, EXAMINATION | BASELINE VISIT | QUARTERLY VISIT | SEMI-ANNUAL VISIT | ANNUAL VISIT |
| Routine physical exam | X | (X) as needed | (X) as needed | X |
| Fasting blood sugar (record results of self-monitoring where applicable) ¹ | X | X | | |
| Complete metabolic panel (electrolytes, creatinine, total cholesterol) | X | | | X |
| Calculate glomerular filtration rate: http://www.kidney.org/professionals/kdoqi/gfr_calculator.cfm | X | | | X |
| Fasting lipid profile (obtain more often if managing a lipid disorder, less often if low risk) | X | | | X |
| A1C | X | (X) if treatment changes, or if clinically indicated | X | X |
| Screen for microalbuminuria (albumin to creatinine ratio in a random spot collection) ² | X | | | X |
| Comprehensive, dilated-eye and vision exam, by an ophthalmologist or optometrist | X | | | X |
| Funduscopic exam (by primary care doctor) | X | | | |
| Foot exam (visual and monofilament) | X | (X) if not reaching target goals | (X) if reaching target goals | X |
| EKG | X | | | |
| <p>¹ Fasting or random glucose (finger stick) monitoring: Methods and times must be determined on a case-by-case basis, depending on the medical needs of the inmate and the severity of the condition.</p> <p>² Screen for microalbuminuria: Abnormal results should be repeated at least 2–3 times over a 3–6 month period to appropriately diagnose, because of the potential for false positives.</p> | | | | |

APPENDIX 3. TREATMENT GOALS FOR NON-PREGNANT INMATES WITH DIABETES

| GLYCEMIC CONTROL | |
|---|-----------------------------------|
| A1C ¹ | <7.0–7.5% |
| Preprandial capillary plasma glucose ² | 90–130 mg/dl |
| Peak postprandial capillary plasma glucose ^{2,3} | <180 mg/dl |
| <p>Key concepts in setting glycemic goals:</p> <ul style="list-style-type: none"> • A1C is the primary target for glycemic control. • Goals should be individualized. • Certain inmate populations, i.e., pregnant women and the elderly, require special considerations. • Less intensive glycemic goals may be indicated in patients with severe or frequent hypoglycemia. • Postprandial glucose may be targeted if A1C goals are not met despite reaching preprandial glucose goals. | |
| BLOOD PRESSURE | |
| Blood pressure goal | <140 / <90 mmHg |
| LIPIDS ⁴ | |
| Age <40 years | |
| No risk factors | None |
| ASCVD risk factor(s)* | Moderate or high-intensity statin |
| ASCVD | High-intensity statin |
| Age 40–75 years | |
| No risk factors | Moderate-intensity statin |
| ASCVD risk factors* | High-intensity statin |
| ASCVD | High-intensity statin |
| Age >75 years | |
| None | Moderate-intensity statin |
| ASCVD risk factors* | Moderate or high-intensity statin |
| ASCVD | High-intensity statin |
| <p>* ASCVD (atherosclerotic cardiovascular disease) risk factors include LDL cholesterol ≥100 mg/dL, high blood pressure, smoking, overweight and obesity, and family history of premature ASCVD.</p> <p>¹ The ADA's <i>Standards of Medical Care in Diabetes – 2017</i> sets the A1C diagnostic cut point as 6.5%. Based on the results of multiple randomized trials and correctional considerations, the BOP recommends A1C <7.0–7.5% as a reasonable treatment goal for most inmates with diabetes. Less stringent goals may be appropriate for some patients.</p> <p>² Many glucometers automatically convert capillary blood glucose values to plasma glucose values. Check the glucometer. Glucometers that do not automatically convert values report blood glucose values that may be 10–15% lower than plasma glucose values.</p> <p>³ Postprandial glucose measurements should be made 1–2 hours after the beginning of the meal.</p> <p>⁴ As per 2013 ACC/AHA <i>Blood Cholesterol Guideline</i>.</p> <p>Adapted from: American Diabetes Association. 2017 Standards of medical care in diabetes. <i>Diabetes Care</i>. 2017;40(suppl 1):S1–S135.</p> | |

APPENDIX 4. INDIVIDUALIZED TREATMENT GOALS FOR OLDER ADULTS WITH DIABETES

| HEALTH STATUS & PATIENT CHARACTERISTICS | RATIONALE | SUGGESTED A1C GOAL | FASTING OR PPG | BEDTIME GLUCOSE | BLOOD PRESSURE | LIPIDS |
|---|--|--------------------|----------------|-----------------|----------------|--|
| HEALTHY <i>Few co-existing chronic illnesses, high cognitive and functional status.</i> | Longer remaining life expectancy | <7.5% | 90–130 mg/dL | 90–50 mg/dL | <140/90 mmHg | Statin unless contraindicated or not tolerated. |
| COMPLEX <i>Multiple co-existing chronic illnesses* or 2+ instrumental ADL impairments or mild-to-moderate cognitive impairment.</i> | Intermediate remaining life expectancy, high risk for hypoglycemia or falls, high treatment burden | <8% | 90–150 mg/dL | 100–180 mg/dL | <140/90 mmHg | Statin unless contraindicated or not tolerated. |
| VERY COMPLEX <i>LTC or end-stage chronic illnesses** or moderate-to-severe cognitive impairment or 2+ ADL dependencies.</i> | Limited remaining life expectancy makes benefit uncertain | <8.5%*** | 100–180 mg/dL | 110–200 mg/dL | <150/90 mmHg | Consider likelihood of benefit (secondary prevention >primary prevention). |

