Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 1/1/24**
(See policy history boxes for previous effective dates)

Title: Hemoglobin A1c Testing Device for Home Use or for Use as a Point-of-Care Device

Description/Background

Diabetes is characterized by high blood sugar levels related to problems with the body's ability to respond to or produce insulin, a hormone created in the pancreas. Insulin is a vital component of the body's mechanism to regulate the amount of glucose in the blood, and to store blood glucose in muscles, liver and fat for when it is needed. Diabetes may lead to serious health problems including an increased risk for heart attack, stroke, and complications related to poor circulation such as nerve damage, kidney failure and blindness. One of the most common complications of diabetes is diabetic neuropathy. Regulation and monitoring of blood glucose levels have been shown to prevent or slow the progression of these conditions and complications.

Glycosylated hemoglobin (HbA1c) is found in red blood cells. It is formed when glucose binds to hemoglobin molecules. Measurements of HbA1c concentrations are used as an indicator of an average blood glucose level for the span of the cell's life (about four months).

The use of a device to measure HbA1c in the home has been proposed as a technique for managing blood glucose concentrations. Unlike home glucose monitoring, which gives an instant reading of blood sugar levels at a single point in time and is used to alter treatment in real time, measurement of HbA1c is an indicator of blood glucose control over a long period of time. Measurement of HbA1c typically involves submission of a blood sample to a laboratory. However, the results of this testing are often not available for several days and patient management may be delayed. This has prompted the development of a number of point-of-care (POC) devices that can measure HbA1c within minutes in a clinic, physician's office or at home.

Regulatory Status

The U.S. Food and Drug Administration has approved several home HbA1c devices through the 510(k) premarket approval process. Examples of devices that include test kits (a complete test system) are A1CNow® and OneDraw™ A1C Test.

Medical Policy Statement

Hemoglobin A1c testing device for home use, in the management of diabetes, is considered **experimental/investigational**. Its incremental benefit above home glucose monitoring has not been established.

Hemoglobin A1c testing, using an FDA approved point-of-care device, in the physician's office is considered **established**. It may be used as an alternative to laboratory measured hemoglobin A1c.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

83037

Other codes (investigational, not medically necessary, etc.):

E1399

Rationale

At this time, there is no evidence in the peer-reviewed medical literature demonstrating improved health outcomes related to home measurement of hemoglobin A1c levels. Although the devices may be accurate, there is no evidence that using such devices is an improvement over the standard of care of obtaining routine lab work. There are no clinical guidelines that support the use of these devices in the home.

A California Technology Assessment Forum (Tice, 2003) analysis stated that "Day to day clinical decisions about diabetes therapy are based on daily glucose testing, not HbA1c. HbA1c levels are usually used to make long-term changes in care in consultation between the patient and their doctor. It is unlikely that home HbA1c testing will improve clinical outcomes for patients with diabetes."

There are no prospective clinical studies demonstrating improvements in compliance or other clinically significant benefits of home A1C testing over laboratory A1C testing. Individual-case exceptions to this policy may be made upon medical review for members who are unable to access laboratory A1C testing.

Government Regulations
National:

National Coverage Determination (NCD) for Glycated Hemoglobin/Glycated Protein (190.21) Effective date 11/25/2002

Indications:
Glycated hemoglobin/protein testing is widely accepted as medically necessary for the management and control of diabetes. It is also valuable to assess hyperglycemia, a history of hyperglycemia or dangerous hypoglycemia. Glycated protein testing may be used in place of glycated hemoglobin in the management of diabetic patients, and is particularly useful in patients who have abnormalities of erythrocytes such as hemolytic anemia or hemoglobinopathies.

Limitations:
It is not considered reasonable and necessary to perform glycated hemoglobin tests more often than every three months on a controlled diabetic patient to determine whether the patient's metabolic control has been on average within the target range. It is not considered reasonable and necessary for these tests to be performed more frequently than once a month for diabetic pregnant women. Testing for uncontrolled type one or two diabetes mellitus may require testing more than four times a year. The above Description Section provides the clinical basis for those situations in which testing more frequently than four times per annum is indicated, and medical necessity documentation must support such testing in excess of the above guidelines. Many methods for the analysis of glycated hemoglobin show significant interference from elevated levels of fetal hemoglobin or by variant hemoglobin molecules. When the glycated hemoglobin assay is initially performed in these patients, the laboratory may inform the ordering physician of a possible analytical interference. Alternative testing, including glycated protein, for example, fructosamine, may be indicated for the monitoring of the degree of glycemic control in this situation. It is therefore conceivable that a patient will have both a glycated hemoglobin and glycated protein ordered on the same day. This should be limited to the initial assay of glycated hemoglobin, with subsequent exclusive use of glycated protein. These tests are not considered medically necessary for the diagnosis of diabetes.

CMS Coding Analysis for Labs (CAL) for Glycated Hemoglobin/Glycated Protein (Addition of CPT Code 83037, Hemoglobin; glycosylated [A1c] by device cleared by FDA for home use) (CAG-00373N) April 2, 2007:

CMS Analysis
…We want to emphasize that Medicare does not pay for glycosylated hemoglobin testing as a clinical laboratory test if the test is performed by the patient or the patient’s family. All Medicare requirements pertinent to clinical laboratory services must be fully met.

