Clinical UM Guideline

Subject:	Outpatient Glycated Hemoglobin and Protein Testing		
Guideline #:	CG-LAB-25	**Publish Date:**	09/27/2023
Status:	Revised	**Last Review Date:**	05/11/2023

Description

Glycated hemoglobin, (also referred to as glycohemoglobin, glycosylated hemoglobin, HbA1, GHb, or A1C), is a term used to describe a series of stable minor hemoglobin components formed from a combination of hemoglobin and glucose. It is used primarily to identify the plasma glucose concentration over time. This document addresses outpatient HbA_{1c} and glycated serum proteins (GSPs) testing, both of which have been used in the monitoring of glycemic control in the management of diabetes mellitus (DM).

For information regarding other methods to assess glycemic control for individuals with DM, see:

- CG-DME-42 Continuous Glucose Monitoring Devices and External Insulin Infusion Pumps

Clinical Indications

Medically Necessary:

Glycated serum protein testing (for example, hemoglobin (HbA_{1c}), albumin, or fructosamine) testing is considered **medically necessary** for any of the following indications (A-F):

A. The individual is between the ages of 35 and 71 and is overweight or obese*****; **or**
B. The individual is of any age, has overweight or obesity, and is from a population with disproportionately high prevalence of diabetes mellitus******; **or**
C. Hyperglycemia has been found on other testing; **or**
D. To test individuals who are pregnant and considered to be at high risk for type 2 diabetes mellitus; **or**
E. Prior testing at least 3 months previously showed results near diabetes mellitus diagnostic thresholds; **or**
F. To evaluate glycemic status for individuals with established diabetes mellitus, prediabetes, or a history of gestational diabetes when done no more often than the following test frequencies:
    1. Up to once yearly for individuals with prediabetes; **or**
    2. Up to two times per year for individuals with diabetes mellitus who are meeting treatment goals; **or**
    3. As needed to assess individuals with diabetes mellitus when the following criteria are met (a or b):
        a. Not meeting treatment goals; **or**
        b. Therapy has recently changed;

    or

    4. Within the first year postpartum and then up to once yearly for individuals who have had gestational diabetes.

Notes:
See the Discussion section below for more information about:
*ADA, ACOG, and USPSTF recommendations about individuals who have overweight or obesity; and
**Populations with high prevalence of diabetes mellitus.

Not Medically Necessary:

Glycated hemoglobin (HbA_{1c}) testing and glycated serum protein (for example, albumin or fructosamine) testing is considered **not medically necessary** when the criteria above are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Medically Necessary:

CPT	
82985	Glycated protein
83036	Hemoglobin; glycosylated (A1C)

ICD-10 Diagnosis	
B20	Human immunodeficiency virus [HIV] disease
C25.4	Malignant neoplasm of endocrine pancreas
D13.7	Benign neoplasm of endocrine pancreas
E08.00-E13.9	Diabetes mellitus
E15	Nondiabetic hypoglycemic coma
E16.0-E16.9	Other disorders of pancreatic internal secretion
E28.2	Polycystic ovarian syndrome
E31.0-E31.9	Polyglandular dysfunction
E66.01-E66.9	Overweight and obesity
E74.00-E74.9	Other disorders of carbohydrate metabolism
E78.00-E78.9	Disorders of lipoprotein metabolism and other lipidemias
E79.0	Hyperuricemia without signs of inflammatory arthritis and tophaceous disease
E83.10-E83.19	Disorders of iron metabolism
E88.02	Plasminogen deficiency
E88.810-E88.819	Metabolic syndrome and other insulin resistance
E89.1	Postprocedural hypoinsulinemia
I10-I1A.0	Hypertensive diseases
I21.01-I22.9	Acute myocardial infarction, subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

