

If a conflict arises between a Clinical Payment and Coding Policy (“CPCP”) and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. “Plan documents” include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. BCBSIL may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSIL has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act (“HIPAA”) approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing (“UB”) Editor, American Medical Association (“AMA”), Current Procedural Terminology (“CPT®”), CPT® Assistant, Healthcare Common Procedure Coding System (“HCPCS”), ICD-10 CM and PCS, National Drug Codes (“NDC”), Diagnosis Related Group (“DRG”) guidelines, Centers for Medicare and Medicaid Services (“CMS”) National Correct Coding Initiative (“NCCI”) Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

## Hemoglobin A1c

**Policy Number: CPCPLAB004**

**Version 1.0**

**Enterprise Medical Policy Committee Approval Date: January 25, 2022**

**Plan Effective Date: May 1, 2022**

## Description

BCBSIL has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

## Reimbursement Information:

1. Measurement of hemoglobin A1c **may be reimbursable** for individuals with a diagnosis of either Type 1 or Type 2 diabetes as follows:
  - a. Upon initial diagnosis to establish a baseline value and to determine treatment goals.
  - b. establish a baseline value and to determine treatment goals.
  - c. Twice a year (every 6 months) in individuals who are meeting treatment goals and who, based on daily glucose monitoring, appear to have stable glycemic control.

- d. Quarterly in individuals who are not meeting treatment goals for glycemic control.
  - e. Quarterly in individuals whose pharmacologic therapy has changed.
2. Measurement of hemoglobin A1c **may be reimbursable** to help in detection and diagnosis of pre-diabetes or Type 2 diabetes in the following populations once every three years:
    - a. Asymptomatic individuals who are overweight or obese as defined by the ADA (BMI  $\geq 25$  kg/m<sup>2</sup> or BMI  $\geq 23$  kg/m<sup>2</sup> in Asian Americans) and who have one or more of the following risk factors:
      - i. First degree relative with diabetes; OR
      - ii. High-risk race/ethnicity (e.g., African American, Latino or Hispanics, Native American, Asian American, Pacific Islanders); OR
      - iii. History of cardiovascular disease; OR
      - iv. Hypertension ( $\geq 140/90$  mmHg or on therapy for hypertension); OR
      - v. HDL cholesterol level  $< 35$  mg/dL (0.90 mmol/L) and/or a triglyceride level  $> 250$  mg/dL (2.82 mmol/L); OR
      - vi. Women with polycystic ovary syndrome; OR
      - vii. Physical inactivity; OR
      - viii. Other clinical conditions associated with insulin resistance (e.g., Severe obesity, acanthosis nigricans)
    - b. Women who were previously diagnosed with gestational diabetes
  3. For pre-diabetic individuals, screening for type 2 diabetes with hemoglobin A1c test once a year **may be reimbursable**.
  4. Diabetes screening with a hemoglobin A1c determination **may be reimbursable** once every 3 years for children (age 10 years and older OR after the onset of puberty, whichever occurs earlier) with the following characteristics:
    - a. Overweight (BMI  $\geq 85$ th percentile) or obese (BMI  $\geq 95$ th percentile) as defined by ADA AND
    - b. Must have one or more of the following additional risk factors:
      - i. Maternal history of diabetes or gestational diabetes mellitus during the child's gestation; OR
      - ii. Family history of type 2 diabetes in first- or second-degree relative; OR
      - iii. High-risk race/ethnicity (e.g., African American, Latino or Hispanics, Native American, Asian American, Pacific Islanders); OR
      - iv. Signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, polycystic ovary syndrome, or small-for-gestational-age birth weight)
  5. Measurement of hemoglobin A1c **may be reimbursable** for pregnant individuals up to once per month during pregnancy.
  6. Measurement of hemoglobin A1c **is not reimbursable** in the following circumstances:
    - a. in individuals who have been transfused within the past 120 days; OR
    - b. in individuals with a condition associated with increased red blood cell turnover, such as sickle cell disease, hemodialysis, recent blood loss or transfusion, or erythropoietin therapy; OR
    - c. in conjunction with measurement of fructosamine; OR
    - d. to diagnose the acute onset of type 1 diabetes in individuals with symptoms of hyperglycemia; OR
    - e. as a screening test for cystic fibrosis-related diabetes.

## Procedure Codes

Codes
82985, 83036, 83037

## References:

AAFP. (2016). Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Recommendation Statement. *Am Fam Physician*, 93(2), Online.

