
STANDARD NURSE PROTOCOL FOR DIABETES MELLITUS IN ADULTS

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DEFINITION

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action or both. Diabetes is characterized by fasting plasma glucose (FPG) **equal to or greater than 126 mg/dL** or random plasma glucose **equal to or greater than 200 mg/dL** (with testing on two separate days) accompanied by symptoms. Symptoms of diabetes mellitus are frequently due to the osmotic diuresis associated with hyperglycemia. Complications of diabetes may be acute and/or chronic. Acute complications include: hyperglycemia, hypoglycemia, diabetic ketoacidosis (**DKA**) and **hyperosmolar hyperglycemic syndrome (HHS)**. The chronic complications of diabetes are most often the result of sustained hyperglycemia and include damage, dysfunction and failure of various organs, such as eyes, kidneys, nerves, heart and vascular system.

ETIOLOGY

Type 1 Diabetes Mellitus

1. Cause: inadequate or absolute lack of insulin production secondary to destruction of the pancreatic Beta cells. Individuals are dependent on exogenous insulin for survival. Type 1 comprises less than 10% of all cases of diabetes.
2. Contributing factors:
 - a. Autoimmune mediated response.
 - b. Idiopathic (No evidence of autoimmunity is present).

Type 2 Diabetes Mellitus

1. Cause: combination of insulin resistance **and/or inadequate insulin production. Increased hepatic glucose production contributes to elevated fasting blood glucose levels. Insulin resistance in the liver and muscle and impaired insulin secretion also contribute to hyperglycemia.**
2. Risk factors:
 - a. Overweight - BMI **equal to or greater than 25 kg/m² and BMI equal to or greater than 23 kg/m² for Asian Americans.**
 - b. Waist circumference **greater than 102cm** (40 inches) for men and **greater than 88cm** (35 inches) for women.
 - c. **Sedentary lifestyle, such as sitting for more than 90 minutes at a time or little to no moderate to vigorous activity in the past 30 days.**
 - d. Age **equal to or greater than 45 years old.**

- e. First degree relative with diabetes.
- f. Race – African-American, Latino, Native American, Asian and Pacific Islander at greater risk.
- g. History of large birth-weight babies – **greater than 9 pounds or history of** diagnosed with gestational diabetes.
- h. History of **A1C equal to or greater than 5.7%, impaired glucose tolerance- 2 hour plasma glucose in 75 –g Oral Glucose Tolerance Test of 140 mg/dL to 199 mg/dL or fasting plasma glucose of 100 mg/dL to 125 mg/dL.**
- i. Hypertensive -**blood pressure equal to or greater than 140/90 mmHg or on therapy for hypertension.**
- j. HDL cholesterol level **less than 35mg/dL** and/or triglyceride level **greater than 250mg/dL.**
- k. **Women with polycystic ovary syndrome.**
- l. **Clinical conditions associated with insulin resistance, such as severe obesity and acanthosis nigricans.**
- m. **History of cardiovascular disease.**

Prediabetes

1. **Patient's blood glucose levels do not meet criteria for diagnosis of diabetes but blood glucose levels are higher than what is considered normal glucose levels.**
2. **Patients who should be screened are those at any age who are overweight or obese (BMI equal to or greater than 25 kg/m² or equal to or greater than 23 kg/m² in Asian Americans) or present with the same risk factors for Type 2 diabetes as listed in the preceding section.**
3. Patients are asymptomatic but at high risk for developing cardiovascular disease and diabetes.
4. **A1C is 5.7-6.4%**
5. Impaired fasting glucose is 100-125 mg/dL.
6. Plasma glucose at 2 hour oral glucose tolerance test (75-gram) between 140-199 mg/dL **is considered Impaired Glucose Tolerance (IGT).**
7. **Impaired fasting glucose and IGT are not clinical entities but are risk factors for diabetes and cardiovascular disease and are associated with obesity, especially abdominal or visceral obesity, dyslipidemia, high triglyceride levels and/or low-density lipoprotein cholesterol, and hypertension.**

Gestational Diabetes (GDM)

1. **Patients who are pregnant, planning to become pregnant, or breast-feeding must be referred to an obstetrician for management of diabetes.**

2. In the past, Gestational Diabetes was defined as any degree of glucose intolerance that was first recognized during pregnancy. It did not matter if the condition may have predated the pregnancy or persisted after the pregnancy. If it persisted post-pregnancy, it was re-classified according to the diagnostic criteria.
3. The epidemic of obesity and more type 2 diabetes in women of child-bearing age has resulted in an increase number of pregnant women with undiagnosed type 2 diabetes.
4. It is now recommended that women with risk factors for Type 2 diabetes be tested on the initial prenatal visit using standard diagnostic criteria.
5. Women with diabetes in the first trimester are classified as having type 2 diabetes. GDM remains as diabetes diagnosed during the second or third trimester when it is clear that it is not overt diabetes.

SUBJECTIVE

1. Patient history may or may not reveal the following:
 - a. Symptoms of hyperglycemia-polyuria, polydipsia, polyphagia, blurry vision, extreme fatigue, slow healing, and or tingling, and pain or numbness in feet and hands (primarily type 2)
 - b. Unexplained weight loss or gain.
 - c. Previously diagnosed with “borderline diabetes” or pre-diabetes, gestational diabetes or impaired glucose tolerance.
 - d. Past or current symptoms of coronary heart disease, heart failure, cerebrovascular disease, peripheral vascular disease, renal disease, gout or sexual dysfunction.
2. The patient, **primarily those with type 2 diabetes**, may be asymptomatic. Elevated glucose levels are often found in routine lab work, during evaluations for surgery or work-up for other conditions. Patients suspected to have type 1 diabetes may report rapid onset of symptoms.
3. There may or may not be a family history or obvious risk factors.
4. The following should be **assessed** and documented in chart:
 - a. Current diabetes self-management routine, if previously diagnosed, to include:
 - 1) **Duration of diabetes, including age and characteristics of onset, such as diabetic ketoacidosis (DKA) or asymptomatic.**
 - 2) **Current and prior medications for diabetes.**

- 3) **Eating patterns, weight history, and nutritional status.**
 - 4) **Prior self-management education/training.**
 - 5) **Self-monitoring of blood glucose (SMBG) pattern and results and A1C results if available.**
 - 6) **Current physical activity-type, frequency, duration.**
 - 7) Frequency of usage and indications for OTC medications, prescriptions, and alternative medications, home remedies, nutritional supplements.
- b. **Acute complications-severe hyperglycemia, DKA, severe hypoglycemia requiring assistance of another, hypoglycemia unawareness. Prior emergency room visits and hospitalizations related to diabetes.**
 - c. History of infections-**type, treatment, resolution time.**
 - d. Family history of diabetes, **chronic kidney disease, premature cardiovascular disease.**
 - f. CHD risk factors-**hypertension, abnormal lipids, high sodium intake, tobacco use, prior myocardial infarction, coronary revascularization, heart failure, stroke, transient ischemic attacks, peripheral arterial disease, sleep apnea.**
 - g. **History of target organ damage: retinopathy (visual disturbances/changes- loss or fluctuation of visual acuity, blurry vision, floaters or history of cataracts, macular degeneration, or ophthalmic procedures); nephropathy (history of renal disease, ankle edema, fatigue, hypertension); peripheral (stocking and glove pattern of numbness, tingling, pain or weakness) and/or autonomic neuropathy (resting tachycardia, fixed heart rate, postural hypotension, syncope, urinary frequency, urgency, incontinence, male or female sexual dysfunction, gastrointestinal complaints such as nausea, vomiting, early satiety, abdominal bloating, and weight loss.).**
 - h. **History of foot ulcers and deformities.**
 - i. **Psychosocial and social situation, including economic factors.**
 - j. **Smoking or other tobacco use including e-cigarettes, alcohol and recreational drug use.**
 - k. Female reproductive history: menstrual history, method of contraception, pregnancies and outcomes.
 - l. **Current immunization status.**