Summary

We believe that point of care testing supports the efficient management of diabetes by treating physicians. The availability of test results during the office visit can reduce or eliminate the need for follow-up telephone contact, which in practice often entails several calls between the patient and the physician and possibly the pharmacy. However, as we noted above, the current NCD does not prevent point of care testing.

There has been apparent confusion regarding the appropriate use of CPT 83037, evidenced by the February 2006 and October 2006 cpt® Assistant. Medicare does not generally pay for clinical laboratory testing performed by the patient or family. We conclude that the current understanding of code CPT 83037 is imprecise, and that its inclusion in the HCPCS table of this NCD could lead to confusion and to the submission of claims to Medicare for services that are not Medicare benefits.

Therefore, we do not believe that the addition of this code flows from the narrative of the NCD and we will not use the CAL process to add this code to the covered code list. We believe that the addition of CPT code 83037 would represent a substantive change to the NCD and that the evidence relevant to the requested addition would appropriately be reviewed in an NCD reconsideration.

Local:

There is no local coverage determination.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

1. Agency for Healthcare Research and Quality (AHRQ), Technology assessment: Point-of-care Testing of Hemoglobin A1c, 2005. http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id35TA.pdf Accessed 7/25/23.
2. Agency for Healthcare Research and Quality (AHRQ), Technology assessment: A proposed framework to evaluate home tests for use in the management of chronic diseases, 2008. http://www.cms.gov/determinationprocess/downloads/id62TA.pdf Accessed 7/25/23.
3. Akalin, S. Intensive glucose therapy and clinical implications of recent data: a consensus statement from the Global Task Force on Glycaemic Control. International Journal of Clinical Practice, 2009, Vol. 63, No. 10, pp. 1421-1425.
4. Al-Ansary, L. et al. Point-of-Care Testing for HbA1C in the Management of Diabetes: A Systematic Review and Metaanalysis. Clinical Chemistry, 2011, Volume 57, No. 4, pp. 568-576.

5. American Diabetes Association. Summary of Revisions: Standards of Medical Care in Diabetes—2019. Diabetes Care. Jan 2019, Vol. 42, No. S1, pp. S4-6.
6. American Diabetes Association. Position Statement: Standards of Medical Care in Diabetes – 2019. Diabetes Care. 2019, Volume 42, Supplement 1. https://care.diabetesjournals.org/content/42/Supplement_1 Accessed 7/25/23.
7. Centers for Medicare & Medicaid Services (CMS), Medicare Coverage Decision Memo for Glycated Hemoglobin/Glycated Protein (Addition of CPT code 83037, Hemoglobin; glycosylated [A1c] by Device Cleared by FDA for home use), Code Analysis for Labs, #CAG-00373N, April 2, 2007.
8. Chang, A., Et al. Evaluation of an over-the-counter glycated hemoglobin (A1c) test kit. Journal of Diabetes Science and Technology. 2010 Vol. 4, No. 6, pp. 1495-1503.
9. Czupryniak, L. Guidelines for the management of type 2 diabetes: is ADA and EASD consensus more clinically relevant than the IDF recommendations? Diabetes Research and Clinical Practice. 2009, Vol. 86, No. S1, pp. S22-25.
10. Hirst JA, et al. Performance of point-of-care HbA1c test devices: implications for use in clinical practice – a systematic review and meta-analysis. Clin Chem Lab Med. 2017 Feb 1, Vol. 55 No. 2, pp. 167-180. doi: 10.1515/cclm-2016-0303.
11. Lenters-Westra, E. et al. Six of Eight Hemoglobin A1C Point-of-Care Instruments Do Not Meet the General Accepted Analytical Performance Criteria. Clinical Chemistry, 2010, Volume 56, No. 1, pp. 44-52.
12. Tice, J. Rapid hemoglobin A1c testing for evaluation of glucose control. California Technology Assessment Forum, October 8, 2003, San Francisco, California.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 7/25/23, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/07	7/30/07	8/30/07	Joint policy established
1/1/09	10/13/08	12/30/08	Routine maintenance
7/1/11	4/19/11	5/3/11	Routine maintenance, title changed from Hemoglobin Glycosylate (HbA1c) Home Device to Hemoglobin A1c Testing Device for Home Use or for Use as a Point-of-care Device
3/1/14	12/10/13	1/6/14	Routine maintenance
1/1/16	10/13/15	10/27/15	Routine maintenance
1/1/17	10/11/16	10/11/16	Routine maintenance
1/1/18	10/19/17	10/19/17	Routine maintenance
1/1/19	10/16/18	10/16/18	Routine maintenance
1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance
1/1/22	10/19/21		Routine maintenance
1/1/23	10/18/22		Routine maintenance (ls)
1/1/24	10/17/23		Routine maintenance (jf) Vendor Managed: NA

Next Review Date: 4th Qtr, 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: HEMOGLOBIN A1C TESTING DEVICE FOR HOME USE OR FOR USE AS A POINT-OF-CARE DEVICE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.