I24.0-I25.9	Other acute ischemic heart disease; chronic ischemic heart disease
K86.0-K86.1	Chronic pancreatitis (alcohol-induced, other)
K91.2	Postsurgical malabsorption, not elsewhere classified
L83	Acanthosis nigricans
O10.011-O11.9	Pre-existing hypertension complicating pregnancy, childbirth and the puerperium; pre-existing hypertension with pre-eclampsia
O24.011-O24.93	Pre-existing, gestational or unspecified diabetes in pregnancy
O26.00-O26.03	Excessive weight gain in pregnancy
O30.101-O30.93	Multiple gestation, triplet, quadruplet, other and unspecified multiple gestation
O99.210-O99.215	Obesity complicating pregnancy, childbirth and the puerperium
O99.411-O99.43	Diseases of the circulatory system complicating pregnancy, childbirth and the puerperium
O99.810-O99.815	Abnormal glucose complicating pregnancy, childbirth and the puerperium
P05.00-P05.19	Newborn light/small for gestational age
P07.00-P07.18	Extremely low/other low birth weight newborn
P70.0-P70.9	Transitory disorders of carbohydrate metabolism specific to newborn
R73.01-R73.9	Elevated blood glucose level
R79.0-R79.9	Abnormal findings of blood chemistry, other or unspecified
T38.3X1A-T38.3X4S	Poisoning by insulin and oral hypoglycemic [antidiabetic] drugs
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status
Z68.23-Z68.45	Body mass index [BMI] 23.0-70 or greater, adult
Z68.53-Z68.54	Body mass index [BMI] pediatric, 85th percentile to greater than or equal to 95th percentile for age
Z72.3	Lack of physical exercise
Z79.4	Long term (current) use of insulin
Z79.84	Long term (current) use of oral hypoglycemic drugs
Z83.3	Family history of diabetes mellitus
Z86.2	Personal history of diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
Z86.31-Z86.39	Personal history of endocrine, nutritional and metabolic diseases
Z86.74-Z86.79	Personal history of sudden cardiac arrest/other diseases of the circulatory system
Z87.59	Personal history of other complications of pregnancy, childbirth and the puerperium

When services are Not Medically Necessary:
For the procedure codes listed above for all other indications.

Discussion/General Information

Diabetes mellitus (DM) is a disease in which an absolute or relative deficiency of insulin secretion leads to elevated levels of glucose in the blood (hyperglycemia). DM has the potential to cause severe and sometimes fatal acute or chronic medical complications. Optimal DM treatment is often able to prevent or delay development of these complications. The onset of DM is often slow, with a period of abnormal carbohydrate metabolism known as

prediabetes often preceding the development of DM. Treatment of prediabetes may prevent or delay the development of DM.

Proactive management of DM requires regular determinations of blood glucose levels. Measuring levels of glycated hemoglobin or other proteins in the blood can indicate the prevailing blood glucose levels over long periods of time. High levels of blood glucose lead to irreversible attachment of a glucose molecule to the N-terminus of protein molecules. The glycated hemoglobin (HbA_{1c}) test has been shown to predict the risk for development of many of the chronic complications in DM and is the most used indicator of long-term glycemic control. HbA_{1c} testing can also be used to screen for or to diagnose prediabetes and DM. Alternative names for HbA_{1c} include glycated hemoglobin, glycosylated hemoglobin, HbA1, A1c or GHb.

HbA_{1c} levels might not be an accurate measure of long-term glycemic control for individuals with aberrant hemoglobins, (such as those with sickle cell disease). The HbA_{1c} level may be artifactually elevated in individuals with vitamin B12 or folate deficiency, for whom red blood cell (RBC) turnover may be reduced. Conversely, those with rapid RBC turnover, as in thalassemia, chronic hemolysis, or recently treated anemia, may have lower than expected HbA_{1c} levels. Alternatives to HbA_{1c} measurement for these individuals include frequent fingerstick glucose measurements, continuous glucose monitoring, or measurement of glycated proteins other than hemoglobin. The non-hemoglobin proteins most used for assessment of glycemic control are glycated fructosamine and glycated albumin. Both of these proteins can be affected by conditions that affect serum protein levels, such as protein-losing enteropathy or the nephrotic syndrome. Albumin and other proteins are eliminated from serum at a faster rate compared to hemoglobin. While HbA_{1c} is considered to reflect glycemic control over the previous 120 days, other glycated proteins may only reflect the average glucose levels for the previous few weeks. More frequent testing may be needed when these tests are used to assess glycemic control.

An RBC has an average life span of 120 days. Since the HbA_{1c} test measures hemoglobin within RBCs, the HbA_{1c} level reflects the average plasma glucose levels over the previous 120 days. Diagnostic and therapeutic targets for HbA_{1c} testing are commonly reported in the US as the percent of hemoglobin that has been glycated in a sample. HbA_{1c} testing may not be reliable for individuals with hemoglobin variants, (such as sickle cell anemia, sickle cell trait, or thalassemia) or for those with shortened RBC lifespans, (such as those with hemolytic anemia). An organization named NGSP (originally the National Glycohemoglobin Standardization Program) certifies HbA_{1c} assays and has information about reliable HbA_{1c} testing that may be available for individuals with hemoglobin variants. Marked discrepancies between measured A1C and plasma glucose levels should prompt consideration that the HbA_{1c} assay may not be reliable for that individual. An updated list of HbA_{1c} assays with information about interferences is available at: NGSP: HbA1c Assay Interferences. Other measures of glycemic control, such as self-monitored blood glucose or continuous glucose monitoring, may be appropriate when HbA_{1c} testing is not thought to be reliable for an individual.