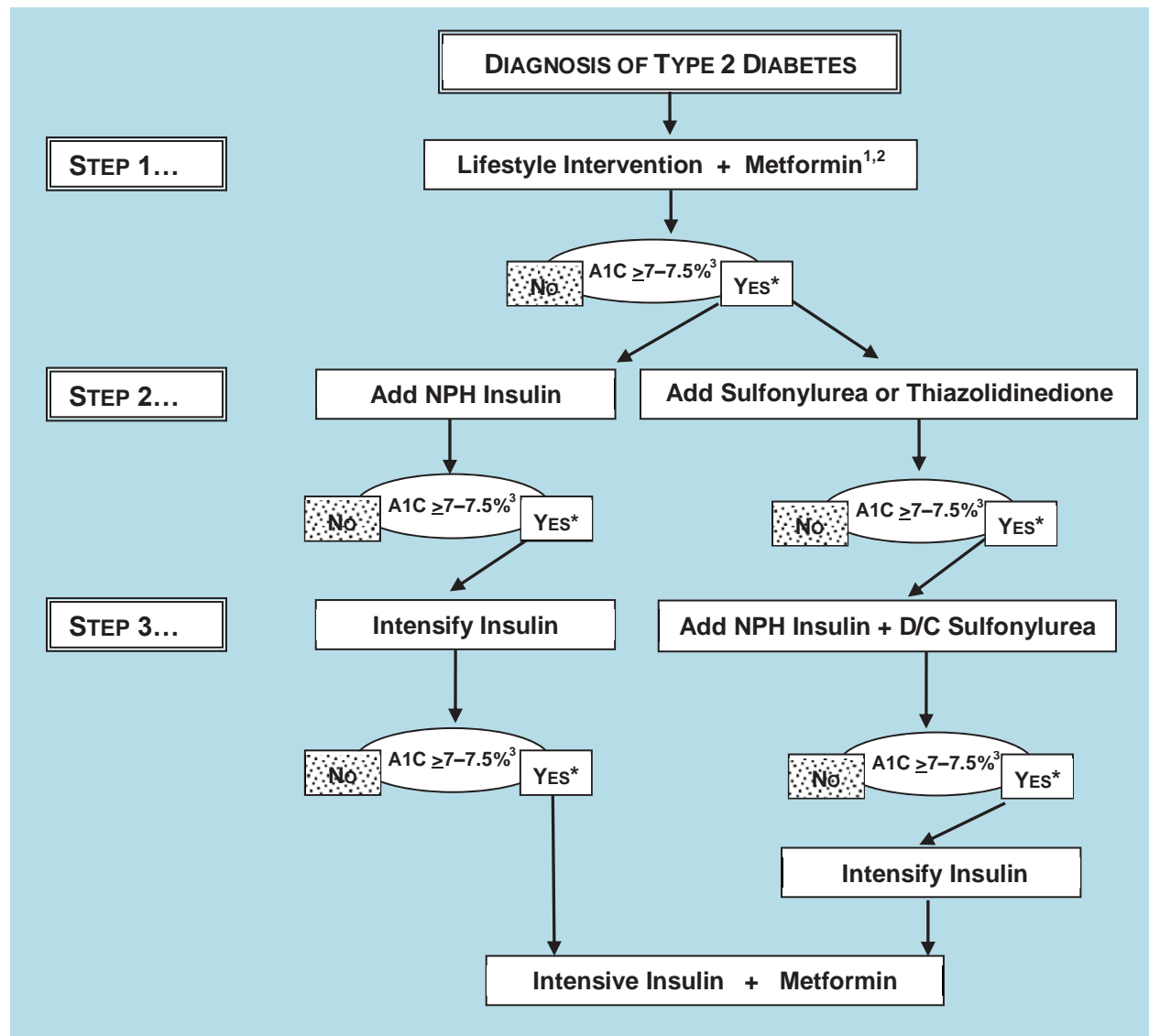
* Coexisting chronic illnesses are defined as conditions serious enough to require medications or lifestyle management (e.g., cancer, CHF, depression, history of MI or stroke). “Multiple” means at least three, but may mean five or more.

** The presence of a single end-stage chronic illness—such as uncontrolled metastatic cancer, stage 3-4 CHF, or CKD requiring dialysis—may cause significant symptoms or impairment and may reduce life expectancy.

*** Looser A1C targets above 8.5% are not recommended as they may increase risk of symptomatic hyperglycemia with acute risks from glycosuria, dehydration, hyperglycemic hyperosmolar states, and poor wound healing.

Adapted from: American Diabetes Association. 2017 Standards of medical care in diabetes. *Diabetes Care*. 2017;40(suppl 1):S1–S135.

APPENDIX 5: BOP TREATMENT ALGORITHM FOR TYPE 2 DIABETES



¹ **EXCEPTION:** Insulin should be utilized if severely uncontrolled DM, i.e., plasma/serum glucose >250 mg/dL, random glucose consistently >300 mg/dL, A1C >10%, ketonuria, or symptomatic diabetes with polyuria, polydipsia, & weight loss. See [indications for using insulin as initial therapy](#) in Section 5.

² Use metformin unless contraindicated, i.e., if eGFR<45 ml/min; if age >80 (unless renal sufficiency established); or chronic liver failure. A sulfonylurea can often substitute for metformin if it is contraindicated.

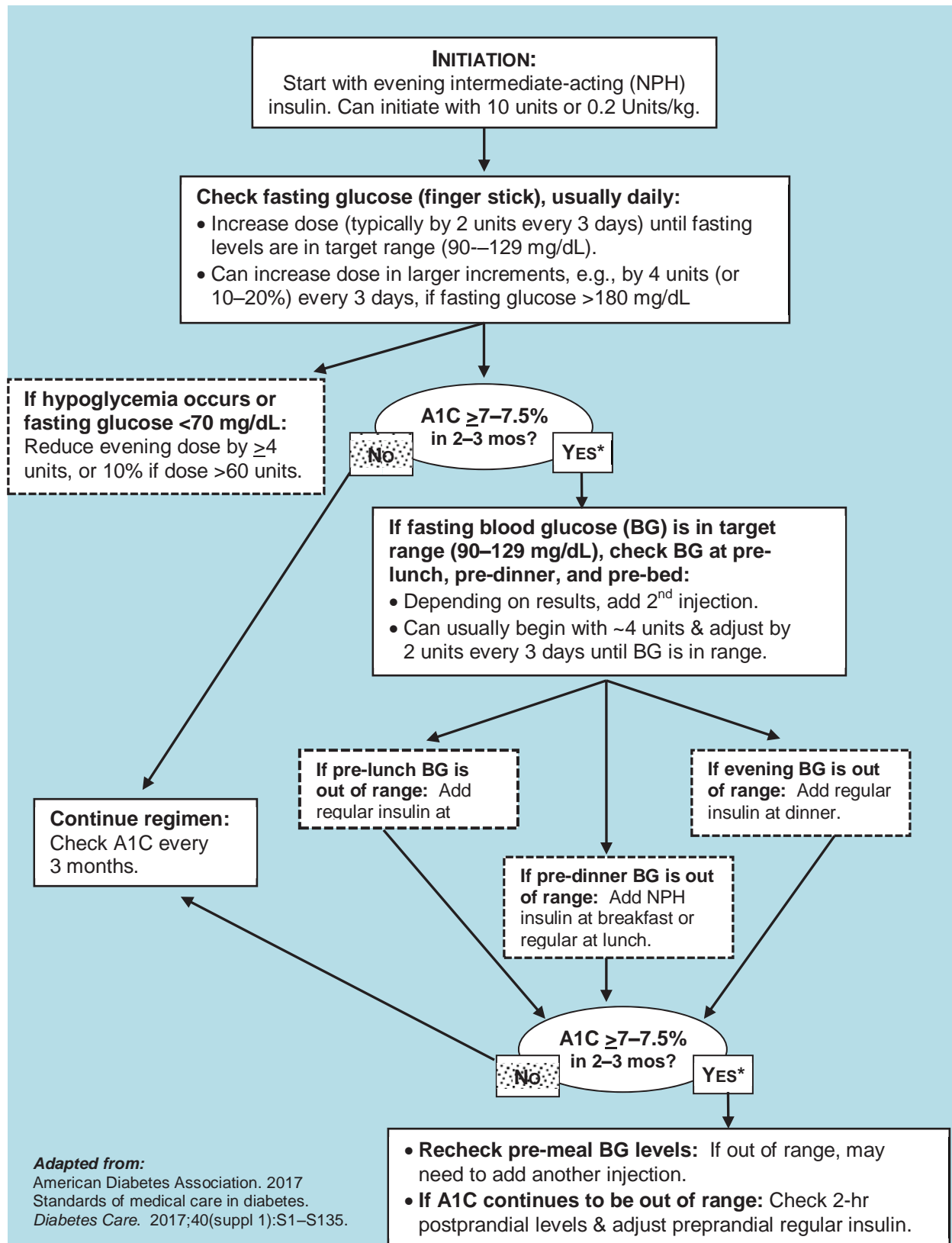
³ Or other individualized A1C goal.

