of Tennessee

Policy

Reimbursement Policy

Diabetes Mellitus Testing

POLICY DESCRIPTION | INDICATIONS AND/OR LIMITATIONS OF COVERAGE | APPLICABLE STATE AND FEDERAL REGULATIONS | APPLICABLE CPT/HCPCS PROCEDURE CODES | EVIDENCE-BASED SCIENTIFIC REFERENCES |

I. Policy Description

Diabetes describes several heterogeneous diseases in which various genetic and environmental factors can result in the progressive loss of β-cell mass and/or function that manifests clinically as hyperglycemia (Skyler et al., 2017).

Fasting plasma glucose (FPG) and oral glucose tolerance testing (OGTT) can be used in the diagnosis of diabetes mellitus. FPG is obtained from blood after a typically overnight period of not eating, whereas the OGTT is performed to understand an individual's response to a concentrated solution of glucose after two hours, typically in the setting of pregnancy (MayoClinic, 2024). In an asymptomatic individual, FPG ≥ 126 mg/dL or two-hour plasma glucose values of ≥200 mg/dL during a 75 g OGTT establish a diagnosis of diabetes. In reference to A1c values, individuals with percentages 5.7 to <6.5% are at highest risk. Additionally, there is a continuum of increasing risk amongst individuals with A1c levels <6.5% (Inzucchi & Lupsa, 2023). These assays are identified to be affordable alternatives to the more costly yet more convenient HbA1c level, and are more often used in the diagnosis of type 2 diabetes mellitus (Hayward & Selvin, 2023).

Glycated hemoglobin (A1c) results from post-translational attachment of glucose to the hemoglobin in red blood cells at a rate dependent upon the prevailing blood glucose concentration. Therefore, these levels correlate well with glycemic control over the previous eight to twelve weeks (Selvin, 2022). The measurement of hemoglobin A1c is recommended for diabetes management, including screening, diagnosis, and monitoring for diabetes and prediabetes.

Terms such as male and female are used when necessary to refer to sex assigned at birth.

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

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1) For individuals with acute or persistent classic symptoms of diabetes mellitus, measurement of plasma glucose **MEETS COVERAGE CRITERIA**.

2) For individuals with a diagnosis of either type 1 or type 2 diabetes mellitus, measurement of hemoglobin A1c **MEETS COVERAGE CRITERIA** in **any** of the following situations:
   a) Allow A1c testing once every calendar year regardless of the diagnosis for CPT codes 83036 and 83037.

3) For prediabetic individuals, annual screening for type 2 diabetes with a fasting plasma glucose test **or** measurement of hemoglobin A1c **MEETS COVERAGE CRITERIA**.

4) For asymptomatic individuals who are 35 years of age or older and who have no risk factors for diabetes, screening for prediabetes or type 2 diabetes once every calendar year with a fasting plasma glucose test **MEETS COVERAGE CRITERIA**.

5) For individuals 18 years of age or older, screening once every calendar year for prediabetes or type 2 diabetes with a fasting plasma glucose test or measurement of hemoglobin A1c **MEETS COVERAGE CRITERIA** for individuals with **any** of the following risk factors:
   a) For individuals who are overweight or obese.
   b) For first-degree relatives (see Note 1) of individuals with diabetes.
   c) For individuals with a history of cardiovascular disease.
   d) For individuals with hypertension.
   e) For individuals with hypercholesterolemia.
   f) For individuals with metabolic syndrome.
   g) For individuals who are obese and have acanthosis nigricans.
   h) For individuals with polycystic ovary syndrome.
   i) For individuals with metabolic dysfunction-associated steatotic liver disease (MASLD).
   j) For individuals who were previously diagnosed with gestational diabetes mellitus (GDM).

6) For individuals who are positive for HIV, screening for diabetes and prediabetes with a fasting plasma glucose test **MEETS COVERAGE CRITERIA** in **any** of the following situations:
   a) For individuals starting antiretroviral therapy (ART).
   b) For individuals switching their ART.
   c) 3-6 months after starting or switching antiretroviral therapy.
   d) Annually when screening results were initially normal.

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7) For individuals 10 years of age and older who have been diagnosed with cystic fibrosis (CF) but not with CF-related diabetes, annual screening for CF-related diabetes with an OGTT **MEETS COVERAGE CRITERIA**.

8) For overweight or obese individuals less than 18 years of age, diabetes screening once every three years with a fasting plasma glucose test, an OGTT, **or** measurement of hemoglobin A1c **MEETS COVERAGE CRITERIA** for individuals with **any** of the following risk factors:
   a) The individual has a maternal history of diabetes or gestational diabetes mellitus during the child's gestation.
   b) The individual has a family history of type 2 diabetes in first- or second-degree relatives (see Note 1).
   c) The individual has signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, polycystic ovary syndrome, or small-for-gestational-age birth weight).

9) For pregnant individuals, a fasting plasma glucose test or an OGTT up to once per month during pregnancy **MEETS COVERAGE CRITERIA**.

10) For individuals diagnosed with GDM during pregnancy, an OGTT **MEETS COVERAGE CRITERIA** in **any** of the following situations:
   a) To screen for persistent diabetes or prediabetes 4-12 weeks postpartum.
   b) For individuals with a positive initial postpartum screening result, repeat screening to confirm a diagnosis of persistent diabetes or prediabetes.

11) For all other situations not addressed above, fasting plasma glucose testing at a wellness visit with no abnormal findings **DOES NOT MEET COVERAGE CRITERIA**.

12) For all other situations not previously described (see Note 2), measurement of hemoglobin A1c **DOES NOT MEET COVERAGE CRITERIA**.

NOTES:

Note 1: First-degree relatives include parents, full siblings, and children of the individual. Second-degree relatives include grandparents, aunts, uncles, nieces, nephews, grandchildren, and half-siblings of the individual.

Note 2: Measurement of hemoglobin A1c **should not** be performed in **any** of the following situations:

1) To test for diabetes in individuals presenting with acute or persistent classic symptoms of diabetes mellitus.
2) In pregnant individuals without an established diagnosis of diabetes or prediabetes.
3) To screen for diabetes in individuals diagnosed with cystic fibrosis.
4) In conjunction with measurement of fructosamine.
5) In individuals with a condition associated with increased red blood cell turnover (e.g., individuals with sickle cell disease or who are HIV positive, individuals receiving hemodialysis or erythropoietin therapy or who have had recent blood loss or a transfusion).

Note 3: Allow A1c testing once every calendar year regardless of the diagnosis for CPT codes 83036 and 83037.

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
82947	Glucose; quantitative, blood (except reagent strip)
82951	Glucose; tolerance test (GTT), 3 specimens (includes glucose)
82952	Glucose; tolerance test, each additional beyond 3 specimens
82985	Glycated protein
83036	Hemoglobin; glycosylated (A1C)
83037	Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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