According to the Centers for Disease Control and Prevention (CDC) 2020 National Diabetes Statistics Report, an estimated 13% of all US adults have DM and 34.5% meet criteria for prediabetes. The prevalence of prediabetes and DM are higher in older adults. Of persons with DM, 21.4% were not aware of or did not report having DM, and only 15.3% of persons with prediabetes reported being told by a health professional that they had this condition. Estimates of the risk of progression from prediabetes to DM vary widely, perhaps because of variation

in the definition of prediabetes or the heterogeneity of prediabetes. The U.S. Preventive Services Task Force (USPSTF) reports that the risk of developing DM increases with increasing HbA_{1c} level and with increasing body mass index (BMI).

It is especially important to detect and tightly control DM during pregnancy. Suboptimal glycemic control has been well established as a cause for numerous poor health outcomes, including spontaneous abortion, fetal anomalies, preeclampsia, fetal demise, macrosomia, neonatal hypoglycemia, hyperbilirubinemia, and neonatal respiratory distress syndrome. Diabetes in pregnancy also increases risks for chronic illnesses in the offspring's later life, including obesity, type 2 DM, and hypertension (ADA, 2022).

Screening for Prediabetes and Type 2 DM

Screening asymptomatic adults for prediabetes and type 2 DM may allow earlier detection, diagnosis, and treatment, with the goal of improving health outcomes.

Overweight and obesity are the strongest risk factors for developing prediabetes and type 2 DM in adults. Other risk factors include older age, family history, history of gestational diabetes, history of polycystic ovarian syndrome, and dietary and lifestyle factors. The prevalence of DM is higher among American Indian/Alaska Native (14.7%), Asian American (9.2%), Hispanic American/Latino (12.5%), and non-Hispanic Black American (11.7%) persons than among non-Hispanic White American (7.5%) persons. Disparities in DM prevalence are thought to be the result of a variety of factors. A large body of evidence demonstrates strong associations between prevalence of DM and social factors, such as socioeconomic status, food environment, and physical environment.

The USPSTF is a panel of experts appointed by the Agency for Healthcare Research and Quality (AHRQ) to evaluate evidence and produce recommendations for preventive health services. In 2021, USPSTF produced an update to their evaluation and recommendations for screening for prediabetes and type 2 DM. Their recommended screening tests for these purposes include measurement of fasting plasma glucose or HbA_{1c} level or an oral glucose tolerance test (USPSTF, 2021[a]).

The 2021 USPSTF document made only one graded recommendation for screening for prediabetes and type 2 DM:

- The USPSTF recommends screening for prediabetes and type 2 DM in adults aged 35 to 70 years who have overweight or obesity. Grade B (USPSTF, 2021[a])

This recommendation is supported by evidence cited in the published article. Grade B recommendations indicate that the USPSTF has found at least fair evidence that the service improves important health outcomes, concludes that benefits outweigh harms, and that the USPSTF recommends that clinicians provide the service to eligible individuals. (USPSTF Grade Definitions)

USPSTF also made an ungraded recommendation concerning the optimal screening interval for adults. Although they note that the evidence is uncertain, they cite cohort and modeling studies that suggest screening every 3 years may be a reasonable approach for adults with normal blood glucose levels. Screening should include an

assessment of risk including height and weight measurements to determine whether the individual has overweight or obesity. They define overweight and obesity as a BMI ≥ 25 and ≥ 30, respectively.

Another ungraded recommendation in the 2021 USPSTF document is to screen individuals who have overweight or obesity and are younger than 35 if they are from a population with a disproportionately high prevalence of DM. They define these populations as American Indian, Alaska Native, Black, Hispanic, Latino, Native Hawaiian, and Pacific Islanders. Noting studies showing that a difference in body fat composition in some persons of Asian descent may result in underestimations of risk, based on BMI thresholds used to define overweight in the US, they recommend that a BMI of 23 or greater may be an appropriate cutoff point for Asian Americans.

The ADA 2022 Standards of Medical Care in Diabetes provide a grade B recommendation that screening of asymptomatic adults for prediabetes and DM should be done with an informal assessment of risk factors or with an assessment questionnaire provided in their document. An ADA grade B recommendation indicates that it is supported by evidence from well-conducted cohort studies.