* Check A1C every 3 months until <7.0–7.5%, or at other individualized treatment goal; then, every 6 months.

Notes:

- For a more complete discussion, see [BOP Treatment Algorithm for Type 2 Diabetes](#) in Section 5.
- Refer to the BOP National Formulary for the formulary status and non-formulary use criteria for specific medications.
- In order to achieve glycemic goals, medications should be adjusted as frequently as titration allows (i.e., as often as every 3 to 4 days for insulin and every one to two weeks for metformin).

APPENDIX 6A: INITIATION AND ADJUSTMENT OF INSULIN REGIMENS IN TYPE 2 DIABETES

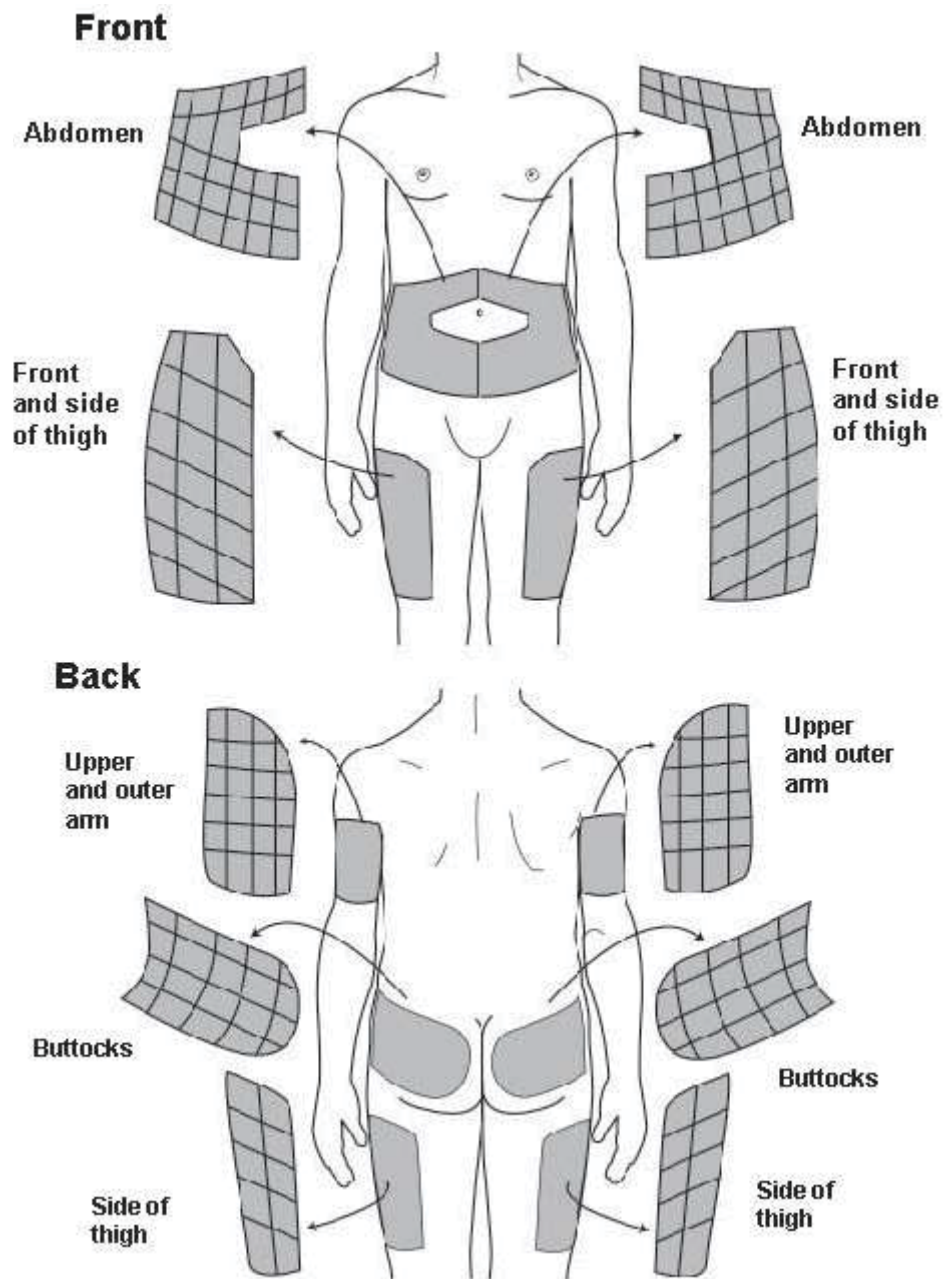


Adapted from:
American Diabetes Association. 2017
Standards of medical care in diabetes.
Diabetes Care. 2017;40(suppl 1):S1–S135.

APPENDIX 6B: STRATEGIES TO REPLACE SLIDING SCALE INSULIN (SSI) FOR LONG-TERM CARE SETTINGS

| CURRENT REGIMEN | SUGGESTED STEPS FOR REPLACING SSI REGIMEN |
|---|--|
| <p>SLIDING SCALE INSULIN THERAPY refers to the use of varying doses of regular insulin in response to hyperglycemia. Sliding scale insulin therapy is not a recommended strategy for long-term management of patients with diabetes.</p> | |
| <p>SSI is the sole insulin treatment.</p> | <ul style="list-style-type: none"> • Review average daily insulin requirement over prior 5–7 days. • Give 50–75% of the average daily insulin requirement as basal insulin. • Stop SSI. • Use noninsulin agents or fixed-dose mealtime insulin for postprandial hyperglycemia. • Consider giving basal insulin in the morning to impact postprandial hyperglycemia and reduce risk of early morning/nocturnal hypoglycemia. |
| <p>SSI is being used in addition to scheduled basal insulin.</p> | <ul style="list-style-type: none"> • Add 50–75% of the average insulin requirement used as SSI to the existing dose of basal insulin. • Use noninsulin agents or fixed-dose mealtime insulin for postprandial hyperglycemia. |
| <p>SSI is being used in addition to basal and scheduled meal time insulin (i.e., correction dose insulin).</p> | <ul style="list-style-type: none"> • If a correction dose is required frequently, add the average correction dose before a meal to the scheduled mealtime insulin dose at the <i>preceding</i> meal. <i>For example:</i> If glucose is consistently elevated before lunch, requiring 2–3 unit corrections, the scheduled breakfast dose of insulin could be increased by the average correction dose (2 units). <i>Similarly,</i> if glucose values are elevated before breakfast, requiring correction doses, the scheduled basal insulin dose could be increased by the average correction dose used. |
| <p>SSI is used in the short-term due to irregular dietary intake or acute illness (<14 days).</p> | <ul style="list-style-type: none"> • Short-term use may be needed for acute illness and irregular dietary intake. • Stop SSI and return to previous regimen as health and glucose stabilize. |
| <p>SSI is used for wide fluctuations in glucose levels in patients with cognitive decline and/or irregular dietary intake on a chronic basis.</p> | <ul style="list-style-type: none"> • Use scheduled basal and mealtime insulin based on individual needs, with the goal of avoiding hypoglycemia. • May use simple scale such as “Give 4 units of mealtime insulin if glucose>300 mg/dL.” • Keep patients hydrated, especially if glucose levels are very high (e.g., >300 mg/dL). |
| <p>Adapted from: 2017 Standards of medical care in diabetes. <i>Diabetes Care</i>. 2017;40(suppl 1):S1–S135..</p> | |