OBJECTIVE 1. Physical examination

- a. Appearance

- 1) Type 1 = Thin, ill appearance, dehydrated, may have had significant weight loss.
 - 2) Type 2 = Frequently overweight or obese.
- b. Height, weight and BMI.
 - c. Routine assessment of blood pressure (standing and sitting or sitting and lying) to assess for **dehydration and autonomic neuropathy**. Blood pressure may be greater than 140/90 mmHg.
 - d. Extremities - assess patient extremities for changes in color, deformity, injury, sensation, temperature changes, muscle strength and deep tendon reflexes (use a 128-Hz tuning fork and a monofilament).
 - e. Mouth - assess for gum problems, tooth decay and oral candidiasis.
 - f. **Visual acuity-assess using Snellen Chart.**
 - g. Arterial Pulses – Palpate and auscultate pulses.
 - h. **Neurological and foot examination including inspection, palpation of dorsalis pedis and posterior tibial pulses, nails for thickening, signs of fungal or bacterial infections, and signs of compromised blood flow. Assess for decreased or absent deep tendon reflexes, numbness or burning sensation or sensory loss may be present.**
 - i. Neck - Palpate the thyroid for an enlarged thyroid. Assess for hoarseness and difficulty swallowing.
 - j. Skin - Inspect for sites of previous insulin injections, shiny spots over tibial bones, loss of hair over lower legs and toes, ulcerations of feet/legs, carbuncles and ulcers, lipohypertrophy or lipoatrophy at insulin injection sites. **In type 2 diabetes early hyperinsulinemia may be evidenced by Acanthosis Nigricans around the neck, waist, inguinal and axillary skin folds (dark velvety hyperpigmentation).**
 - k. Cardiovascular – Auscultate the heart for heart rate, rhythm and sounds. Assess for orthostatic hypotension, hypertension, decreased capillary refill, absent pedal pulses, impaired circulation.
 - l. Abdomen - Perform abdominal exam. Palpate for an enlarged liver.
 - m. Inspect the hands for mobility and deformities.
2. Diagnostic laboratory findings (Non-Pregnant Adults)
 - a. **Confirmed A1C equal to or greater than 6.5%**
OR
 - b. Confirmed fasting plasma glucose level **equal to or greater than 126 mg/dL** on at least two different occasions (on subsequent days).

OR

- c. Confirmed random plasma glucose level **equal to or greater than 200 mg/dL** (with classic symptoms of diabetes), on two different occasions.

ASSESSMENT Diabetes Mellitus (Type 1 or Type 2)

PLAN **DIAGNOSTIC AND FOLLOW-UP STUDIES**

Inform the patient of the importance of abnormal results and follow-up and referrals. If a service is not available in the clinic, the patient should be given resource/referral information that must be appropriately documented in the patient's record. The patient's follow-through on the recommendations should be documented at the next visit.

1. A1C – **Initially and** every six months for well controlled patients on diet therapy or oral medication. Every three months for patients poorly controlled or when medications have been changed. **A1C target goals should be individualized based on patient desires, values, and willingness to participate in management, potential risks of hypoglycemia and other adverse events, patient's age and duration of diabetes, comorbidities and established vascular complications. Treatment goal is generally <7%, however, any lowering of A1C levels has benefit.**
2. Initial lipid profile.. **Lipid management is an integral part of diabetes management. Lipid management is addressed in appendix F.**
3. **Metabolic profile initially and annually.**
4. Serum creatinine, potassium, and sodium **or more frequently based on medication profile.**
5. ECG annually (or as indicated).
6. **Annual dilated eye exam.**
7. **Spot urine for albumin to creatinine ratio.**
8. **TSH as indicated by findings on physical examination or suggestive history.**
9. **Annual dental examination.**
10. Weight and calculation of BMI on each visit; height annually.
11. Referral to other specialties and services as needed.
12. Urine cultures as indicated. Urinalysis for ketones, protein and sediment.
13. **Refer women of reproductive age to Women's Health.**

THERAPEUTIC

NON-PHARMACOLOGIC

1. **A patient-centered approach is highly recommended in the care of patients with diabetes. It is defined in articles by the**

American Diabetes Association (see references) as “providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.”

- 2. Diabetes Self-Management Education/Training (DSME/DSMT) is considered an essential element for persons with diagnosed diabetes. DSME/T provides the knowledge, skills and support necessary for diabetes self-care. Refer to the Patient Education Counseling Section for specific components of DSME and DSMT. For Medicare reimbursement, DSMT coding must be used.**
- 3. For patients with prediabetes, the goals are to decrease the risk of diabetes and cardiovascular disease through intensive lifestyle interventions through participation in lifestyle change programs to promote and maintain moderate weight loss (7% of body weight).**
 - a. Promote healthy food choices with consistency in day-to-day carbohydrate intake and the limitation of sucrose-containing and high glycemic index foods. The Dietary Approaches to Stop Hypertension (DASH) Eating Plan can be used as a basis for meal planning to help manage blood glucose, blood pressure and cholesterol.**
 - b. Increase physical activity to at least 150 minutes per week of moderate-intensity aerobic activity such as walking.**
 - c. Patients with prediabetes should be referred to lifestyle change programs or Diabetes Prevention Programs.**
- 4. Nutrition Therapy-Evidence suggests that there is no ideal percentage of calories from carbohydrate, protein and fat for all persons with diabetes. More emphasis is placed on a pattern approach rather than specific macronutrient and micronutrient recommendations. Macronutrient distribution should be based on individualized assessment of current eating patterns, preferences and metabolic goals. The goals of nutrient therapy are:**
 - a. Promote and support healthful eating patterns.**
 - b. Attain glycemic, blood pressure and lipid goals.**
 - c. Achieve and maintain body weight goals.**
 - d. Delay or prevent complications of diabetes.**
 - e. Address individual nutrition needs based on personal and cultural preference, access to healthy food choices, willingness and ability to make behavior changes, and barriers to change.**

- f. **Maintain pleasure of eating by providing positive messages about food choices while limiting food choices only when indicated by scientific evidence.**
 - g. **Provide patients with practical tools for day-to-day meal planning. A variety of meal planning tools, DASH Eating Plan, Therapeutic Lifestyle Changes Diet, USDA Choose My Plate, Mediterranean style, and vegetarian and vegan eating plans may be used.**
5. **Physical activity has been shown to improve blood glucose control by decreasing insulin resistance and increasing metabolism, reducing cardiovascular risk factors, contributing to weight loss and improved sense of well-being.**
- a. **Patients should reduce sedentary time by breaking up extended amounts of time (greater than 90 minutes) sitting.**
 - b. **Adults should be advised to perform at least 150 minutes per week of moderate-intensity aerobic physical activity spread over at least 3 days per week with no more than 2 consecutive days without exercise.**
 - c. **Adults should do muscle strengthening activities that involve all major muscle groups 2 or more days per week.**
 - d. **Patients over the age of 65 or those with disabilities should follow the above guidelines to the extent possible, and if not possible, they should be as physically active as possible.**
 - e. **Consideration of existing diabetes related health issues identified during the patient's assessment, such as cardiovascular disease, hypertension, peripheral and/or autonomic neuropathy, and microvascular changes, should be considered when recommending a physical activity program.**
6. **Monitoring**
- a. **Self-Monitoring of Blood Glucose (SMBG):**
 - 1) **Used to assess effectiveness of meal plan, exercise and medication.**
 - 2) **Patients with Type 2 diabetes being treated with medication should perform SMBG on a regular, consistent basis until blood glucose targets are reached. One example of a testing schedule is performing a fasting and one other test during the day on an alternating routine, such as pre-**

meal testing on alternate days (pre-lunch one day, pre-evening one day and at bedtime on the third day). If fasting and pre-meal values are within target values but A1C values do not correlate, post-prandial blood glucose values may provide guidance in reviewing composition and portion sizes of meals. Once 50% of blood glucose values are within target blood glucose range, SMBG frequency can be modified to treatment (e.g., meal planning only, 2-3 times per week; oral medications once per day on alternating fasting and pre-meal schedule). Frequency of monitoring may depend on patient's willingness and physical ability to perform SMBG, financial resources, comorbid conditions and ability to take action when abnormal values occur.

- 3) Individualized target blood glucose ranges are based on treatment regimen, age, and presence of complications such as hypoglycemia unawareness. The recommended target goals for most patients: pre-meal glucose between 80-130 mg/dL and peak post-prandial glucose less than 180mg/dL. Discuss target glucose levels with the patients and have them write down their target glucose levels in their logbook.
 - 4) The patient's SMBG records should be reviewed on each visit to identify patterns of blood glucose levels to consider adjustments in the management plan. Provide the patient with feedback to support and encourage continued monitoring as well as behavior and lifestyle changes.
 - 5) Additional testing may be indicated during times of stress, especially infection/illness.
- b. **A1C testing, which reflects average blood glucose concentration over the past 90-120 days, should be performed at least two times per year in patients meeting target treatment goals and quarterly in patients whose therapy is changed or who are not meeting treatment goals. Reduction of A1C to 7% or less has been shown to reduce microvascular complications and long-term reduction in macrovascular disease.**
- c. **Weight monitoring-Weight loss has been shown beneficial for persons with diabetes, particularly type 2 diabetes, to reduce insulin resistance. Nutritional**

interventions and increase physical activity can promote controlled weight loss. Unintentional weight loss may occur as a result of uncontrolled hyperglycemia or other underlying causes. Weight gain should be monitored and possible reasons explored, such as medications and need for additional nutritional counseling.

