Coverage Guidelines

A1C Testing at Point-of-Care (POC)

Disclaimer:
Please note that Baptist Health Plan Coverage Guidelines are updated throughout the year. A printed version may not be most up to date version available. The health plan reserves the right to review and update this policy as needed. Refer to the website to ascertain that you are utilizing the most current available version. Clinical guideline policies are not intended to serve as treatment guidelines or treatment recommendation. Treating providers must use their own clinical judgment in rendering care to their patient population.

For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern. In addition, coverage for Medicare Advantage members may differ. This is a result of applicable coverage statements by the Center for Medicare and Medicaid Services (CMS). The National Coverage Determinations, Local Coverage Determinations, and Local Medical Review Policies may be found at the CMS website, [http://www.cms.gov](http://www.cms.gov). Please note that for all plans, the member’s health plan benefits that are in effect on the rendered date of service must be used in coverage determinations.

DEFINITION

The A1C test measures overall blood glucose control for the past two to three months and is considered the “gold standard” measure of diabetes control. Long-term A1C testing can identify patients with poor glycemic control and facilitate their improvement.1

Point-of-care (POC) A1C testing may be completed at the physician’s office with just a drop of blood and provides results in about five minutes, or the A1C testing can be sent to a central laboratory requiring venipuncture and provides results to the physician within a few days.

Blood samples analyzed in a POC setting are not standardized for diagnosing diabetes.2

COVERAGE CRITERIA

A1C testing at POC is considered medically necessary when used in the setting of diabetes management:3

- At least four times* a year;

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For members whose drug regimen has changed, or
For members who are not meeting glycemic goals, or
Whose drug regimen has changed.

* Testing more than four times a year for members with uncontrolled diabetes requires medical necessity documentation written by a physician.4

Twice a year for members with stable glycemic control.

**A1C testing at POC is NOT currently considered medically necessary or is considered experimental / investigational** in the following instances: 5

- When used to diagnose diabetes, or
- When not performed by a health care provider, or
- More often than every three months for members with controlled diabetes, or
- More often than every month for pregnant members.

**MEDICAL BACKGROUND**

Diabetes mellitus is a group of chronic progressive metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion and/or action. In the United States, 29.1 million people (9.3% of the population) suffer from diabetes mellitus, which 27.8% of them are undiagnosed. Total direct and indirect costs for people with diagnosed diabetes is estimated to be $245 billion in 2012.6 Diagnosis and management of the disease are important in preventing long-term complications such as cardiovascular disease, blindness and end-stage kidney disease.

Hemoglobin A1C (HbA1c) or glycated hemoglobin is a laboratory test used for the diagnosis and management of diabetes. A1C is a stable modified form of hemoglobin that is created by the irreversible interaction between hemoglobin and glucose. Since the life span of a hemoglobin-carrying red blood cell (RBC) is 120 days, the level of A1C reflects the patient’s plasma glucose levels over the preceding 2 to 3 months. A normal A1C level is below 5.7 percent. HbA1c has become the “gold standard” for assessing metabolic control and more successful management of glucose as measured by HbA1c level is directly related to reduction in diabetic complications.7

The advantages of A1C testing include no need to fast, greater pre-analytical stability, and less fluctuation due to stress or illness. However, A1C testing can be unreliable for diagnosing or monitoring diabetes in people with certain conditions. A falsely elevated A1C level can occur in conditions that increase lifespan of RBCs including iron and B12 deficiencies, renal failure, and alcoholism. A falsely low A1C result can occur in disease states causing a decrease in the lifespan of RBCs or the percentage of hemoglobin A, such as sickle cell trait, hemolytic anemia, or blood loss.8

A1C testing does not detect hypoglycemia or glycemic variability. Therefore, for patients with type 1 diabetes or type 2 diabetes with severe insulin deficiency glycemic control is best evaluated by the combination of results from blood glucose test and A1C test.
When the A1C test is used for diagnosis, the blood sample must be sent to a laboratory that uses a National Glycohemoglobin Standardization Program (NGSP)-certified method for analysis to ensure the results are standardized. Blood samples analyzed in a POC setting are not standardized for diagnosing diabetes.  

The frequency of A1C testing should depend on the clinical situation, the treatment regimen, and the clinician’s judgment. Patients with type 2 diabetes with stable glycemic control may do well with testing only twice per year. Unstable or highly intensively managed patients (e.g., pregnant women with type 1 diabetes) may require testing more frequently than every 3 months.

Based on American Diabetes Association recommendations A1C goal for many non-pregnant adults is 7%. Due to physiological increases in red blood cell turnover, A1C levels fall during normal pregnancy. A1C level less than 6.5 percent is considered the target level for glycemic control during pregnancy.

Standard laboratory tests for HbA1c requires venipuncture and the results are provided after several days. Also, laboratory instruments are expensive and require trained personnel for operation. In recent years A1C has been incorporated into POC devices which are cost-effective and allow for immediate availability of the results, which provides the opportunity for more timely treatment changes, leading to better outcomes in diabetes management.

In a prospective, controlled trial, Miller et al showed that management decisions were significantly more appropriate in the POC testing group than in the laboratory testing group.

While several studies of POC A1C testing showed a significant reduction of A1C, none followed patients longer than 12 months. A retrospective cross-sectional study of over 4,500 diabetic patients at two separate centers was conducted to determine the value of POC A1C testing beyond one year. This study provided evidence that POC A1C testing at 1.5 years and at 3.5 years continued to impact the A1C scores.

Three NGSP-certified POC products are available in the United States: the handheld A1CNow and two bench-top models called the Axis-Shield Afinion Analyzer and the Siemens DCA Vantage.

A1C now has a smaller size in comparison to the two other devices and it is the cheapest device. Afinion has the shortest analysis time, which is 3 minutes. The bench-top models have features like memory capacity, data export and color touch display.

### REGULATORY INFORMATION

Devices used for A1C testing at POC require FDA approval.

State specific mandates include:

Kentucky – No legislative mandates were found for coverage of A1C testing at POC.
Indiana – No legislative mandates were found for coverage of A1C testing at POC.
Tennessee – No legislative mandates were found for coverage of A1C testing at POC.

Baptist Health Plan Coverage Guidelines are created to provide members and providers with peer-reviewed, current medical information.
State and federal laws/mandates and contract language have priority over Coverage Guidelines and must be taken into consideration before eligibility for coverage is determined.
Baptist Health Plan Coverage Guidelines may or may not mirror Centers for Medicare & Medicaid Services benefits or coverage offered by any other health insurance company.

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E08.00-E13.9 Diabetes mellitus

024.011-02.93 Diabetes mellitus in pregnancy, childbirth, and the puerperium

O99.810-O99.815 Abnormal glucose complicating pregnancy, childbirth and the puerperium

REFERENCES


### SEARCH TERMS

- Blood sugar
- Diabetes Mellitus
- Glycated hemoglobin
- Hemoglobin A1c
- Hyperglycemia
- Mellitus
- Point of care
- Sugar