APPENDIX 6C: INSULIN ADMINISTRATION SITES



Source: Cleveland Clinic : Drugs, Devices, and Supplements: Instructions for Medicines You Inject (Insulin). Available at: https://my.clevelandclinic.org/health/drugs_devices_supplements/hic_injectable_insulin_medications/hic_About_Your_Insulin. Accessed 3/31/2016

APPENDIX 7: ORAL AGENTS FOR TREATMENT OF TYPE 2 DIABETES

| ORAL AGENTS FOR TREATMENT OF TYPE 2 DIABETES — DOSING AND SIDE EFFECTS | | | | | |
|---|--|---|----------------------|---|---|
| Agent | Initial Dose & Treatment | Maximum Dose | Initial Elderly Dose | Side Effects | Drug Interaction |
| BIGUANIDES | | | | | |
| <p>→ Caution is advised for use of metformin therapy in patients with stable mild to moderate renal impairment. Contraindications to metformin therapy: elevated creatinine (>1.7mg/dL), or a creatinine clearance <30mL/min in the elderly; history of renal insufficiency, hepatic dysfunction, or serious cardiovascular or pulmonary compromise.</p> | | | | | |
| Metformin (Glucophage) | <ul style="list-style-type: none"> • 500 mg with a meal. • Based on patient's tolerance to metformin & glycemic response, increase dosage by 500 mg/day at weekly intervals, adding a dose to another meal. • TID dosing not required for efficacy, but may decrease GI complaints. • Doses <1500 mg/day unlikely to achieve therapeutic effect as monotherapy. • Doses >2000 mg/day have little added benefit. | 2550 mg/day (850 mg TID) OR 2500 mg/day | 500 mg | Nausea and diarrhea, which usually subside over 1 week; to alleviate, may limit rate of dose increase. Hypoglycemia only if metformin is given with sulfonylurea or insulin. | Alcohol; cimetidine; amiloride; digoxin; morphine; procainamide; quinidine; ranitidine; triamterene; trimethoprim; vancomycin; furosemide; calcium channel blocking agents, especially nifedipine. → Withhold 48 hours prior to and following surgery or IV contrast x-ray studies. |
| SULFONYLUREAS (SUs) — SECOND GENERATION | | | | | |
| Glimepiride (Amaryl) | <ul style="list-style-type: none"> • 1–2 mg daily with breakfast or first main meal. • Increase at 1–2 mg increments every 1–2 weeks, as needed. → Use glimepiride only if creatinine clearance is ≥30 mL/min. | 8 mg once daily | 0.5–1 mg | Hypoglycemia & weight gain. | Alcohol; coumadin; azole antifungals; asparaginase; corticosteroids; thiazide diuretics; lithium; beta blockers; cimetidine; ranitidine; cyclosporine; quinolones; MAO inhibitors; chloramphenicol; octreotide; pentamidine. |
| Glipizide, short-acting (Glucotrol) | <ul style="list-style-type: none"> • 5 mg/day, 30 min before breakfast. • Increase dose by 2.5–5 mg weekly, as needed. → Use glipizide only if creatinine clearance is ≥10 mL/min. | 40 mg/day Give BID when dose reaches 15 mg. | 2.5 - 5 mg | Hypoglycemia & weight gain. | Same as glimepiride above. |
| Glipizide, extended release (Glucotrol XL) | <ul style="list-style-type: none"> • 5 mg/day at breakfast. • Increase dose by 2.5–5 mg at 3-month intervals, based on A1C. → Use glipizide only if creatinine clearance is ≥10 mL/min. | 20 mg/day | 2.5 mg | Hypoglycemia & weight gain. | Same as glimepiride above. |

(Appendix 7 – page 1 of 4)

| ORAL AGENTS FOR TREATMENT OF TYPE 2 DIABETES — DOSING AND SIDE EFFECTS | | | | | |
|--|---|---|----------------------|---|--|
| Agent | Initial Dose & Treatment | Maximum Dose | Initial Elderly Dose | Side Effects | Drug Interaction |
| Glyburide (DiaBeta, Micronase) | <ul style="list-style-type: none"> 2.5–5 mg/day. Increase dose by 2.5–5 mg no more often than every 7 days. → Use glyburide only if creatinine clearance is ≥ 50 mL/min. | 20 mg/day | 1.25–2.5 mg | Hypoglycemia & weight gain. | Same as glimepiride above. |
| Glyburide, micro-crystalline (Glynase) | <ul style="list-style-type: none"> 1.5–3 mg/day. Increase dose by ≤ 1.5 mg weekly, if needed. → Use glyburide only if creatinine clearance is ≥ 50 mL/min. | 12 mg/day | 1.25 mg | Hypoglycemia & weight gain. | Same as glimepiride above. |
| GLITAZONES (THIAZOLIDINEDIONES OR TZDs) | | | | | |
| Pioglitazone (Actos) | <ul style="list-style-type: none"> 15–30 mg once daily. Increase to 45 mg once daily monotherapy or 30 mg once daily as combo therapy. | 45 mg/day in monotherapy 30 mg/day in combo therapy | 15 mg | Edema, weight gain. → Decreases oral contraceptive efficacy. | Erythromycin; calcium channel blocker; corticosteroids; cyclosporine; HMB-CoA reductase inhibitors; triazolam; trimetrexate; ketoconazole; itraconazole |
| Rosiglitazone (Avandia) | <ul style="list-style-type: none"> 4 mg once daily or 2 mg BID. Increase to 8 mg once daily or 4 mg BID in 12 weeks, as needed. | 8 mg/day | 2 mg | Edema; fluid retention may cause or exacerbate CHF; weight gain; possible increased risk of MI; increased LDL-C. | Same as pioglitazone above. |
| ALPHA-GLUCOSIDASE INHIBITORS | | | | | |
| Acarbose (Precose) | <ul style="list-style-type: none"> 25 mg TID with first bite of meals; lower dose may be needed if gastrointestinal distress is noted. Increase dose to 50 mg TID with meals after 4–8 weeks. | 100 mg TID with meals OR 50 mg TID with meals (in patients ≤ 60 kg) | 25 mg | Diarrhea (33%), abdominal pain (12%), flatulence (77%). → Serum transaminase elevations may occur at doses >50 mg TID. | Absorbents; intestinal agents such as activated charcoal; digestive enzyme preparations containing carbohydrate-splitting enzymes such as amylase or pancreatin |
| Miglitol (Glyset) | <ul style="list-style-type: none"> 25 mg TID at the start of each meal. | 100 mg TID | | Flatulence, diarrhea, abdominal pain. | Digoxin, propranolol, ranitidine, GI enzymes |
| GLINIDES | | | | | |
| Nateglinide (Starlix) | <ul style="list-style-type: none"> 120 mg TID, 1 to 30 minutes before meals. Patients close to A1C goal may be started at 60 mg TID. | 120 mg TID | 60 mg | Hypoglycemia & weight gain | Beta-adrenergic blocking agents; drugs metabolized by the cytochrome p450 system; erythromycin; ketoconazole; miconazole; sulfonamides; MAO inhibitors; NSAIDs; anticoagulants (warfarin derivatives). |