- d. Regularly assess for cardiovascular risk factors and the presence of macrovascular disease.**
 - 1) See Appendix F for lipid management guidelines.**
 - 2) Monitor blood pressure and insure that hypertension is being treated to target goal of systolic blood pressure less than 140 mmHg and diastolic blood pressure less than 90 mmHg.**

3)

Assess for symptoms of macrovascular disease:

- a) chest pain**
 - b) decreased tolerance for physical activity**
 - c) chronic fatigue**
 - d) shortness of breath**
 - e) swelling of feet and ankles**
 - f) sudden numbness or weakness on one side of the body**
 - g) inability to walk or weakness, paralysis on one side of the body**
 - h) pain in the calves when walking or pain in feet when at rest**
 - i) coolness of lower extremities**
- e. Smokers, e-cigarette users, or other nicotine users- Utilize Ask, Advise and Refer (AAR) model and provide cessation counseling and referral to the Georgia Quit Line 1-877-270-STOP (7867) using the Quit Line Fax Back Form as appropriate.**
- f. Foot evaluation and care-Early recognition and appropriate management of patients with insensate feet is important to reduce risk of amputation.**
 - 1) All patients with diabetes should have an annual comprehensive foot examination as described in the Objective Section. Patients with insensate feet, foot deformities, ulcers and complaints of numbness and/or burning, should, at minimum, have a visual inspection of their feet at each visit.**

- 2) All patients should receive general foot care instructions. Patients with neuropathy, insensate feet, history of foot ulcers, or deformities as well as those with visual impairment, should be given enhanced foot care instructions and/or referral to a specialist or podiatrist. See Patient Education/Counseling Section for additional information.
- g. Psychological assessment and care-Depression is not uncommon in persons with diabetes and may affect a patient's ability to perform self-management activities.
- 1) Patients should routinely be asked how diabetes and its care is impacting their lives, if they are feeling anxious, down or helpless, changes in sleep patterns, and additional financial burden of diabetes.
 - 2) The Patient Health Questionnaire (PHQ)-9 is a brief depression self-report scale that is a useful screening tool and can be found at:
[http://phqscreeners.com/pdfs/02 PHQ-9/English.pdf](http://phqscreeners.com/pdfs/02_PHQ-9/English.pdf).
 - 3) Referral to mental health resources may be appropriate for patients who might benefit from a more comprehensive evaluation and when poor glycemic control persists despite ongoing adjustments in management regimen.
- h. Dental patients with diabetes, especially if poorly controlled, are at greater risk for periodontal disease. This can lead to difficulty chewing, pain, possible loss of teeth, and persistent bad breath. Patients should brush and floss daily, regular visits to a dentist, good glucose control, and avoidance of tobacco products.
- i. Immunizations are important preventive services for persons with diabetes to reduce diabetes-related hospitalizations and to prevent morbidity and mortality.
- 1) Provide routine vaccinations as for the general population
 - 2) Annual flu vaccinations
 - 3) Administer pneumococcal poly-saccharide vaccine23 (PPSV23) to all patients with diabetes
 - 4) Adults 65 years of age or greater, if not previously vaccinated should receive pneumococcal conjugate13 (PCV 13) vaccine

- followed by PPSV23 within 6-12 months after initial vaccination.
- 5) Adults 65 years of age or greater, if previously vaccinated with PPSV23 should also receive a PCV13 vaccine no sooner than 12 months after receiving PPSV23.
 - 6) Administer hepatitis B vaccine to unvaccinated adults, aged 19-59 years, with diabetes. Consider administering hepatitis B vaccination at the discretion of the treating clinician to unvaccinated persons aged equal to and older than 60 years.

Pharmacologic- Diabetes Medication Management, Type 2 Diabetes

In patients with markedly symptomatic and/or elevated blood glucose levels (≥ 300 - 350 mg/dL) or A1c (≥ 10 - 12 %) consider initiating insulin therapy. If insulin therapy is indicated please refer these patients to an outside provider.

Note: Be familiar with local discount drug programs and keep an up-to-date list (may change frequently). To the extent possible, order medications from these lists. Consult with the delegating physician as appropriate.

1. **Monotherapy- Metformin is the preferred first agent, unless it is contraindicated or not tolerated.**
 - a. **Biguanides: Metformin (Glucophage):**
Mechanism of action: Inhibits hepatic glycogenolysis and gluconeogenesis. Enhances insulin sensitivity in muscle and fat.
 - 1) **Efficacy: 1-1.5 % ↓ A1c; Greater effect on FPG>PPG**
 - 2) **Side effects: Gastrointestinal , Lactic acidosis (rare), Vitamin B12 deficiency**
 - 3) **Contraindications: Avoid in renal impairment (Men: SCr ≥ 1.5 mg/dL, Women: SCr ≥ 1.4 mg/dL)**
 - 4) **Advantages: No weight gain, No hypoglycemia**
 - 5) **Cost: Low**
 - 6) **Dosing: Take with meals; Due to GI side effects start once daily and titrate up as tolerated (500 mg per week or 850 mg increases every 2 weeks)**
 - 7) **Elderly patients should not be titrated to maximum dose**

Drug	Initial Dose	Max Dose	Supplied
Metformin (Glucophage)	500 mg once or	2000 mg	500, 850, 1000 mg tab

	twice daily with meals		ER: 500, 750 mg tab
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- b. A sulfonylurea or meglitinide (see below) may be used as first line therapy in patients unable to take Metformin.

Considerations: Consider adding additional agents if A1C goal is not reached after 3 months of monotherapy OR if A1C is equal to or greater than 9%. Please see list below for additional agents.

2. Dual therapy: Sulfonylureas, DPP-4 inhibitor, meglitinides may be added as second line therapy. Use appropriate monitoring of FPG and A1C measurements to ensure that the patient is not subjected to excessive drug exposure or increased probability of secondary drug failure. If glucose targets are not achieved after a suitable trial of combination therapy and lifestyle changes, consider discontinuing these drugs and refer to an outside provider for initiation of insulin therapy.

a. **Sulfonylureas (SU):**

Mechanism of action: Stimulates pancreatic insulin secretion.

- 1) **First generation: Not recommended in current guidelines (Chlorpropamide, Tolbutamide)**
- 2) **Second generation agents: Glimepiride (Amaryl); Glipizide (Glucotrol); Glyburide (DiaBeta, Micronase).**
 - 1) **Efficacy: 1-2% ↓ A1c; ↓PPG, reduced efficacy over time.**
 - 2) **Side effects: Hypoglycemia, Weight gain**
 - 3) **Contraindications: Avoid in poor renal function**
 - i) **Glimepiride: CrCl less than 30 ml/min**
 - ii) **Glipizide: CrCl less than 10 ml/min**
 - iii) **Glyburide: CrCl less than 50 ml/min**
 - 4) **Cost: Low**
 - 5) **Dosing: Do not cut/crush/chew Extended Release (ER) formulations;**
 - i) **Glimepiride daily dose may be increased by 1-2 mg at weekly or bi-weekly intervals.**
 - ii) **Glipizide doses greater than 15 mg/day should be given in divided doses. Extended Release is dosed once daily. Titration of dose if**

- needed should be no more frequently than every 7 days. Elderly patients initial dosing of 2.5 mg and titrating at 1 to 2 week intervals.
- iii) Glyburide should be titrated as needed at 2.5 mg daily at weekly intervals. Use conservative initial and maintenance doses in elderly patients.

Drug	Initial Dose	Max Dose	Supplied
Glimepiride(Amaryl)	1-2 mg daily give with first main meal	8 mg	1, 2, 4 mg tab
Glipizide(Glucotrol) Glipizide XL	5 mg once or twice daily 30 minutes before meals (once for ER formulation) Extended Release: 5 mg once daily	40 mg (max effective dose = 20 mg) Extended Release: 20 mg/day	5, 10 mg tab ER: 2.5, 5, 10 mg tab Extended Release: 2.5 mg, 5 mg, 10 mg tab
Glyburide(DiaBeta, Micronase)	2.5-5 mg once daily with breakfast or first meal	20 mg	1.25, 2.5, 5 mg tab

Note: Meglitinides (See below under Specific Situation therapy) may be used in place of Sulfonylureas in patients with a sulfa allergy and/or irregular meals schedules or who have late rise in postprandial glucose levels on SU's.