The ADA makes a stronger (grade A) recommendation for this interview-based screening of children with an identified DM risk factor and with overweight or obesity (BMI ≥ 85th percentile or ≥ 95th percentile, respectively). Screening of children should begin after the onset of puberty or at age 10, whichever occurs sooner. The identified risk factors may include:

- Maternal history of DM or gestational DM during the child's gestation;
- Family history of type 2 DM in first- or second-degree relative;
- High risk race/ethnicity (African American, Asian American, Latino, Native American, Pacific Islander);
- Signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, polycystic ovary syndrome, or small-for-gestational-age birth weight).

An ADA grade A recommendation indicates that it is supported by clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered.

The ADA also recommends blood tests for adults who have overweight or obesity (BMI ≥ 25 kg/m2 or ≥ 23 kg/m2 in Asian Americans) and who have one or more of the following risk factors:

- 35 years of age or older;
- First-degree relative with DM;
- High-risk race/ethnicity (African American, Asian American, Latino, Native American, Pacific Islander);
- History of CVD;
- Hypertension (≥ 140/90 mm Hg or on therapy for hypertension);
- HDL cholesterol level < 35 mg/dL (0.90 mmol/L) and/or a triglyceride level > 250 mg/dL (2.82 mmol/L);
- Individuals with polycystic ovary syndrome;
- Physical inactivity;

- Other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans);
- HIV infection.

The ADA states that testing can be done by fasting plasma glucose, 2-hour glucose tolerance testing, or with an HbA_{1c} level. (Evidence grade B; ADA, 2022)

In addition to the risk factors identified above by the ADA, the American College of Obstetrics and Gynecology (ACOG) identifies the following risk factors as indications to perform a screening test for individuals with obesity or overweight at their first prenatal visit (ACOG, 2018):

- Individuals with polycystic ovarian syndrome;
- Individuals with previous gestational diabetes (GDM);
- Individuals who have given birth to an infant weighing 4000g (about 9 pounds) or more.

ACOG states that the best screening test for type-2 DM or early GDM has not been established. They refer to ADA's statement that HbA_{1c} can be used for early pregnancy type-2 DM screening, but that HbA_{1c} may not be suitable for use alone in this setting because it is less sensitive than glucose tolerance testing. (ACOG, 2018)

ACOG recommends that "All pregnant women should be screened for GDM with a laboratory-based screening test(s) using blood glucose levels." They concur with the ADA that GDM screening should be done at 24-28 weeks. (ACOG, 2018)

USPSTF provided updated guidance on screening for GDM in 2021 (USPSTF, 2021[b]). This document makes a grade B recommendation to screen asymptomatic pregnant persons at or after 24 weeks of gestation. A separate grade I (insufficient information) recommendation stated that "The current evidence is insufficient to assess the balance of benefits and harms of screening for gestational diabetes in asymptomatic pregnant persons before 24 weeks of gestation." (USPSTF, 2021)

The ADA recommends repeat testing at least every 3 years for individuals who have normal screening test results and for individuals who have had GDM. Individuals who have prediabetes (A1C $\geq$ 5.7% [39 mmol/mol], impaired glucose tolerance, or impaired fasting glucose) should be tested yearly. They recommend testing more frequently if initial results are near thresholds or if the individual's risk status changes. The testing frequency recommendation is given a grade of C, indicating that it is supported by poorly controlled or uncontrolled studies.

The ADA recommends that all individuals who are pregnant or are planning to become pregnant receive interview-based screening with testing done if risk factors are identified (grade B recommendation; ADA, 2022). They also make a Grade E recommendation to consider testing all pregnant individuals at their first prenatal visit. An ADA evidence grade of E indicates that it is based on expert consensus or clinical experience. They emphasize the importance of screening individuals in populations at high risk for DM as noted above. Also, as noted above, testing in follow-up to risk screening can be done by fasting plasma glucose, 2-hour glucose tolerance testing, or with an HbA_{1c} level (Evidence grade B). Individuals whose early

pregnancy test shows impaired glucose metabolism should be monitored as noted in the section below on monitoring glycemic control.

When the initial screen and test (if done) are negative, individuals who are pregnant should universally receive rescreening between 24- and 28-weeks' gestation with an oral glucose tolerance test, or with a glucose loading test followed by an oral glucose tolerance test. The ADA notes that an HbA_{1c} level done at 15 weeks gestation or later is not a reliable indicator of gestational DM or of preexisting DM.