(Appendix 7 – page 2 of 4)

| ORAL AGENTS FOR TREATMENT OF TYPE 2 DIABETES — DOSING AND SIDE EFFECTS | | | | | |
|--|---|---|----------------------|---|---|
| Agent | Initial Dose & Treatment | Maximum Dose | Initial Elderly Dose | Side Effects | Drug Interaction |
| Repaglinide (Prandin) | <ul style="list-style-type: none"> • 0.5 mg with each meal if A1C <8%. • 1–2 mg with each meal if A1C ≥8%. • Increase by 1 mg weekly, as needed. → Contraindicated in moderate-to-severe hepatic dysfunction. | 4 mg with meals (max 16 mg per day) | 0.5 mg | Hypoglycemia & weight gain. | Same as nateglinide above. |
| DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS | | | | | |
| Alogliptin (Nesina) | <ul style="list-style-type: none"> • 25 mg daily. • If CrCl is 30 to 60 mL/min, initial dose is 12.5 mg daily. • If CrCl <30 mL/min, initial dose is 6.25 mg daily. | 25 mg daily | 25 mg daily | Arthralgia, nasopharyngitis, headache, upper respiratory infection. | MAO-Inhibitors, SSRIs, quinolone antibiotics, salicylates. → May require dose reduction of concomitant insulin therapy. Concomitant SU use is not recommended; reduce SU dose if used. |
| Linagliptin (Tradjenta) | <ul style="list-style-type: none"> • 5 mg once daily. | 5 mg daily | 5 mg daily | Same as alogliptin above. | CYP3A4 inducers, MAO-Inhibitors, SSRIs, quinolone antibiotics, salicylates. → May require dose reduction of concomitant insulin therapy. Concomitant SU use is not recommended; reduce SU dose if used. |
| Saxagliptin (Onglyza) | <ul style="list-style-type: none"> • 2.5 to 5 mg once daily. • If CrCl <50 mL/min, 2.5 mg once daily. | 5 mg daily Max dose with strong CYP3A4/5 inhibitors is 2.5 mg daily. | 2.5 mg | Same as alogliptin above. | Same as linagliptin above (drug interactions and cautions in yellow). Potential for additional drug interactions. |
| Sitagliptin (Januvia) | <ul style="list-style-type: none"> • 100 mg once daily. • If CrCl is 30-49 mL/min, dose is 50 mg daily. • If CrCl <30 mL/min, dose is 25 mg daily. | 100 mg | 100 mg | Same as alogliptin above. | Same as linagliptin above (drug interactions and cautions in yellow). |

(Appendix 7 – page 3 of 4)

| ORAL AGENTS FOR TREATMENT OF TYPE 2 DIABETES — DOSING AND SIDE EFFECTS | | | | | |
|--|--|--------------|----------------------|---|---|
| Agent | Initial Dose & Treatment | Maximum Dose | Initial Elderly Dose | Side Effects | Drug Interaction |
| SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT-2) INHIBITORS | | | | | |
| Canagliflozin (Invokana) | <ul style="list-style-type: none"> • 100 mg once daily. • Increase to 300 mg once daily. • If CrCl < 45-60 mL/min, max dose is 100 mg daily. → Do not use if CrCl < 45 mL/min. | 300 mg daily | 100 mg daily | Genitourinary infections, polyuria, hypotension, increased fracture risk. → Ketoacidosis and serious UTI resulting in hospitalization is possible. | Carbamazepine, efavirenz, fosphenytoin, MAO-Inhibitors, phenobarbital, phenytoin, primidone, rifampin, ritonavir, quinolone antibiotics. → Increased risk of hypotension and hyperkalemia with concomitant anti-HTN therapies. |
| Dapagliflozin (Farxiga) | <ul style="list-style-type: none"> • 5 mg once daily. • May increase to 10 mg once daily. → Do not use if CrCl < 60 mL/min. | 10 mg daily | 5 mg daily | Same as canagliflozin above. | MAO-Inhibitors, SSRIs, salicylates, quinolone antibiotics. |
| Empagliflozin (Jardiance) | <ul style="list-style-type: none"> • 10 mg once daily, • May increase to 25 mg daily. → Do not use if CrCl < 45 mL/min. | 25 mg daily | 10 mg daily | Same as canagliflozin above. | Same as dapagliflozin above. |

(Appendix 7 – page 4 of 4)

APPENDIX 8: ALTERNATIVE MEDICATIONS FOR TREATMENT OF TYPE 2 DIABETES

ALPHA GLUCOSIDASE INHIBITORS (AGIs)

- Agents in this category, **ACARBOSE** and **MIGLITOL**, decrease postprandial hyperglycemia by inhibiting carbohydrate digestion and absorption. In order for these medications to be effective, they must be taken 15 minutes before or after the start of a meal.
- AGIs, which reduce A1C levels by only 0.5–1%, are somewhat less effective than sulfonylureas and biguanides in controlling hyperglycemia. An AGI is best used in a combination regimen to treat diabetes; they are particularly useful in patients with predominantly postprandial hyperglycemia (mild fasting hyperglycemia with disproportionately elevated A1C).
- **Side Effects:** Significant gastrointestinal symptoms may occur with AGIs, including flatulence, diarrhea, and abdominal cramps. Symptoms tend to diminish over time and are minimized if therapy is initiated gradually.

CLINICAL PRECAUTIONS:

- *AGIs are contraindicated in patients with cirrhosis or inflammatory bowel disease (e.g., Crohn's disease, ulcerative colitis), or if creatinine >2.0 mg/dl.*
- *Hypoglycemic reactions to acarbose or miglitol therapy must be treated with glucagon or glucose (IV or oral), since oral treatment with sucrose will be blocked by the acarbose or miglitol.*

GLINIDES – NON-SULFONYLUREA SECRETAGOGUES (NON-SUSS) (AKA MEGLITINIDES)

- Drugs in this category, including **REPAGLINIDE** and **NATEGLINIDE**, stimulate insulin secretion from the pancreas, but they have shorter half-lives than the similar-acting sulfonylureas. Therapy with repaglinide reduces A1C levels, comparable to monotherapy with sulfonylureas or metformin; nateglinide is somewhat less effective.
- **Side Effects:** Non-SUS agents can cause weight gain and hypoglycemia, but these adverse effects may be less pronounced than with sulfonylureas.