- b. **Dipeptidyl Peptidase- 4 (DPP-4) inhibitors: Alogliptin (Nesina); Linagliptin(Tradjenta); Sitagliptin (Januvia); Saxagliptin(Onglyza)**
Mechanism of Action: Inhibits degradation of endogenous incretins resulting in increased insulin secretion in response to elevated blood glucose,

decreased glucagon secretion, slowed gastric emptying, and increased satiety.

- 1) Efficacy: 0.5-0.8% ↓ A1c; ↓FPG and ↓PPG
- 2) Side effects: Urticaria, Angioedema, ↑serum ALT, may worsen heart failure (Saxagliptin)
- 3) Contraindications: Avoid in patients with a history or those at risk for pancreatitis. Avoid in patients with impaired renal function (see chart below)

Drug	CrCl 30-50 ml/min	CrCl less than 30 ml/min
Alogliptin(Nesina)	12.5 mg daily	6.25 mg daily
Linagliptin(Tradjenta)	None	None
Sitagliptin (Januvia)	50 mg daily	25 mg daily
Saxagliptin(Onglyza)	CrCl less than 50 ml/min = 2.5 mg daily	

- 4) Advantages: Weight neutral, No hypoglycemia
- 5) Cost: High
- 6) Dosing: Take with or without food; Starting dose is usually maintenance dose. Obtaining a liver test panel and assessing the patient before initiating therapy is recommended. Use caution in patients with abnormal liver tests. During therapy, if liver injury is suspected (e.g. fatigue, jaundice, dark urine), interrupt therapy, measure serum liver tests, and investigate possible etiologies and consult with medical consultant.

Drug	Initial Dose	Max Dose	Supplied
Alogliptin(Nesina)	25 mg daily	25 mg daily	6.25, 12.5, 25 mg tab
Linagliptin(Tradjenta)	5 mg daily	5 mg daily	5 mg tab
Sitagliptin (Januvia)	100 mg daily	100 mg daily	25, 50, 100 mg tab
Saxagliptin(Onglyza)	2.5-5 mg daily	5 mg daily	2.5, 5 mg tab

Specific Situation therapy

- c. Meglitinides -Can be used in patients that are unable to take a SU due to sulfa allergy or in patients with irregular meal schedules or who develop late postprandial hypoglycemia on a sulfonylurea. (Repaglinide (Prandin), Nateglinide (Starlix))

Mechanism of Action: Stimulates pancreatic insulin secretion.

- 7) **Efficacy: 0.5 -1.5% ↓A1c; ↓ PPG; Repaglinide is shown to reduce A1C more than Nateglinide**
- 8) **Side effects: GI disturbances, upper respiratory infections or congestion problems, hypoglycemia (risk greater with Repaglinide)**
- 9) **Contraindications: Repaglinide should not be given with gemfibrozil.**
- 10) **Cost: High**
- 11) **Dosing: Repaglinide: Increase in weekly intervals as needed; Skip doses for both medications if meal is skipped**

Drug	Initial Dose	Max Dose	Supplied
Repaglinide (Prandin)	Not previously treated or A1C less than 8%, 0.5 mg 15 minutes before meals. Previously treated of A1C greater than 8%, 1-2 mg 15 minutes before each meal.	16 mg	0.5, 1, 2 mg tab
Nateglinide (Starlix)	If A1C is near goal, 60 mg three times a day. If A1C is greater than 8%, 120 mg three times a day (take 1-30 minutes before meals)	120 mg three times a day	60, 120 mg tab

Considerations: Consider initiating triple therapy if A1C is equal to or greater than 10 to 12% or blood glucose is equal to or greater than 300 to 350 mg/dL. Please see list below for triple therapy combinations.

- 3. Triple therapy combinations within the drug classes covered by this protocol.

- a. **Metformin + Sulfonylurea + DPP-4 inhibitor**
 - OR**
 - b. **Metformin+Meglitinides+DPP4**
4. **Lipid management is an integral part of diabetes management. See Appendix F.**

PATIENT EDUCATION/COUNSELING

- 1. **Patients with prediabetes should be referred to lifestyle change programs for healthy lifestyle changes (eating habits, weight loss, increase in physical activity)**
- 2. **Patients diagnosed diabetes should receive diabetes self-management education/training (DSME/T) according to the National Standards for DSME/T at the time of diagnosis and as needed thereafter.**
 - a. **DSME/T is an ongoing process to facilitate knowledge, skills and ability necessary for diabetes self-care support sustainability of behaviors needed to manage diabetes on an ongoing basis.**
 - b. **DSMT coding must be used when applying for Medicare reimbursement.**
- 3. **The overall objectives for DSME/T are:**
 - a. **Support informed decision making, self-care behaviors, and problem solving skills**
 - b. **Active collaboration between the patient and health care team to improve clinical outcomes, health status, and quality of life**
 - c. **Patient centered to be respectful and responsive to individual preferences, needs and values.**
- 4. **The components of diabetes self-management education include:**
 - a. **Initial assessment to identify the patient's:**
 - 1) **Needs, priorities, learning potential**
 - 2) **Beliefs that he/she can make a change in behavior**
 - 3) **Factors that may help and/or hinder the person in carrying out the management plan**
 - 4) **Assistance in selecting appropriate educational and behavioral interventions.**

- 5) **Assessment should include questions such as:**
- a) **How is diabetes affecting your life and your family's life?**
 - b) **What questions do you have?**
 - c) **What is the hardest part about your diabetes or what is causing you the most concern?**
 - d) **What would you like to learn about diabetes?**
 - e) **What success have you had in the past making changes in your life?**
- b. **Goal setting defines specific steps to facilitate behavior change. Goal setting is a collaborative effort between the nurse and the patient. The process begins by helping patients determine 1-2 priority areas they wish to change then helping them identify behavior change steps. Goals should be written in measurable terms that can be monitored and measured. A useful acronym is SMART objectives:**
- 1) **Specific**
 - 2) **Measurable**
 - 3) **Achievable**
 - 4) **Realistic**
 - 5) **Time-bound**
 - 6) **Examples: I will walk 30 minutes every day after dinner, I will eat 3 meals a day at about the same time each day, I will check my blood sugar every morning before breakfast and write it down.**
- c. **The education plan describes the strategies to help the patient reach the desired health outcomes. Strategies may include referral to local DSME/T Programs, Chronic Disease Self-Management Programs, Diabetes Prevention Programs, local diabetes support groups, Registered/Licensed Dietitian or other resources. The plan needs to include a written commitment (contract) by the patient to work toward accomplishing their goals and follow through with their management plan.**
- d. **Implementation is the execution of the plan to insure that the patient has the knowledge, skills and resources to follow through on the plan. The nurse may provide the self-management education and/or refer the patient to community resources.**
- e. **Evaluation and monitoring includes regular**

assessment the patient's progress with behavior goals and the impact of behavior changes on health status. Evaluation also includes assessment of knowledge, skills and satisfaction.

5. The American Association of Diabetes Educators (AADE) has defined 7 self-care behaviors (AADE7 Self-Care Behaviors) as a framework for patient-centered diabetes education and care that focuses on the behaviors that are essential for health status and quality of life. This framework provides an organized method for providing education and a tool to track and evaluate progress. The AADE7 Self Care Behaviors are:

a. Healthy Eating

- 1) Make healthy food choices from all food groups. Use DASH Meal Planning or Dietary Guidelines to discuss food groups and healthy choices. American Diabetes Association also has a handout "Best Foods for You."**
- 2) Discuss portion sizes, using divided plate methods, such as "choose my plate" and visual prompts, such as deck of cards, size of ping pong ball.**
- 3) Evenly spaced meals, particularly if taking medication.**
- 4) Consistent carbohydrate intake, preferably from vegetables, fruits, whole grain products, legumes, and low-fat dairy products.**
- 5) Limit food and beverages high in added sugars.**
- 6) A variety of eating patterns are acceptable for diabetes management. See Therapeutic Section for additional information and Appendix G for education resources.**
- 7) Encourage to limit fast food consumption.**
- 8) Discuss reading food labels to the extent of patient's ability to understand and comprehend.**
- 9) The amount of dietary saturated fat, cholesterol, trans fat recommendations for patients with diabetes is the same as for the general population in reducing the risk for cardiovascular disease.**
- 10) Sodium reduction to less than 2,300 mg/day is appropriate for patients with diabetes. If the patient has hypertension, reduction to 1,500 mg/day is recommended.**
- 11) If adults with diabetes choose to drink alcohol, they should be advised to limit consumption to it should be limited to 1 drink per day for women**

and up to 2 drinks per day for men. Patients should be advised that alcohol consumption may put them at greater risk for hypoglycemia especially if they are taking glucose lowering medications.