Diagnosis of Prediabetes and DM

A DM diagnosis can be confirmed in the presence of classic symptoms and a random plasma glucose level ≥ 200 mg/dL (ADA, 2022 diagnosis standard). Classic DM symptoms include polyuria, polydipsia, thirst, and weight loss. The diagnosis should be considered in the presence of less pronounced symptoms when there is hyperglycemia. In this circumstance, the ADA recommends that the serologic confirmation should be made with two tests. These two tests can be from the same or from different samples and can be of the same or different test type. Test types used in diagnosing DM include the HbA_{1c} level, fasting plasma glucose, or a 2-hour glucose tolerance test. A random plasma glucose test should only be considered confirmatory in the presence of classic symptoms.

The ADA recommends the following diagnostic test findings criteria for screening and diagnosis of DM or prediabetes:

	Prediabetes	Diabetes
HbA1c	5.7–6.4% (39–47 mmol/mol)*	≥6.5% (48 mmol/mol)†
Fasting plasma glucose	100–125 mg/dL (5.6–6.9 mmol/L)*	≥126 mg/dL (7.0 mmol/L)†
2-hour plasma glucose during 75-g oral glucose tolerance test	140–199 mg/dL (7.8–11.0 mmol/L)*	≥200 mg/dL (11.1 mmol/L)†
Random plasma glucose	—	≥200 mg/dL (11.1 mmol/L)‡

*For all three tests, risk is continuous, extending below the lower limit of the range and becoming disproportionately greater at the higher end of the range.
†In the absence of unequivocal hyperglycemia, diagnosis requires two abnormal test results from the same sample or in two separate samples.
‡Only diagnostic in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis.

The ADA recommends close follow-up and repeat testing in 3–6 months when the initial test result is near a diagnostic threshold.

Monitoring Glycemic Control

The ADA recommends that nonpregnant adults with established DM should maintain an HbA_{1c} level less than 7% to reduce long-term microvascular and neuropathic complications. Less stringent HbA_{1c} goals may be appropriate for individuals with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions, or long-standing DM in whom the goal is difficult to

achieve, despite DM self-management education, appropriate glucose monitoring, and effective doses of multiple glucose-lowering agents including insulin (ADA, 2021; NICE, 2021).

The 2022 ADA Standards of Medical Care in Diabetes (ADA, 2022) provides recommendations for monitoring glycemic control in individuals with DM. Options for this monitoring include measurement of HbA_{1c}, self-monitored blood glucose monitoring, or continuous glucose monitoring (CGM). They point out that the clinical trials demonstrating the benefits of improved glycemic control used HbA_{1c} as the measure of that control.

The 2022 ADA standards include the following recommendations for repeat measurements of HbA_{1c} in individuals with confirmed DM:

> 6.1 Assess glycemic status (A1C or other glycemic measurement such as time in range or glucose management indicator) at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control). (Evidence grade E)
>
> 6.2 Assess glycemic status at least quarterly and as needed in patients whose therapy has recently changed and/or who are not meeting glycemic goals. (Evidence grade E)

The ADA notes several issues that can affect the reliability of HbA_{1c} testing in pregnancy. Pregnancy is associated with faster RBC turnover. This can artifactually lower the HbA_{1c} level. As a measure of glycemic control over long periods of time, HbA_{1c} measurement does not detect the postprandial hyperglycemia that is thought to cause macrosomia. For these reasons, the ADA recommends that self-monitored blood glucose should be the primary indicator of glycemic control in pregnancy. HbA_{1c} levels can be used as a secondary measure of glycemic control. The target HbA_{1c} level is 6.0% in pregnancy if that level can be maintained without episodes of hypoglycemia (ADA 2022). Both ADA and ACOG recommend testing individuals who have had gestational diabetes within the first year postpartum and then up to once yearly thereafter (ADA, 2022; ACOG, 2018).

Definitions

Acanthosis nigricans: A skin pigmentation problem characterized by dark, velvety, and thick patches of skin usually formed in the skin folds and creases.

Diabetes can be classified into the following general categories:

Diabetic ketoacidosis: A complication of diabetes that results from increased levels of a chemical called ketones in the blood. It causes excessive thirst, frequent urination, fatigue, and vomiting. Urgent medical attention is usually recommended.

Polycystic ovarian syndrome (also known as PCOS): The most common endocrine disorder in women of reproductive age. The syndrome is named after the characteristic cysts which may form on the ovaries. Causes are believed to be genetic or environmental. Treatment involves exercise and weight loss.