CLINICAL PRECAUTION: *Because their long-term safety profile has not been determined, non-SUS agents ordinarily should not be used as first-line agents.*

GLUCAGON-LIKE PEPTIDE (GLP)-1 AGONISTS

There are two kinds of glucagon-like peptide (GLP)-1 agonist agents, short-acting and long-acting:

- **Short-Acting:** **EXENATIDE** (Byetta) is the only short-acting GLP-1 agonist approved for use in the United States. It acts as an incretin mimetic, stimulating insulin production in response to high blood glucose levels, inhibiting the release of glucagon after meals, and slowing the rate of gastric emptying. An A1C reduction of 0.5-1% is expected with the use of short-acting GLP-1 agonists.
These medications are approved for use in combination with metformin or a sulfonylurea. Exenatide is administered as a subcutaneous injection in the thigh, abdomen, or upper arm, twice daily within one hour prior to the breakfast and evening meals; it should not be administered after meals. It is supplied in pre-filled syringes that provide 60 doses, and must be kept refrigerated. The pen should be discarded 30 days after the first use.
- **Long-Acting:** There are several approved long-acting GLP-1 agonists, **LIRAGLUTIDE** (Victoza), extended release **EXENATIDE** (Bydureon), **ALBIGLUTIDE** (Tanzeum), and **DULAGLUTIDE** (Trulicity). Liraglutide is injected once daily; the other agents are injected subcutaneously once weekly. An A1C reduction of 0.8-1.9% is expected with the use of long-acting GLP-1 agonists. Long-acting GLP-1 agonists have been studied in combination therapy with metformin and basal insulin.
- **Side Effects:** Administration of GLP-1 agonists can cause significant nausea, vomiting, and diarrhea, which may lead to weight loss. These side effects are more pronounced in short-acting GLP-1 agonists than long-acting GLP-1 agonists. Hypoglycemia may occur when these medications are used with a sulfonylurea; therefore, the dose of the sulfonylurea may need to be decreased when initiating GLP-1 agonists. Since these agents slow gastric emptying, the rate and extent of absorption of orally administered medications may be altered. Other medications should be given at least one hour before GLP-1 agonist administration.

CLINICAL PRECAUTIONS:

- *Exenatide should not be used in patients with creatinine clearance less than 30 mL/min or with end stage renal disease. It should not be used in patients with severe gastrointestinal disease, including gastroparesis. Stop medication in the event of severe abdominal pain.*
- *Exercise caution if using GLP-1 agonists other than exenatide in patients with renal impairment (CrCl <30 mL/min). Limited data is available on their use in patients with renal impairment.*

(Appendix 8 – page 1 of 2)

DIPEPTIDYL PEPTIDASE-4 (DPP-4) INHIBITORS

- Several dipeptidyl peptidase 4 (DPP-4) inhibitors are approved for use in type 2 diabetes: **ALOGLIPTIN** (Nesina), **SITAGLIPTIN** (Januvia), **SAXAGLIPTIN** (Onglyza), and **LINAGLIPTIN** (Tradjenta). DPP-4 inhibitors work as incretin enhancers, slowing the breakdown of endogenous glucagon-like peptide-1 via inhibition of the DPP-4 enzyme. DPP-4 inhibitors have only a modest effect on GLP-1 levels, compared with GLP-1 agonists. The expected reduction in A1C is only 0.6–0.8%.
- DPP-4 inhibitors are given by mouth and are approved for use both as monotherapy and in combination with metformin and/or glitazones.
- **Side Effects:** DPP-4 inhibitors have not been shown to cause weight gain or weight loss, and do not cause hypoglycemia.

CLINICAL PRECAUTIONS:

- *The doses of alogliptin, saxagliptin, and sitagliptin must be modified in patients with renal disease. No dose adjustments are necessary for linagliptin.*
- *Several drug-drug interactions exist for these agents. A thorough review is recommended before adding to the therapy of complex patients.*

SODIUM GLUCOSE COTRANSPORTER-2 (SGLT-2) INHIBITORS

- There are three approved SGLT-2 Inhibitors: **CANAGLIFLOZIN** (Invokana), **DAPAGLIFLOZIN** (Farxiga), and **EMPAGLIFLOZIN** (Jardiance). The SGLT2 inhibitors block glucose reabsorption in the kidney, increasing the amount of glucose excreted in the urine. These oral agents can reduce the A1C up to 1% and can be used in combination with other oral therapies.
- The benefits of SGLT2 inhibitors are weight loss, lower blood pressure, no risk of hypoglycemia, and efficacy at all stages of type 2 diabetes. However, cost is a disadvantage for these therapies.
- **Side Effects:** Side effects include genitourinary infections, frequent urination, and dizziness/hypotension. There are warnings regarding rare, but serious, ketoacidosis.

CLINICAL PRECAUTIONS:

- *Euglycemic ketoacidosis is possible with SGLT-2 inhibitors. The risk of ketoacidosis is higher for patients initiating therapy, those with major illness, or reduced food or fluid intake.*
- *Do not use with reduced renal function. Decreased efficacy and increased side effects are observed in use with CrCl <45 mL/min.*

PRAMLINTIDE

- Pramlintide (Symlin) acts by slowing gastric emptying, preventing an increase in serum glucagon and increasing the feeling of fullness following a meal.
- Pramlintide is an injectable amylin agonist that is only approved for use in patients using insulin. Adding pramlintide to the treatment regimen of a patient who is using insulin is expected to lower the A1C by 0.5–0.7%. Pramlintide is used as adjunctive treatment in patients with type 1 diabetes who use mealtime insulin, and in patients with type 2 who use insulin with or without concurrent sulfonylureas and/or metformin.
- Pramlintide alone does not cause hypoglycemia, but it can cause hypoglycemia when used with insulin. The mealtime preprandial dose of insulin should be reduced when pramlintide is initiated. Prescribing information for pramlintide suggests lowering the mealtime preprandial dose of insulin by 50%.
→ See **BLACK BOX WARNING** below.
- Pramlintide is administered as a subcutaneous injection in the abdomen or thigh, prior to major meals containing at least 250 calories and 30 gm of carbohydrates.
- **Side Effects:** Gastrointestinal adverse effects are common with pramlintide. Nausea, vomiting, and diarrhea may occur and can cause weight loss.

BLACK BOX WARNING:

Symlin is used with insulin and has been associated with an increased risk of insulin-induced hypoglycemia, particularly in patients with type 1 diabetes. When severe hypoglycemia associated with Symlin occurs, it is seen within three hours following a Symlin injection. If severe hypoglycemia occurs while operating a motor vehicle, heavy machinery, or while engaging in other high risk activities, serious injuries may occur. Appropriate patient selection, careful patient instruction, and insulin dose adjustments are critical elements for reducing this risk.

