South Atlantic Medical Group	**Clinical Protocol: Diabetes Management**	**SUBDEPARTMENT:** N/A
	POLICY NO.	**ORIGINAL EFFECTIVE DATE:** 12/01/2019 / **REVIEWED/REVISED DATE(S):** 11/15/2023, 03/6/2024
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TITLE OF POLICY: Screening and Monitoring of Diabetes		

PROTOCOL OVERVIEW

This Clinical Protocol advises on guidelines, indications, and criteria for the diagnosis of diabetes. "Diabetes is defined by elevated levels of glycemia (glucose and glycated hemoglobin), and controlling glycemia is an integral component of the management of diabetes. Measurements of instantaneous glucose levels (self-monitoring of blood glucose [with finger sticks and a glucose meter] and real-time continuous glucose monitoring [CGM]) are used to manage diabetes from hour to hour and from day to day, to aid in dose selection in insulin-treated patients, and for safety. Measures of chronic glycemia (e.g., glycated hemoglobin or CGM-derived mean glucose, time-in-range, and glucose management indicator [GMI]) are used to determine the overall efficacy of diabetes management with the aim of reducing risk for long-term complications.

Glycated hemoglobin (A1C, hemoglobin A1C, HbA1c), which reflects average levels of blood glucose over the previous two to three months, is the most widely used test to monitor chronic glycemic control."

INDICATIONS

Generally, FPG, 2-h PG during 75-g OGTT, and A1C are equally appropriate for diagnostic screening. It should be noted that the tests do not necessarily detect diabetes in the same individuals.

To avoid misdiagnosis or missed diagnosis, the A1C test should be performed using a method that is certified by the NGSP and standardized to the Diabetes Control and Complications Trial (DCCT) assay.

Marked discordance between measured A1C and plasma glucose levels should raise the possibility of A1C assay interference and consideration of using an assay without interference or plasma blood glucose criteria to diagnose diabetes.

In conditions associated with an altered relationship between A1C and glycemia, such as hemoglobinopathies including sickle cell disease, pregnancy (second and third trimesters and the postpartum period), glucose-6-phosphate dehydrogenase deficiency, HIV, hemodialysis, recent blood loss or transfusion, or erythropoietin therapy, only plasma blood glucose criteria should be used to diagnose diabetes.

Patient in a hyperglycemic crisis or with classic symptoms of hyperglycemia and a random plasma glucose ≥200 mg/dL [11.1 mmol/L]) are considered diabetic, and otherwise, the diagnosis requires two abnormal test results, either from the same sample or in two separate test samples.

Criteria for the diagnosis of diabetes:

A1C ≥6.5%, The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.*
OR
FPG ≥126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h.*
OR
Two-hour plasma glucose ≥200 mg/dL (11.1 mmol/L) during an OGTT. The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.*
OR
In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L).
*In the absence of unequivocal hyperglycemia, criteria 1–3 should be confirmed by repeat testing.

Special considerations should be made for gestational diabetes, post-transplant related diabetes and other individualized concerns.

SUMMARY OF GLYCEMIC RECOMMENDATIONS FOR HEDIS

November 2023 NCQA Technical Specs

DIABETES Comprehensive Diabetes Care (18-75 years)	
HbA1c Testing	Percent of members with one HbA1c test during year
HbA1c Poor Control, >9.0%	Percent of members with HbA1c result of higher than 9.0
HbA1c Good Control, <8.0%	Percent of members with HbA1c result of lower than 8.0
Eye Exam, Retinal	Percent of members who have had an annual retinal exam in the measurement year, or have had a negative exam in the year prior
Medical Attention for Nephropathy	Percent of members who have had attention to the presence of nephropathy
Blood Pressure Control, <140/90 mmHg	Percent of members with acceptable BP<140/90 mm Hg

RECOMMENDED RECORDS

- History and physical
- Diabetic foot exam/peripheral neuropathy monitoring 3
- HA1C monitoring every 3 months
- Diabetic retinopathy screening
- Proteinuria screening
- Blood pressure control and monitoring and consideration for ACE Inhibitor
- Evaluating best available treatment agent and lifestyle changes including diet, exercise and weight loss

DISCUSSION

In 2009, the International Expert Committee that included representatives of the ADA, the International Diabetes Federation (IDF), and the European Association for the Study of Diabetes (EASD) recommended use of A1C to diagnose diabetes, with a threshold of ≥6.5%. In 2010 the ADA adopted this criterion. The A1C has several advantages over Fasting Plasma Glucose and Oral Glucose Tolerance Testing, including greater convenience, since fasting is not required; evidence to suggest greater preanalytical stability; and less day-to-day perturbations during periods of stress or illness.