b. Being Active

- 1) Assess current activity level and discuss ways patient would be willing to increase activity.
- 2) Encourage patient to identify someone to walk with or do other types of physical activity.
- 3) An appropriate physical activity plan takes into consideration the need to balance food and medication with the frequency, timing, and intensity of activity level. See Therapeutic Section for specific recommendations and Appendix G for education resources.

c. Taking Medication

- 1) Patients should be counseled on importance of taking medication as ordered and should be able to verbalize the name of the medication, the reason for taking it, dose, frequency, time of day to take it, action for missed dose, side effects, and action to take if occur, such as recognition and prevention of hypoglycemia.
- 2) Patients should be counseled to bring all medications, including OTCs and herbal supplements, to all appointments. Recommend that the patient discuss any OTC and/or other nonprescription agent use with the pharmacist prior to purchase.
- 3) Assess medication adherence on each visit.
- 4) Discuss barriers, such as cost issues and complexity of regimen (multi-day dosing for diabetes and other health conditions).
- 5) Patients must be counseled on risks, recognition and treatment of hypoglycemia.

d. Monitoring

- 1) Self-monitoring of blood glucose (SMBG) provides the patient with diabetes feedback about the effects of food intake, medications, and physical activity.

a) The choice of blood glucose monitor is

- b) based on cost of monitor and test strips. Patient's dexterity, number of steps to perform a test, size of the readout, required size of blood sample as well as the size and shape of monitor and test strips are important determinates in the selection of a blood glucose monitor.**
- c) Patient instruction regarding use of blood glucose monitor should include proper storage of meter and strips, technique for obtaining adequate blood sample, proper disposal of lancets/sharps, times to check blood glucose, how to record the results in a logbook and what the results mean, what to do when the results are outside of target range, and importance of bringing the meter, testing supplies and logbook to each appointment.**
- d) Establish target blood glucose levels and discuss with the patient. Have patients write down the target ranges in the logbook**
- e) The frequency of SMBG is outlined in the Therapeutic Section.**
- f) See Appendix G for education resources.**

2) A1C Measurement

- a) A1C measurement reflects blood glucose concentration over approximately 90-120 days and is used as a longer term picture of glycemic control. Patients should be aware of the terminology, the target numbers and how this information is used.**
- b) Patients need to understand that A1C testing does not replace SMBG, which provides more real-time information on the effects of meals/food intake, physical activity and medications.**
- c) The frequency of A1C measurement and target ranges are outlined in the Therapeutic Section.**

e. Problem-Solving

1) Hypoglycemia

- a) Patients taking medications for diabetes must be counseled on risks for**

hypoglycemia: delaying or skipping meals, physical activity, taking too much medication, or drinking alcohol.

- b) Symptoms of hypoglycemia include: sweating, palpitations, pallor, tremors, behavior change, confusion, and drowsiness. Severe, untreated hypoglycemia can lead to loss of consciousness or seizure.**
- c) Treatment of hypoglycemia is 10-15 grams of easily absorbed carbohydrate such as 3-4 glucose tablets or 4 ounces of juice or regular soda.**

2) Hyperglycemia

- a) Patients must be counseled on risks for hyperglycemia: eating too much, omission of prescribed medications, lack of physical activity, infection or illness, and taking medications that may increase blood glucose levels.**
- b) Symptoms of hyperglycemia include: increased thirst and urination, fatigue, blurry vision, and headaches.**
- c) Patients should be counseled to test their blood glucose level when symptoms occur contact the healthcare provider when blood glucose levels are 250 mg/dL or greater on 2 occasions or if experiencing symptoms of illness or infection.**

3) Sick Day Management

- a) Patients should be counseled to drink 8 oz. of fluid per hour, test their blood glucose at least every 4 hours or more frequently if continues to rise, continue medications as able and to notify health care provider if vomiting occurs on more than one occasion, unable to retain liquids, diarrhea lasting more than 6 hours, and symptoms of hyperglycemia become worse.**
- b) Patients, especially elderly persons who live alone, should be instructed to have someone check on them on a regular basis when they are not feeling well.**

f. Reducing risks

- 1) Targeted behaviors and therapeutic goals have been established to reduce the risk or slow the progression of diabetes complications, such as cardiovascular and kidney disease, amputations, vision problems, and dental problems.**
- 2) Blood Pressure**
 - a) Patients should be aware of the importance of regular blood pressure measurement, blood pressure goals, taking blood pressure medications if prescribed, and the importance of blood pressure control in prevention of diabetes complications.**
 - b) If the patient is doing home blood pressure monitoring, have them bring the equipment to be sure the patient understands how to use it and logbooks for appointments to validate accuracy and provide feedback of the results.**
 - c) Blood pressure goals are defined in the Therapeutic Section.**
- 3) Weight**
 - a) Weight goals should be mutually agreed upon.**
 - b) Encourage patients to weigh themselves once weekly and record in a logbook.**
 - c) Advise patients to report any significant weight change between appointments, particularly weight loss accompanied by polyuria and polydipsia.**
- 4) Daily Foot Care**
 - a) Patients or significant other (if patient has impaired vision) should be instructed: to inspect feet daily for cuts, calluses, blisters, thick or ingrown nail, and signs of infection; wash and dry feet thoroughly, especially between the toes, moisturize except between the toes, cut nails straight across and smooth rough edges with an emery board, inspect footwear for foreign objects, and to always wear footwear-never go barefoot.**

- b) **See Appendix G for education resources.**
- 5) **Daily Dental Care**
- a) **Instructed patient on importance of twice daily brushing and flossing and regular dental visits.**
 - b) **Patients should be counseled on importance of blood glucose control and cessation of tobacco products as preventative measures for periodontal disease.**
 - c) **See Appendix G for education resources.**
- 6) **Smoking Cessation**
- a) **Smoker, e-cigarette, or nicotine user- Utilize Ask, Advise and Refer (AAR) model and provide cessation counseling and referral to the Georgia Quit Line 1-877-270-STOP (7867) using the Quit Line Fax Back Form as appropriate.**
- 7) **Lipids**
- a) **Briefly counsel all patients on lifestyle behaviors to reduce cardiovascular risk factors focusing on reduction of saturated, trans fat and cholesterol intake (incorporate TLC meal planning messages into Healthy Eating messages), weight loss, increased physical activity, smoking/tobacco cessation, and blood glucose control.**
 - b) **All patients with diabetes are presumptive candidates for statin therapy. See Appendix F for management of lipids in patients with diabetes.**
- 8) **Nephropathy**
- a) **Counsel patients on the importance of glucose and blood pressure control.**
 - b) **Counsel patients to avoid or limit use of certain pain medicine, such as nonsteroidal anti-inflammatory drugs (ibuprofen).**

9) Immunizations-Refer to Therapeutic section for immunization guidelines.

g. Healthy coping

- 1) Identify patients showing signs of coping difficulties and undue stress (unexplained weight changes, poor glycemic control, and changes in cognition, concentration, and ability to focus). Questions that may give insight into a patient's feelings and emotions are:
 - a) In the past 2 weeks, have you consistently felt sad or blue?
 - b) What drives you crazy about your diabetes?
 - c) What is scary for you about having diabetes?
- 2) Assist patients with identifying problems they are experiencing, explore options, select one to work on, and then make a plan to address the problem.
- 3) Identify support systems such as family members or friends to talk with. Encourage the patient to bring someone with them to their appointments.
- 4) DSME/T and support groups have shown positive impact on improved patient coping skills. Patient-centered care and feedback related to efforts for behavior change have also had positive results.

FOLLOW-UP

1. Frequency of Clinic Appointments

- a. When beginning or adjusting drug therapy, see patients every 2-4 weeks to evaluate response to medications and lifestyle changes based on SMBG results and to assess for signs and symptoms of hypo- and hyperglycemia.
- b. Once blood glucose goals are reached and maintained for 3-4 visits, frequency of appointments may be reduced to 4-6 week intervals to monitor/assess for symptoms of complications, progress with behavioral

goals and ongoing self-management education and support.