(Appendix 8 – page 2 of 2)

APPENDIX 9: INFECTION CONTROL FOR DIABETES CARE PROCEDURES

The potential for transmission of bloodborne pathogens exists with diabetes care procedures, including insulin administration and capillary blood glucose monitoring. Outbreaks of hepatitis B have been reported in association with blood glucose monitoring in nursing homes. The following infection control procedures should be followed to prevent transmission of bloodborne pathogens in BOP facilities during diabetes care procedures.

DIABETES CARE PROCEDURES AND TECHNIQUES

- Prepare medications such as insulin in a centralized medication area; multiple-dose insulin vials should be assigned only to individual patients and labeled appropriately.
- Never reuse needles, syringes, or lancets.
- Restrict use of fingerstick capillary blood sampling devices to individual patients. Consider selecting single-use lancets that permanently retract upon puncture.
- Dispose of used fingerstick devices and lancets at the point of use in an approved sharps containers.
- Environmental surfaces such as glucometers should be decontaminated regularly and anytime that contamination with blood or body fluids occurs or is suspected.
- Glucometers generally should be assigned to individual patients. If a glucometer that has been used for one patient must be reused for another patient, the device must be cleaned and disinfected. Local facilities should have procedures for decontamination based on the manufacturer's recommendations.
- Any trays or carts used to deliver medications or supplies to individual patients should remain outside patient rooms. Do not carry supplies and medications in uniform pockets.
- Because of possible inadvertent contamination, unused supplies and medications taken to a patient's bedside during fingerstick monitoring or insulin administration should not be used for another patient.

HAND HYGIENE AND GLOVES

- Wear gloves during fingerstick glucose monitoring, administration of insulin, and any other procedure that involves potential exposure to blood or body fluids.
- Change gloves between patient contacts. Before touching clean surfaces, change gloves that have touched potentially blood-contaminated objects or fingerstick wounds.
- Remove and discard gloves in appropriate receptacles after every procedure that involves potential exposure to blood or body fluids, including fingerstick blood sampling.
- Perform hand hygiene (i.e., handwashing with soap and water or use of an alcohol-based hand rub) immediately after removal of gloves and before touching other medical supplies intended for use on other residents.

MEDICAL MANAGEMENT

- Review regularly the individual patients' schedules for fingerstick blood glucose sampling and insulin administration and reduce the number of percutaneous procedures to the minimum necessary for appropriate medical management of diabetes and its complications.
- Assure that adequate staffing levels are maintained to perform all scheduled diabetes care procedures, including fingerstick blood glucose monitoring.
- Consider the diagnosis of acute viral hepatitis infection in inmates with diabetes who develop an illness that includes hepatic dysfunction or elevated aminotransaminase levels (AST or ALT).

(Appendix 9 – page 1 of 2)

TRAINING AND OVERSIGHT

- Provide a full hepatitis B vaccination series to all previously unvaccinated correctional facility health care workers.
- Establish responsibility for oversight of infection control activities. Investigate and report any suspected case that may represent a newly acquired bloodborne infection.
- In accordance with BOP policy, maintain control of sharps and lancets in the work area.
- Have staff demonstrate knowledge of standard precautions guidelines, as well as proficiency in the application of these guidelines during procedures that involve possible exposure to blood or body fluid.
- For staff members who assume responsibilities involving percutaneous procedures, provide infection control training that includes practical demonstration of aseptic techniques and instruction regarding reporting exposures or breaches. Provide annual retraining to all staff members who perform procedures that involve exposure to blood or body fluids.
- Assess compliance with infection control recommendations for fingerstick glucose monitoring (such as hand hygiene and glove changes between patients) by periodically observing personnel and tracking use of supplies.

Adapted from:

CDC. Transmission of hepatitis B virus among persons undergoing blood glucose monitoring in long-term-care facilities — Mississippi, North Carolina, and Los Angeles County, California, 2003–2004. *MMWR* 2005;54(09):220–223. Available from: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5409a2.htm>

(Appendix 9 – page 2 of 2)

APPENDIX 10: RESOURCES FOR INFORMATION ON DIABETES

American Diabetes Association

<http://www.diabetes.org>

800-342-2383

American Dietetic Association

<http://www.eatright.org>

800-366-1655

Centers for Disease Control and Prevention

<http://www.cdc.gov/diabetes>

877-232-3422

**Lower Extremity Amputation Prevention
Program (LEAP),
Health Resources & Services Administration
(HRSA)**

<http://www.hrsa.gov/leap/>

**National Institute of Diabetes and Digestive
and Kidney Diseases (NIDDK)**

<http://www.niddk.nih.gov>

800-860-8747

National Kidney Foundation

<http://www.kidney.org>

800-622-9010

APPENDICES 11–13: INMATE HANDOUTS

The following Appendices are designed as handouts for BOP inmates:

Appendix 11: Fact Sheet on Type 2 Diabetes

Appendix 12: The Three Keys to Controlling Your Diabetes

Appendix 13: Eating to Manage Your Diabetes in the Bureau of Prisons

APPENDIX 11: FACT SHEET ON TYPE 2 DIABETES

1. What is diabetes?

Diabetes is a chronic disease that can be controlled by a combination of diet, exercise, and medical care. People with diabetes have too much sugar (glucose) in their blood—sugar builds up in the blood instead of going into the cells.

2. What are the symptoms of diabetes?

Most people with diabetes may not notice any symptoms at first. However, some symptoms of diabetes are:

- ▶ Frequent urination
- ▶ Increased thirst and increased hunger
- ▶ Unexplained weight loss
- Weakness, fatigue, drowsiness
- Wounds and cuts that heal slowly
- Blurred vision or changes in vision

3. What puts you at risk for diabetes?

- ▶ You are age 45 and older.
- ▶ You are a member of a high-risk ethnic group (African American, Hispanic/Latino, American Indian, Asian American, or Pacific Islander).
- ▶ You are overweight.
- ▶ You have high blood pressure (at or above 140/90).
- ▶ You have a family history of diabetes.
- ▶ You have a history of diabetes during pregnancy.
- ▶ You weighed more than nine pounds at birth.

4. What are the possible complications of diabetes?

- ▶ Eye damage – poor vision, retina damage, cataracts, glaucoma, blindness
- ▶ Kidney damage – progressive failure, which may require hemodialysis or organ transplantation
- ▶ Heart problems – damaged blood vessels, which may lead to heart attacks and strokes
- ▶ Nerve damage – problems with nerve sensations and with moving muscles; loss of reflexes
- ▶ Decreased ability to fight infections
- ▶ Sores and ulcers of the legs and feet

5. How is diabetes controlled? And why is it important to control it?

Diabetes is controlled by a combination of diet, exercise, and medication. The goals are to **(1)** keep your blood sugar near normal, **(2)** control your blood pressure, **(3)** lower your cholesterol and fat levels, and **(4)** lose weight or maintain a healthy weight. Research shows that keeping blood sugar as near to normal as possible means fewer complications from the disease. Strict control of blood sugar helps to prevent kidney failure, amputations, blindness, heart attacks, and stroke.