Type 1 diabetes: Diabetes that is due to autoimmune β-cell destruction, usually leading to absolute insulin deficiency, including latent autoimmune diabetes of adulthood.

Type 2 diabetes: Diabetes that is due to a progressive loss of adequate β-cell insulin secretion frequently in the background of insulin resistance.

Specific types of diabetes due to other causes: Includes monogenic diabetes syndromes (such as neonatal diabetes and maturity-onset diabetes of the young), diseases of the exocrine pancreas (such as cystic fibrosis and pancreatitis), and drug- or chemical-induced diabetes, (such as with glucocorticoid use, in the treatment of HIV/AIDS, or after organ transplantation).

Gestational diabetes mellitus: Diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation (ADA, 2022).

Fructosamine or glycated protein: Refers to glycosylated protein present in a serum or plasma sample. Glycated protein refers to measurement of the component of the specific protein that is glycated usually by colorimetric method or affinity chromatography.

Glycated hemoglobin (HbA_{1c} [also referred to as glycohemoglobin, glycosylated hemoglobin, HbA_{1c}, HbA1, or A1C]): HbA1c, also called A1C, is a measure of the amount of glucose attached to hemoglobin (Hb) in red blood cells. The higher the glucose levels over the previous 2-3 months, the higher the A1C. The A1C test is used to monitor the glucose levels of patients who have been diagnosed with diabetes. This laboratory test of whole blood assesses glycemic control over a period of 4-8 weeks and appears to be the more appropriate test for monitoring diabetic individuals who are capable of maintaining long-term, stable glycemic control. Glycated hemoglobin (equivalent to hemoglobin A1) refers to the total glycosylated HGb present in erythrocytes, usually determined by affinity or ion-exchange chromatographic methodology. HGbA1c refers to the major component of HGb A1, usually determined by ion-exchange affinity chromatography, immunoassay or agar gel electrophoresis. Measurement of HbA1c may be performed every 3 months to determine whether an individual's average metabolic control has been maintained within the target range. For more comprehensive information regarding HbA1c assay interferences, see https://ngsp.org/interf.asp. (NGSP, updated June, 2022).

Glycated serum protein (GSP): This laboratory test of total serum or plasma levels assesses the individual's glycemic control over a period of 1-2 weeks. It is generally considered reasonable to monitor GSP levels monthly in pregnant diabetics. Low laboratory test results for HbA1c or GSP may indicate significant, persistent hypoglycemia, in nesidioblastosis or insulinoma, conditions which are accompanied by inappropriate hyperinsulinemia. A below normal test value is helpful in establishing the hypoglycemic state in these conditions.

Macrosomia: A condition in which a newborn baby is born much larger than average for their gestational age. At full term, a weight of more than 8 pounds, 13 ounces is considered macrosomia. This condition is commonly caused by medical conditions of the mother during the pregnancy, such as obesity or diabetes. Additional causes are related to genetics or a medical condition in the newborn.

References

Peer Reviewed Publications:

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2. Koga M, Murai J, Saito H, Kasayama S. Glycated albumin and glycated hemoglobin Are influenced differently by endogenous insulin secretion in patients with type 2 diabetes. Diabetes Care. 2010; 33:270–272.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American College of Obstetrics and Gynecology (ACOG). Practice Bulletin Gestational Diabetes. Obstetrics & Gynecology. 2018; 131(2):e49-e64.
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Websites for Additional Information

1. American Diabetes Association. Information about diabetes and A1C. Available at: Understanding A1C | ADA (diabetes.org). Accessed on March 29, 2023.
2. United States Preventive Services Task Force (USPSTF). 2018. Grade definitions. Available at: https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/grade-definitions#:~:text=B%20%2D%20Recommended%3A%20The%20USPSTF%20recommends,concludes%20that%20benefits%20outweigh%20harms. Accessed on March 29, 2023.

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A1C
Albumin
Hemoglobin, glycated or glycosylated Hgb
Glycohemoglobin
HbA_{1c}
HbA1
Protein, total serum glycated or glycosylated GSP
Fructosamine.

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
	09/27/2023	Updated Coding section with 10/01/2023 ICD-10-CM changes; added E88.810-E88.819 replacing E88.81, added I1A.0 to end of range.
Revised	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Expanded the MN criteria for testing to include additional glycated serum proteins (for example, albumin and fructosamine). Revised MN statement addressing testing frequency. Updated the Discussion, Coding, Index and References sections.
New	11/10/2022	MPTAC review. Initial document development.