- 2. Triage assessment is performed at each visit and includes the information components listed below:**
 - a. Chief complaint.**
 - b. Physical examination includes:**
 - 1) Weight, Body Mass Index, and waist circumference. Measure height annually.**
 - 2) Sitting and standing BP (particularly for patient complaints suggestive of orthostatic**
 - 3) Temperature and pulse rate.**
 - 4) Heart and lung sounds, particularly if shows evidence of edema.**
 - 5) Assessment of extremities for edema and change if perfusion.**
 - 6) Foot inspection for lesions, ingrown nails, fungal infections.**
 - c. Frequency/severity of hypo-hyperglycemia.**
 - d. Review medications and medication adherence.**
 - e. Review, discuss and provide feedback on SMBG, weight, and physical activity records.**
 - f. Review behavior goals and discuss progress.**
 - g. Assess status of DSME/T participation. Identify learning needs and provide appropriate instructions**
 - f. Discuss adherence difficulties and psychosocial issues.**
 - g. Assess for symptoms of other diabetes complications.**
 - h. ER/Hospital visits or change in medical history since the last visit.**
- 3. Order appropriate laboratory studies:**
 - a. A1C**
 - 1) Quarterly if treatment changes or patient is not meeting target blood glucose goals.**
 - 2) Every 6 months if stable**
 - b. Annual fasting lipid profile**
 - c. Obtain baseline serum creatinine and repeat in 3 months if taking Metformin, a Sulfonylurea and/or a DPP4 agents. If serum creatinine elevates to 1.4 mg/dL or greater for women or 1.5 mg/dL or greater for men, consult with delegating physician. If level remains stable, repeat annually.**
 - d. Baseline and annual serum liver tests should be obtained on patients taking Sulfonylureas and/or DPP4 agents.**
 - e. Spot urine for albumin to creatinine ratio.**

- f. **Baseline ECG. Repeat as indicated if the patient develops new signs and/or symptoms of heart disease (e.g., chest pain or abnormal heartbeats) or evidence of congestive heart failure (e.g., peripheral edema, shortness of breath); otherwise, once every 5 years is acceptable.**

REFERRAL/CONSULTATION

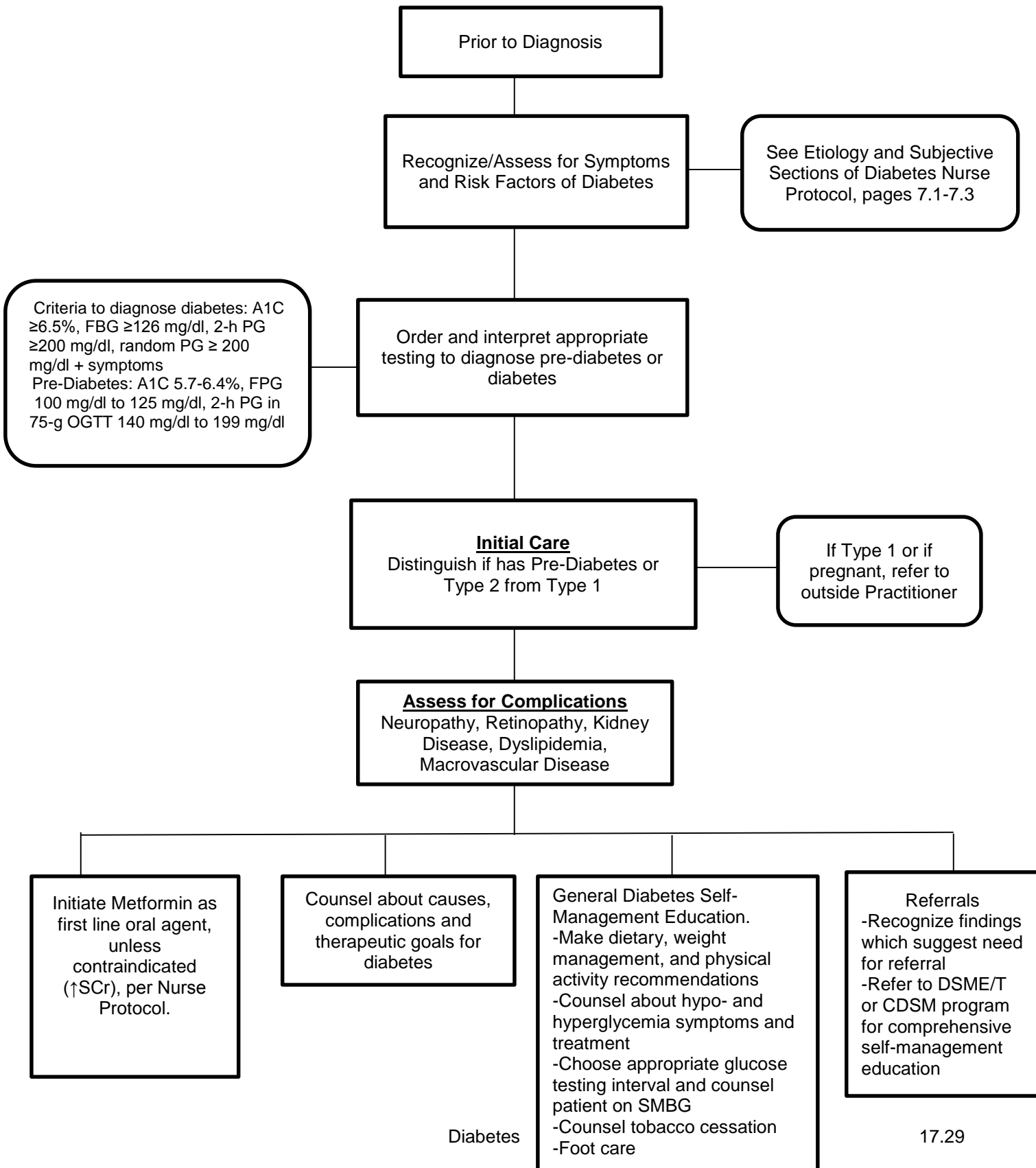
1. **All patients should have, at minimum, a nutritional evaluation and development of an appropriate meal plan by a Registered Dietitian or Public Health Nutritionist, if available.**
2. **Refer all patients to a Diabetes Self-Management Education/Training Program and/or Chronic Disease Self-Management Program and local diabetes support groups.**
3. **Assess, advise and refer tobacco, e-cigarette and nicotine users to cessation programs.**
4. **Medical Consultation - In addition to periodic review by a physician, special consultation with delegating physician is indicated if:**
 - a. **Patients who do not reach and/or maintain target blood glucose and/or A1C levels with the limited pharmacologic agents and dosing covered by this Nurse Protocol.**
 - b. **Patients present with blood glucose levels equal to or greater than 300 mg/dL and/or A1C levels equal to or greater than 10%.**
 - c. **Recurrent episodes of hypoglycemia (glucose level less than 70 mg/dL) or after one episode of severe hypoglycemia [loss of consciousness or glucose level less than 40 mg/dL].**
 - d. **Patients presenting with features suggesting possibility of Type 1 diabetes should be discussed with the delegating/ consulting physician.**
 - e. **Positive ketonuria.**
 - f. **Pregnancy**
 - g. **Systolic pressure is 180 mmHg or greater.**
 - h. **Diastolic pressure is 110 mmHg or greater.**
 - i. **Abnormal, total cholesterol is 200 mg or higher, LDL is 100 mg/dL or greater, HDL equal to or less than 40 mg/dL in men and less than 50 mg/dL in women, fasting triglyceride is 500 mg/dL or greater , serum creatinine of 1.4 mg/dL or greater for women or 1.5 mg/dL for men or greater, serum potassium of 3.5 mEq or less or 5.5 mEq or greater, or positive urinary albumin creatinine ratio equal to or greater than 30 mg/dL.**
 - j. **New onset angina, intermittent claudication, acute vision loss, acute foot injury or ulceration and/or**

abnormal ECG

- k. Refer all patients for annual dilated eye examination.**
- l. Refer all patients for dental evaluation and care.**
- m. Referral to mental health resources may be indicated in patients exhibiting signs of depression, poor coping mechanisms, and/or alcohol and/or substance abuse.**
- n. Document all referrals and the results, including any communication with the provider regarding actions taken. Also document patient refusal and the reason for the refusal to follow up on referrals.**
- o. Presence of complications or other medical conditions.**