ADA. (2010). Diagnosis and classification of diabetes mellitus. *Diabetes Care*, 33 Suppl 1, S62-69. doi:10.2337/dc10-S062

ADA. (2017). Statistics About Diabetes. Retrieved from <https://www.diabetes.org/resources/statistics/statistics-about-diabetes>

ADA. (2021a). 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes — 2020. *Diabetes Care*, 43(Supplement 1), S14. doi:10.2337/dc20-S002

ADA. (2021b). 4. Comprehensive Medical Evaluation and Assessment of Comorbidities: Standards of Medical Care in Diabetes — 2020. *Diabetes Care*, 43(Supplement 1), S37. doi:10.2337/dc20-S004

ADA. (2021c). 6. Glycemic Targets: Standards of Medical Care in Diabetes — 2020. *Diabetes Care*, 43(Supplement 1), S66. doi:10.2337/dc20-S006

ADA. (2021d). 13. Children and Adolescents: Standards of Medical Care in Diabetes—2020. *Diabetes Care*, 43(Supplement 1), S163. doi:10.2337/dc20-S013

ADA. (2021). 14. Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes — 2020. *Diabetes Care*, 43(Supplement 1), S183. doi:10.2337/dc20-S014

Al-Badri, A., Hashmath, Z., Oldland, G. H., Miller, R., Javaid, K., Syed, A. A., . . . Chirinos, J. A. (2018). Poor Glycemic Control Is Associated With Increased Extracellular Volume Fraction in Diabetes. *Diabetes Care*. doi:10.2337/dc18-0324

Al Mansari, A., Obeid, Y., Islam, N., Fariduddin, M., Hassoun, A., Djaballah, K., . . . Chaudhury, T. (2018). GOAL study: clinical and non-clinical predictive factors for achieving glycemic control in people with type 2 diabetes in real clinical practice. *BMJ Open Diabetes Res Care*, 6(1), e000519. doi:10.1136/bmjdr-2018-000519

Arbiol-Roca, A., Pérez-Hernández, E. A., Aisa-Abdellaoui, N., Valls-Guallar, T., Gálvez-Carmona, F., Mariano-Serrano, E., . . . Ruiz-Morer, M. R. (2021). The utility HBA1c test as a screening biomarker for detecting gestational diabetes mellitus. *Clinical Biochemistry*, 90, 58-61. doi:<https://doi.org/10.1016/j.clinbiochem.2021.01.002>

CDC. (2020). National Diabetes Statistics Report 2020 Estimates of Diabetes and Its Burden in the United States. Retrieved from <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>

- Committee, D. C. C. P. G. E. (2018). Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Retrieved from <http://guidelines.diabetes.ca/docs/CPG-2018-full-EN.pdf>
- Cowie, C. C., Rust, K. F., Byrd-Holt, D. D., Gregg, E. W., Ford, E. S., Geiss, L. S., . . . Fradkin, J. E. (2010). Prevalence of Diabetes and High Risk for Diabetes Using A1C Criteria in the U.S. Population in 1988–2006. *Diabetes Care*, 33(3), 562. doi:10.2337/dc09-1524
- de Boer, I. H., Caramori, M. L., Chan, J. C. N., Heerspink, H. J. L., Hurst, C., Khunti, K., . . . Rossing, P. (2020). KDIGO 2020 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. *Kidney International*, 98(4), S1-S115. doi:10.1016/j.kint.2020.06.019
- DiMeglio, L. A., Acerini, C. L., Codner, E., Craig, M. E., Hofer, S. E., Pillay, K., & Maahs, D. M. (2018). ISPAD Clinical Practice Consensus Guidelines 2018: Glycemic control targets and glucose monitoring for children, adolescents, and young adults with diabetes. *Pediatr Diabetes*, 19 Suppl 27, 105-114. doi:10.1111/pedi.12737
- FDA. (2021). Devices@FDA. Retrieved from <https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm>
- Gambino, R. (2007). Glucose: a simple molecule that is not simple to quantify. *Clin Chem*, 53(12), 2040-2041. doi:10.1373/clinchem.2007.094466
- Garber, A. J., Abrahamson, M. J., Barzilay, J. I., Blonde, L., Bloomgarden, Z. T., Bush, M. A., . . . Davidson, M. H. (2015). AACE/ACE comprehensive diabetes management algorithm 2015. *Endocr Pract*, 21(4), 438-447. doi:10.4158/ep15693.cs
- Garber, A. J., Abrahamson, M. J., Barzilay, J. I., Blonde, L., Bloomgarden, Z. T., Bush, M. A., . . . Umpierrez, G. E. (2019). CONSENSUS STATEMENT BY THE AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY ON THE COMPREHENSIVE TYPE 2 DIABETES MANAGEMENT ALGORITHM - 2019 EXECUTIVE SUMMARY. *Endocr Pract*, 25(1), 69-100. doi:10.4158/cs-2018-0535
- Goodney, P. P., Newhall, K. A., Bekelis, K., Gottlieb, D., Comi, R., Chaudrain, S., . . . Skinner, J. S. (2016). Consistency of Hemoglobin A1c Testing and Cardiovascular Outcomes in Medicare Patients With Diabetes. *J Am Heart Assoc*, 5(8). doi:10.1161/jaha.116.003566
- Gu, J., Pan, J. A., Fan, Y. Q., Zhang, H. L., Zhang, J. F., & Wang, C. Q. (2018). Prognostic impact of HbA1c variability on long-term outcomes in patients with heart failure and type 2 diabetes mellitus. *Cardiovasc Diabetol*, 17(1), 96. doi:10.1186/s12933-018-0739-3
- Hanssen, K. F., Bangstad, H. J., Brinchmann-Hansen, O., & Dahl-Jorgensen, K. (1992). Blood glucose control and diabetic microvascular complications: long-term effects of near-normoglycaemia. *Diabet Med*, 9(8), 697-705. Retrieved from <http://dx.doi.org/>
- Hoelzel, W., Weykamp, C., Jeppsson, J. O., Miedema, K., Barr, J. R., Goodall, I., . . . Wiedmeyer, H. M. (2004). IFCC reference system for measurement of hemoglobin A1c in human blood and the national standardization schemes in the United States, Japan, and Sweden: a method-comparison study. *Clin Chem*, 50(1), 166-174. doi:10.1373/clinchem.2003.024802