As with most diagnostic tests, a test result diagnostic of diabetes should be repeated to rule out laboratory error, unless the diagnosis is clear on clinical grounds, such as a patient with hyperglycemic crisis or classic symptoms of hyperglycemia and a random plasma glucose ≥ 200 mg/dl. It is preferable that the same test be repeated for confirmation since there will be greater likelihood of concurrence in this case. However, if the different tests (such as A1C and FPG) are both above the diagnostic thresholds, the diagnosis of diabetes is also confirmed. If two different tests are available in an individual and the results are discordant, the test whose result is above the diagnostic cut point should be repeated, and the diagnosis is made on the basis of the confirmed test. That is, if a patient meets the diabetes criterion of the A1C (two results ≥ 6.5%) but not the FPG (≤126 mg/dl or 7 mmol/l), or vice versa, that person should be considered to have diabetes.

Several prospective studies that used A1C to predict the progression to diabetes demonstrated a strong, continuous association between A1C and subsequent diabetes. Those with an A1C between 5.5 and 6.0% had a substantially increased risk of developing diabetes with 5-year incidences ranging between 9-25%. An A1C range of 6.0-6.5% had a 5-year risk between 25-50% and relative risk 20 times higher compared to an A1C of 5.0%. Baseline A1C was a stronger predictor of subsequent diabetes and cardiovascular events than fasting glucose. Hence, it is reasonable to consider an A1C range of 5.7% - 6.4% as identifying individuals with high risk for future diabetes, a state that may be referred to as “prediabetes”. These individuals should be informed of their risk and counseled about effective strategies to lower that risk. Interventions should be most intensive and follow-up most vigilant for those with A1C’s above 6.0%, who should be at high risk.

Based on the results of clinical trials and the known risk of progression of “prediabetes” to diabetes, persons with A1C of 5.7-6.4% should be counseled on lifestyle changes with goals of 7% weight loss and moderate physical activity of at least 150 min/week. Regarding the more difficult issue of drug therapy for diabetes prevention, a consensus panel felt that Metformin should be the only drug considered. For other drugs, the issues of cost, side effects, and lack of persistence in effect in some studies led the panel to not recommend their use in diabetes prevention.

Because A1C is thought to reflect average glycemia over several months and has strong predictive value for diabetes complications, A1C testing should be performed routinely in all patients with diabetes, at initial assessment and then as part of continuing care. Measurement approximately every 3 months determines whether a patient's glycemic targets have been reached and maintained. Some patients with stable glycemia well within target range may do well with testing only twice a year, while unstable or intensively managed patients (e.g., pregnant type 1 patients) may be tested more frequently than every 3 months. A1C does not provide a measure of glycemic variability or hypoglycemia. For patients prone to glycemic variability (especially type 1 patients, or type 2 patients with severe insulin deficiency), glycemic control is best judged by the combination of results of self-monitoring of blood glucose (SMBG) testing and A1C. The A1C may also serve to check on the accuracy of the patient's meter (or the patient's reported SMBG results) and the adequacy of the SMBG testing schedule.

Lowering the A1C to around 7% or below has been shown to reduce microvascular and neuropathic complications of diabetes and, if implemented soon after the diagnosis of diabetes, is associated with long-term reduction in macrovascular disease. Therefore, a reasonable goal for most non-pregnant adults is an A1C ≤ 7%. Because several randomized trials suggest a small but incremental benefit in microvascular outcomes with A1C values closer to normal, providers might reasonably suggest more stringent A1C goals for selected individual patients, if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Such patients might include those with short duration of diabetes, long life expectancy, and no significant cardiovascular disease. Conversely, less stringent A1C goals may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions and those with longstanding diabetes in whom the general goal is difficult to attain despite appropriate glucose monitoring and effective doses of multiple glucose-lowering agents including insulin.

CITATION

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