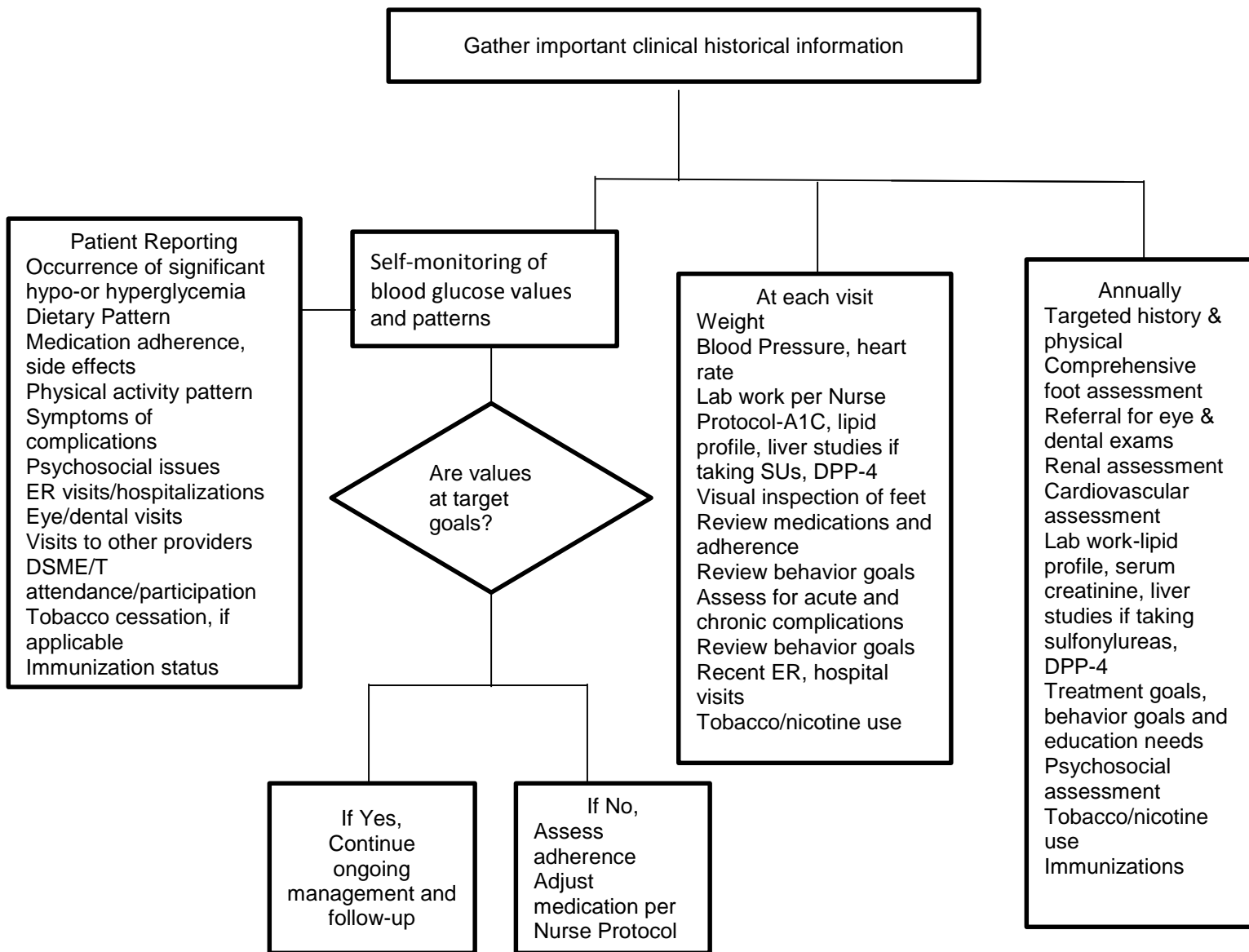
APPENDIX A

Clinical Tasks in the Care of Patients with Diabetes



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APPENDIX B
Clinical Tasks in the Follow-up Care of Patients with Diabetes



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APPENDIX C

TREATMENT ALGORITHM OF TYPE 2 DIABETES

Nutrition and Physical Activity Inadequate?
FPG > 120 mg/dL
HbA1c > 7%

First-Line Therapies

Metformin
Overweight
Dyslipidemic
Insulin Resistant

OR

Sulfonylurea
Lean

MONOTHERAPY
ADEQUATE?
FPG < 130 mg/dL
HbA1c < 7%

CONTINUE

MONOTHERAPY INADEQUATE?
FPG > 130 mg/dL
HbA1c > 7%

INITIATE ORAL COMBINATION
THERAPY

COMBINATION THERAPY
ADEQUATE?
FPG < 130 mg/dL
HbA1c < 7%

CONTINUE

COMBINATION THERAPY INADEQUATE?
FPG > 130 mg/dL
HbA1c > 7%

Consider:

- Adding a third oral agent
- Referral to outside Provider for insulin therapy

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APPENDIX D

Summary of recommendations for adults with diabetes

Glycemic control	
A1C	<7.0%*
Preprandial capillary plasma glucose	80–130 mg/dL
Peak postprandial capillary plasma glucose†	<180 mg/dL
Blood pressure	<140/90 mmHg

Lipids‡

All patients with diabetes should be considered presumptive candidates for statin therapy.

- For patients between 40-75 years of age
 - If they have known CV disease or any listed risk factor, treat with a high potency statin
 - If they have no known CV disease or listed risk factors, treat with a medium potency statin
- For patients less than 40 years of age
 - If they have known CV disease, treat with a high potency statin
 - If they have any listed CV risk factor, treat with a medium potency statin
 - If they have no listed CV risk factors, continue annual monitoring as below
- For patients older than 75 years
 - If they have known CV disease, treat with a high potency statin
 - Otherwise, treat with a medium potency statin

Key concepts in setting glycemic goals:

- A1C is the primary target for glycemic control
- Goals should be individualized
- Certain populations (children, pregnant women, and 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

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APPENDIX E

Correlation between A1C level and mean plasma glucose levels on multiple testing over 2–3 months

A1C (%)	Mean plasma glucose	
	mg/dL	mmol/L
6	135	7.5
7	170	9.5
8	205	11.5
9	240	13.5
10	275	15.5
11	310	17.5
12	345	19.5

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APPENDIX F

Management of Lipids in Patients with Diabetes

Background

Diabetic patients are at substantial risk of cardiovascular disease (CV). Heart attack is the leading cause of death in persons with diabetes. This risk is due to the effect of diabetes itself as well as the other CV risk factors frequently present in diabetic individuals, such as high blood pressure and elevated lipids. The primary purpose of lipid management in diabetic patients is to lessen their risk of heart attack and stroke. Control of blood sugar and of blood pressure should also be part of a unified strategy to control CV risk in diabetic patients.

Blood lipids are comprised of low density lipoprotein (LDL) cholesterol, high density lipoprotein (HDL) cholesterol and triglycerides. Elevated levels of LDL cholesterol and low levels of HDL cholesterol are risk factors for cardiovascular disease. Statin medications, such as simvastatin (Zocor) and atorvastatin (Lipitor), primarily decrease levels of LDL cholesterol and have been shown to substantially lower the incidence of cardiovascular disease in diabetic patients. These medications are the drugs of choice for lowering LDL levels and CV risk in diabetic patients with or without a known history of cardiovascular events. All diabetic patients, regardless of medication use, should be counseled about healthy diet and exercise habits.

The 2013 American Heart Association (AHA) guidelines for management of cholesterol identified 4 groups of patients who should be treated with cholesterol lowering medications. Because of the demonstrated impact of statins on CV risk in diabetics, patients with diabetes were one of those four. Therefore, with limited exceptions described below, patients with diabetes are presumptive candidates for statin therapy.

An important component of the 2013 AHA guidelines was eliminating the use of specific cholesterol level targets (goal-directed therapy). So, those guidelines did not include any particular LDL level to be achieved by treatment. In its place, the aim of therapy was recommended to be treating each patient with a potent enough drug given at the correct dose. Based on clinical trials, using an appropriate dose of a strong enough drug will achieve the maximum reduction of CV risk, while avoiding unnecessary testing and dose titration. This approach was adopted in the 2015 American Diabetes Association (ADA) Standards of Care for Patients with Diabetes.

Evaluation and Management

Every patient diagnosed with diabetes should undergo testing for blood lipids as

described in the Objective section of the diabetes nurse protocol. That testing includes a fasting lipid profile, which provides separate LDL, HDL and triglyceride values, and a blood chemistry which includes liver enzymes. A total cholesterol test, which does not separate the lipid components, should not be used.

All patients should also be asked about any prior reaction to cholesterol medications (which drug, what reaction) and any history of liver disease. In addition, all patients should be questioned to assess the presence of, or risk factors for, cardiovascular disease. Evaluate each patient for the following:

- Any previous diagnosis of coronary artery disease, heart attack, ischemic stroke, or peripheral vascular disease
- LDL cholesterol at or above 100 mg/dL
- Diagnosis of hypertension
- Smoking
- Overweight and obesity (BMI at or above 25)

Based on the 2013 AHA and 2015 ADA guidelines, the results of cholesterol tests should be used as follows—

- HDL – Although low HDL is a risk factor for CV disease, trials have not shown benefit from medications which raise HDL. HDL does not form the basis for any medication therapy choices. Low HDL values can benefit from exercise, which will be covered in usual counseling for diabetic patients.
- Triglycerides – The relationship between triglycerides and CV disease is not clear, and triglyceride levels should not be treated in order to lower CV disease rates. Very high triglyceride levels can cause other problems, so patients with such values should be referred for evaluation as below. Modest elevations in triglyceride levels can be improved through a healthy diet, which will be covered in usual counseling for diabetic patients.
- LDL – Elevated LDL cholesterol levels are associated with higher rates of CV disease. As described in the Background section, however, specific LDL cholesterol levels will not be a target for therapy. LDL levels do provide important information about CV risk levels and medication adherence.