6. What are the symptoms of blood sugar that is too low (hypoglycemia)?

- ▶ Shakiness
- ▶ Sweating and clammy feeling
- ▶ Extreme fatigue
- ▶ Hunger
- Irritation or confusion
- Rapid heart rate
- Blurred vision

APPENDIX 12: THE THREE KEYS TO CONTROLLING YOUR DIABETES

Years ago, the diabetic diet was strict and boring. Today, you do not need special foods. In fact, the foods that are good for you are actually good for everyone. Diabetes cannot be cured, but it can be controlled so that you can lead a normal life. Keeping good control of your diabetes helps to delay or even prevent possible complications.

There are three keys to controlling diabetes: diet, exercise, and medication.

All three are equally important. Eating the right foods and limiting how much you eat, along with regular exercise, help you achieve and maintain a healthy weight. Keeping good control of your blood glucose also requires that your food intake and your level of activity balance with the medication you are taking.

Follow these steps to maintain a healthy weight *and* good blood glucose control:

- **Eat a wide variety of foods every day.** Increase high-fiber foods such as grains, beans, vegetables, and fruits to fill you up.
- **Limit concentrated sweets** such as sugar, honey, jelly, syrup, cakes, cookies, candy, ice cream, pies, pastries, regular soda, and other sugary drinks. Concentrated sugars do not cause diabetes, and you don't need to avoid them totally. However, they are very high in calories—and the more calories you eat, the higher your blood glucose!
- **Limit fats** such as butter, margarine, cheese, fried foods, cream soups, gravy, salad dressings, mayonnaise, and breakfast meats (bacon, sausage, etc.). Limiting fats will help you keep your calories down, as well as helping you control your cholesterol levels.
- **Control portion sizes.** Too much of even the right foods can also cause high blood glucose. If you want to lose weight, cut down on portion sizes.
- **Never skip meals.** Eat all three meals and include snacks as needed. Eat your meals at about the same time every day.
- **Exercise.** Increase your activity level (as permitted by your doctor). This will decrease your blood glucose level.
- **Monitor your weight.** Weigh yourself only once a week to determine if your diet is effective. If you are overweight, a weight loss of 1–2 pounds per week is a good goal.
- **Take medication as directed.** If you take pills or insulin injections for your diabetes, always take your medication as your doctor has recommended. Feel free to ask about the possible side effects of your medications.

APPENDIX 13: EATING TO MANAGE YOUR DIABETES IN THE BUREAU OF PRISONS

The **heart-healthy** food options that are offered on the BOP National Menu should be “at the heart” of your diabetes management plan. These foods are **(1)** lower in calories to help with weight management, **(2)** lower in sodium to help with blood pressure control, and **(3)** lower in fat to help manage cholesterol levels.

Do you take diabetes medication? Be consistent with your carbohydrates.

If you take diabetes pills that help your body make more insulin, or if you take set doses of insulin every day, eating consistently makes it easier for you to gain control of your blood glucose. Eating similar amounts of carbohydrates at meals and snacks, from one day to the next, can help you keep your blood glucose in a healthy range.

Five Steps for Counting Your Carbohydrates:

Step 1: Know which foods have carbohydrates.

Foods with the most carbohydrates include:

- Breads, crackers, and cereals
- Pasta, rice, and grains
- Starchy vegetables such as potatoes, corn, and peas
- Beans, lentils, and other legumes
- Milk and yogurt
- Fruits and fruit juice
- Sweets such as cakes, cookies, and pastries
- Regular sodas and other sugary drinks

Step 2: Know your carbohydrate and blood glucose goals.

Your carbohydrate goals depend on the diabetes medications and/or insulin you use, your body weight, and how active you are.

- In diabetes meal planning:
1 serving/choice of a food with carbohydrate = about 15 grams of carbohydrate
- A general rule of thumb:
Men: 4 to 5 carbohydrate servings/choices (60 to 75 grams) at each meal
Women: 3 to 4 carbohydrate servings/choices (45 to 60 grams) at each meal
- If you eat snacks, choose foods that are 1 to 2 carbohydrate servings/choices (15 to 30 grams).
- **If you take insulin or diabetes medications that may cause low blood sugar, do not skip meals!**

(continued on next page)

Step 3: Read and understand the “Nutrition Facts” on food labels.

The “Nutrition Facts” on food packages lists how many grams of carbohydrate are in a standard serving of that particular food. However, you will still need to figure out how many carbohydrate servings (15 grams of carbohydrate) are in that standard serving of food.

- Look first at the label’s standard **Serving Size**.
- Then, check the grams of **Total Carbohydrate** in a standard serving size.
In this example, there are 10 grams of carbohydrate in a standard serving (1 cup) of this food.
- Divide the grams of **Total Carbohydrate** by 15. This number equals the number of carbohydrate servings in a standard serving of this food.
In this example, divide 10 by 15 = 2/3. So, if you ate one cup of this food, you would have eaten 2/3 of a carbohydrate serving.
- **Note:** You may ignore the grams of **Sugars** on the “Nutrition Facts” panel because they are already included in the grams of **Total Carbohydrate**.

| Nutrition Facts | |
|---|--------------------------------|
| Serving Size 1 cup (4 oz) | |
| Serving Per Container 3 | |
| Amount Per Serving | |
| Calories 75 Calories from Fat 27 | |
| | % Daily Value* |
| Total Fat 3 g | 5% |
| Saturated Fat 0 g | 0% |
| Cholesterol 0 mg | 0% |
| Sodium 300 mg | 4% |
| Total Carbohydrate 10 g | 3% |
| Dietary Fiber 5 g | 20% |
| Sugars 3 g | |
| Protein 2 g | |
| Vitamin A 80% - Vitamin C 60% - Calcium 4% - Iron 4% | |
| * Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs: | |
| | Calories: 2,000 2,500 |
| Total Fat | Less than 65g 80g |
| Sat Fat | Less than 20g 25g |
| Cholesterol | Less than 300mg 300mg |
| Sodium | Less than 2,400mg 2,400mg |
| Total Carbohydrate | 300g 375g |
| Dietary Fiber | 25g 30g |
| Calories per gram: | |
| Fat 9 • Carbohydrate 4 • Protein 4 | |

Step 4: Write down your food intake and your blood glucose levels.

Keep a food record that lists (1) each time you eat a meal or a snack, (2) your food choices, and (3) the amounts of each food. The more days and meals you can record, the more information you will have about how different amounts of carbohydrates affect your blood glucose, allowing you and your doctor to make adjustments in your diet as needed.

Step 5: Review your records.

If you are above your blood glucose target: Check the carbohydrates in your last meal or snack to see which foods or amounts may have caused your blood glucose to be too high. If you are below your blood glucose target, you may have not eaten enough carbohydrates.

Remember: Any blood glucose below 70 mg/dl must be treated immediately.

Sources:

Academy of Nutrition and Dietetics (formerly the American Dietetic Association), Diabetes Care and Education Practice Group. *Carbohydrate Counting: Focus on Consistency for People Who Use Diabetes Pills and Basic Insulin Regimens* [patient handout]. 2008.

Academy of Nutrition and Dietetics (formerly the American Dietetic Association). Carbohydrate counting for people with diabetes. *Nutrition Care Manual*.