IEC. (2009). International Expert Committee report on the role of the A1C assay in the diagnosis of diabetes. *Diabetes Care*, 32(7), 1327-1334. doi:10.2337/dc09-9033

Inzucchi, S., Lupsa, Beatrice. (2021). Clinical presentation and diagnosis of diabetes mellitus in adults - UpToDate. Retrieved from [https://www.uptodate.com/contents/clinical-presentation-and-diagnosis-of-diabetes-mellitus-in-adults?source=search\\_result&search=a1c&selectedTitle=5~150](https://www.uptodate.com/contents/clinical-presentation-and-diagnosis-of-diabetes-mellitus-in-adults?source=search_result&search=a1c&selectedTitle=5~150).

Kanyal Butola, L., Ambad, R., Kanyal, D., & Vagga, A. (2021). Glycated Haemoglobin-Recent Developments and Review on Non-Glycemic Variables.

LeRoith, D., Biessels, G. J., Braithwaite, S. S., Casanueva, F. F., Draznin, B., Halter, J. B., . . . Sinclair, A. J. (2019). Treatment of Diabetes in Older Adults: An Endocrine Society\* Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*, 104(5), 1520-1574. doi:10.1210/jc.2019-00198

Ludvigsson, J. F., Neovius, M., Söderling, J., Gudbjörnsdóttir, S., Svensson, A. M., Franzén, S., . . . Pasternak, B. (2019). Maternal Glycemic Control in Type 1 Diabetes and the Risk for Preterm Birth: A Population-Based Cohort Study. *Ann Intern Med*, 170(10), 691-701. doi:10.7326/m18-1974

Malkani, S., & Mordes, J. P. (2011). The implications of using Hemoglobin A1C for diagnosing Diabetes Mellitus. *Am J Med*, 124(5), 395-401. doi:10.1016/j.amjmed.2010.11.025

Mamtora, S., Maghsoudlou, P., Hasan, H., Zhang, W., & El-Ashry, M. (2021). Assessing the Clinical Utility of Point of Care HbA1c in the Ophthalmology Outpatient Setting. *Clinical ophthalmology (Auckland, N.Z.)*, 15, 41-47. doi:10.2147/OPHT.S287531

Mañé, L., Flores-Le Roux, J. A., Pedro-Botet, J., Gortazar, L., Chillarón, J. J., Llauradó, G., . . . Benaiges, D. (2019). Is fasting plasma glucose in early pregnancy a better predictor of adverse obstetric outcomes than glycated haemoglobin? *Eur J Obstet Gynecol Reprod Biol*, 234, 79-84. doi:10.1016/j.ejogrb.2018.12.036

McCulloch, D. (2020). Estimation of blood glucose control in diabetes mellitus - UpToDate. Retrieved from [https://www.uptodate.com/contents/estimation-of-blood-glucose-control-in-diabetes-mellitus?source=see\\_link&sectionName=Glycated%20hemoglobin&anchor=H3#H3](https://www.uptodate.com/contents/estimation-of-blood-glucose-control-in-diabetes-mellitus?source=see_link&sectionName=Glycated%20hemoglobin&anchor=H3#H3).