Drug management decisions can be made according to the below algorithm.

- For patients between 40-75 years of age—
 - If they have known CV disease or any listed risk factor, treat with a high potency statin
 - If they have no known CV disease or listed risk factors, treat with a medium potency statin
- For patients less than 40 years of age—
 - If they have known CV disease, treat with a high potency statin

- If they have any listed CV risk factor, treat with a medium potency statin
- If they have no listed CV risk factors, continue annual monitoring as below
- For patients older than 75 years—
 - If they have known CV disease, treat with a high potency statin
 - Otherwise, treat with a medium potency statin

If a patient has difficulty obtaining a recommended agent due to cost, patient assistance or similar programs, Medicaid eligibility and any community programs should be explored to attempt to get the preferred agent. If no assistance is available, a less potent but more affordable agent can be substituted.

1. Follow-Up and Referral

- For patients started on statin therapy:
 - Counsel regularly about diet and exercise strategies
 - Repeat a fasting lipid profile annually in order to monitor adherence
 - Repeat a comprehensive metabolic profile (CMP) annually, and with concerns, to look for elevated liver enzymes.
 - Refer for evaluation or discuss with the physician consultant if
 - Liver enzymes are elevated. Stop the drug while awaiting results.
 - The patient experiences unexplained muscle pain. Stop the drug while awaiting results.
 - Triglycerides are greater than 350mg/dL
- For patients not started on statin therapy:
 - Counsel regularly about diet and exercise strategies
 - Repeat a fasting lipid profile annually to monitor risk
 - Reassess CV risk factors annually
 - If the patient reaches 40 years of age, or develops CV risk factors, then appropriate therapy should be started
 - Refer for evaluation or discuss with the physician consultant if triglycerides are greater than 350mg/dL

Medication - Statins

The primary medication class used to lower LDL cholesterol is statin agents. The statins, HMG-CoA reductase inhibitors, decrease the activity of an enzyme in the liver which is part of the process of manufacturing LDL cholesterol. This class of medications has been shown to reduce CV risk in diabetic and other patient groups.

For purposes of selecting appropriate therapeutic regimens, statins are grouped according to magnitude of LDL reduction into high, medium and low potency levels. Note that some agents can cross potency groups depending on their dose.

High Potency	Medium Potency	Low Potency
Atorvastatin 40-80mg daily	Atorvastatin 10-20mg daily	Simvastatin 10mg daily
Rosuvastatin 20-40mg daily	Rosuvastatin 5-10mg daily	Pravastatin 10-20mg daily
	Simvastatin 20-40mg daily	Lovastatin 20mg
	Pravastatin 40-80mg daily	
	Lovastatin 40mg daily	

When initiating statin, reasonable starting doses are:

- Rosuvastatin 10mg daily,
- Atorvastatin 20mg daily,
- Simvastatin 20mg daily,
- Pravastatin 20mg daily,
- Lovastatin 20mg daily.

- Doses can be doubled every 2-4 weeks until the target dose is achieved.
- If a patient has difficulty tolerating a particular agent, the case should be discussed with the consulting physician.
- Nurses should be familiar with \$4 and other discount drug programs available locally.
- Statins are generally safe medications. They rarely cause elevations in liver enzymes or muscle pain; severe muscle damage is possible but very rare. If a patient has known or suspected liver disease, a statin should not be initiated without physician consultation. If a patient on statins develops elevated liver enzymes or muscle pain, the drug should be stopped and physician consultation obtained.
- Statins should not be used in pregnant patients.
- Patients should not breastfeed while taking a statin.
- A review for any drug interactions should occur.

APPENDIX G

Referral Sources for DSME/T and DPP/Lifestyle Change Programs

AADE Programs-

<http://www.diabeteseducator.org/ProfessionalResources/accred/Programs.html#Georgia>

DPP/Lifestyle Change Programs-

https://nccd.cdc.gov/DDT_DPRP/State.aspx?STATE=GA

Not currently reimbursed by Medicare

Stanford programs

<http://patienteducation.stanford.edu/organ/cdsitegeorgia.html>

Not currently reimbursed by Medicare

EDUCATIONAL RESOURCES

Websites with patient handouts on multiple topics/issues regarding Diabetes Self-Management:

American Diabetes Association (see Professional tab):

<http://professional.diabetes.org/PatientEducationLibrary.aspx>

National Diabetes Education Initiative:

<http://www.ndei.org/patienteducation.aspx>

National Institute of Diabetes, Digestive and Kidney Diseases:

<http://www.niddk.nih.gov/health-information/health-topics/diabetes/Pages/default.aspx>

National Diabetes Education Program: <http://ndep.nih.gov/resources/index.aspx>

American Association of Diabetes Educators (AADE7 topics)

http://www.diabeteseducator.org/DiabetesEducation/PWD_Web_Pages/Learn_about_AADE7_Seven_Self-Care_Behaviors.html and
http://www.diabeteseducator.org/ProfessionalResources/Library/Holiday_Eating_Patient_Resources.html

Healthy Eating:

Free handouts

U.S. Department of Agriculture: <http://www.choosemyplate.gov>

DASH Meal Planning

http://www.nhlbi.nih.gov/files/docs/public/heart/dash_brief.pdf

<http://www.nhlbi.nih.gov/health/health-topics/topics/dash/followdash>

2010 (most current) Dietary Guidelines

<http://www.health.gov/dietaryguidelines/dga2010/dietaryguidelines2010.pdf>

Therapeutic Lifestyle Changes (TLC) Diet

https://www.nhlbi.nih.gov/files/docs/public/heart/chol_tlc.pdf

National Diabetes Information Clearinghouse (NDIH) Health Eating Resources:

http://www.diabetes.niddk.nih.gov/dm/pubs/eating_ez/

American Diabetes Association Create Your Plate

<http://www.diabetes.org/food-and-fitness/food/planning-meals/create-your-plate/>

Charge for Materials

Mediterranean Diet:

<http://oldwayspt.org/resources/heritage-pyramids/mediterranean-pyramid/overview> (does have free download of pyramid)

Vegan/Vegetarian:

<http://oldwayspt.org/resources/heritage-pyramids/vegetarian-diet-pyramid/overview> (does have free download brochure)

Portion Control:

<http://www.webmd.com/diet/printable/wallet-portion-control-size-guide>

<http://www.webmd.com/diet/printable/portion-control-size-guide>

<http://commonhealth.virginia.gov/documents/wellnotes/PortionControlFactSheet.pdf>

http://www.cdc.gov/diabetes/prevention/pdf/handout_session4.pdf

Physical Activity:

American Association of Diabetes Educators

www.diabeteseducator.org/export/sites/aade/resources/pdf/general/AADE7_being_active.pdf

Activity Pyramid

<https://www.wellspan.org/media/3648/activitypyramid-2009.pdf>

http://www.cdc.gov/diabetes/prevention/pdf/handout_session5.pdf

http://www.cdc.gov/diabetes/prevention/pdf/posthandout_session8.pdf

Healthy Coping/Problem Solving

http://www.cdc.gov/diabetes/prevention/pdf/handout_session9.pdf

http://www.cdc.gov/diabetes/prevention/pdf/handout_session15.pdf

http://www.cdc.gov/diabetes/prevention/pdf/handout_session11.pdf

Depression and Diabetes

http://www.nimh.nih.gov/health/publications/depression-and-diabetes/depression-and-diabetes_142131.pdf

Kidney Disease

<http://nkdep.nih.gov/resources/get-checked-kidney-disease-508.pdf>

Foot Care

http://ndep.nih.gov/media/NDEP4_TakeCareOfFeet_4c_508.pdf

Eye Care

https://public.health.oregon.gov/DiseasesConditions/ChronicDisease/Diabetes/resourcebank/Documents/Eye_exam.pdf

<https://nei.nih.gov/sites/default/files/health-pdfs/diabeticretino.pdf>

www.dshs.state.tx.us/diabetes/patient.shtm

Dental Care

http://www.nidcr.nih.gov/oralhealth/Topics/Diabetes/Documents/DiabetesDentalTipsEN_082714_508C.pdf

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