Miller, W. G., Myers, G. L., Ashwood, E. R., Killeen, A. A., Wang, E., Ehlers, G. W., . . . Toth, A. (2008). State of the art in trueness and interlaboratory harmonization for 10 analytes in general clinical chemistry. *Arch Pathol Lab Med*, 132(5), 838-846. doi:10.1043/1543-2165(2008)132[838:sotait]2.0.co;2

Mitsios, J. P., Ekinci, E. I., Mitsios, G. P., Churilov, L., & Thijs, V. (2018). Relationship Between Glycated Hemoglobin and Stroke Risk: A Systematic Review and Meta-Analysis. *J Am Heart Assoc*, 7(11). doi:10.1161/jaha.117.007858

Moran, A., Pillay, K., Becker, D., Granados, A., Hameed, S., & Acerini, C. L. (2018). ISPAD Clinical Practice Consensus Guidelines 2018: Management of cystic fibrosis-related diabetes in children and adolescents. *Pediatr Diabetes*, 19 Suppl 27, 64-74. doi:10.1111/pedi.12732

NACB. (2011). Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus. In D. Sacks (Ed.), *LABORATORY MEDICINE PRACTICE GUIDELINES*. Retrieved from <https://www.aacc.org/science-and-practice/practice-guidelines/diabetes-mellitus>

Nathan, D. M., Singer, D. E., Hurxthal, K., & Goodson, J. D. (1984). The clinical information value of the glycosylated hemoglobin assay. *N Engl J Med*, 310(6), 341-346. doi:10.1056/nejm198402093100602

NGSP. (2019, 06/2019). College of American Pathologists (CAP) GH5 Survey Data: Retrieved from <http://www.ngsp.org/CAP/CAP19a.pdf>

NICE. (2020). Type 2 diabetes in adults: management. Retrieved from <https://www.nice.org.uk/guidance/ng28/chapter/1-Recommendations>

Petersen, P. H., Jorgensen, L. G., Brandslund, I., De Fine Olivarius, N., & Stahl, M. (2005). Consequences of bias and imprecision in measurements of glucose and hba1c for the diagnosis and prognosis of diabetes mellitus. *Scand J Clin Lab Invest Suppl*, 240, 51-60. doi:10.1080/00365510500236135

Qaseem, A., Wilt, T. J., Kansagara, D., Horwitch, C., Barry, M. J., & Forciea, M. A. (2018). Hemoglobin A1c Targets for Glycemic Control With Pharmacologic Therapy for Nonpregnant Adults With Type 2 Diabetes Mellitus: A Guidance Statement Update From the American College of Physicians. *Ann Intern Med*, 168(8), 569-576. doi:10.7326/m17-0939

Rohlfing, C., Wiedmeyer, H. M., Little, R., Grotz, V. L., Tennill, A., England, J., . . . Goldstein, D. (2002). Biological variation of glycohemoglobin. *Clin Chem*, 48(7), 1116-1118. Retrieved from <http://dx.doi.org/>

Saito, Y., Noto, H., Takahashi, O., & Kobayashi, D. (2019). Visit-to-Visit Hemoglobin A1c Variability Is Associated With Later Cancer Development in Patients With Diabetes Mellitus. *Cancer J*, 25(4), 237-240. doi:10.1097/ppo.0000000000000387

Selvin, E., Crainiceanu, C. M., Brancati, F. L., & Coresh, J. (2007). Short-term variability in measures of glycemia and implications for the classification of diabetes. *Arch Intern Med*, 167(14), 1545-1551. doi:10.1001/archinte.167.14.1545

Skyler, J. S., Bakris, G. L., Bonifacio, E., Darsow, T., Eckel, R. H., Groop, L., . . . Ratner, R. E. (2017). Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*, 66(2), 241-255. doi:10.2337/db16-0806

Tommerdahl, K. L., Brinton, J. T., Vigers, T., Nadeau, K. J., Zeitler, P. S., & Chan, C. L. (2019). Screening for cystic fibrosis-related diabetes and prediabetes: Evaluating 1,5-anhydroglucitol, fructosamine, glycated albumin, and hemoglobin A1c. *Pediatr Diabetes*, 20(8), 1080-1086. doi:10.1111/pedi.12914

USPSTF. (2016). Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Recommendation Statement. *Am Fam Physician*, 93(2), Online.

van 't Riet, E., Alsema, M., Rijkkelijkhuizen, J. M., Kostense, P. J., Nijpels, G., & Dekker, J. M. (2010). Relationship between A1C and glucose levels in the general Dutch population: the new Hoorn study. *Diabetes Care*, 33(1), 61-66. doi:10.2337/dc09-0677

Weykamp, C., John, W. G., Mosca, A., Hoshino, T., Little, R., Jeppsson, J. O., . . . Siebelder, C. (2008). The IFCC Reference Measurement System for HbA1c: a 6-year progress report. *Clin Chem*, 54(2), 240-248. doi:10.1373/clinchem.2007.097402

WHO. (2016). Global Report on Diabetes. Retrieved from <http://www.who.int/diabetes/global-report/en/>

WHO. (2020). Diagnosis and Management of Type 2 Diabetes. Retrieved from <https://www.who.int/publications/i/item/who-ucn-ncd-20.1>

**Policy Update History:**

5/1/2022	New policy
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