

### Clinical UM Guideline

Subject: Outpatient Laboratory-based Blood Glucose Testing

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# **Description**

This document addresses laboratory testing to determine blood glucose concentration. Blood glucose determination may be done using whole blood, serum, or plasma. This document does not address blood glucose testing in the hospital or emergency department settings. This document also does not address self-testing of blood glucose monitoring (BGM) using test strips.

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

- CG-DME-42 Continuous Glucose Monitoring Devices
- CG-DME-50 Automated Insulin Delivery Systems
- CG-DME-51 External Insulin Pumps
- CG-LAB-25 Outpatient Glycated Hemoglobin and Protein Testing

### **Clinical Indications**

# Medically Necessary:

Blood glucose testing is considered medically necessary for individuals who meet any of the following criteria (A through Q):

- A. Signs or symptoms of either of the following:
  - a. Hypoglycemia; or
  - b. Hyperglycemia; or
- B. Overweight or obesity\* of any age; or
- C. From a population with a high prevalence of diabetes mellitus\*\*; or
- D. Impaired fasting glucose has been found on other testing;or
- E. Pregnant and considered to be at high risk for type 2 diabetes mellitus; or
- F. Prior testing at least 3 months previously showed abnormal blood glucose resultspr
- G. Insulin resistance syndrome; or
- H. Carbohydrate intolerance; or
- I. Hypoglycemia disorders, such as nesidioblastosis or insulinoma; or
- J. Catabolic or malnutrition states; or
- K. Tuberculosis; or
- L. Unexplained chronic or recurrent infection; or
- M. Alcohol use disorder; or
- N. Coronary artery disease; or
- O. Unexplained skin conditions (including pruritis, local skin infections, ulceration and gangrene without an established cause) pr
- P. Chronic glucocorticoid therapy; or
- Q. 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;  $\mbox{\bf or}$
  - $2. \ \ \text{Up to two times per year for individuals with diabetes mellitus who are meeting treatment goals \textbf{pr} }$
  - 3. 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
- \*\* See discussion section for information regarding populations with high prevalence of diabetes mellitus.

#### **Not Medically Necessary:**

Blood glucose 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
82947 Glucose; quantitative, blood (except reagent strip)
82948 Glucose; blood, reagent strip

82962 Glucose; blood by glucose monitoring device(s) cleared by the FDA-specifically for home use

ICD-10 Diagnosis

A15.0-A19.9 Tuberculosis

A20.0-A49.9 Certain zoonotic/other bacterial diseases

B25.0-B49 Other viral diseases, mycoses B77.0-B78.9 Ascariasis, Strongyloidiasis

C25.4 Malignant neoplasm of endocrine pancreas

C48.0 Malignant neoplasm of retroperitoneum
D13.7 Benign neoplasm of endocrine pancreas

E03.0-E05.91 Other hypothyroidism, other nontoxic goiter, thyrotoxicosis (hyperthyroidism)

E08.00-E13.9 Diabetes mellitus

E15-E16.9 Other disorders of glucose regulation and pancreatic internal secretion

E22.0-E24.9 Hyperfunction, hypofunction and other disorders of the pituitary gland, Cushing's syndrome

E28.2 Polycystic ovarian syndrome E34.0-E34.9 Other endocrine disorders

E40-E46 Malnutrition

E63.0-E64.9 Other nutritional deficiencies, sequelae of malnutrition and other nutritional deficiencies

E66.01-E66.9 Overweight and obesity
E72.50-E72.59 Disorders of glycine metabolism

E73.0-E74.9 Lactose intolerance, other disorders of carbohydrate metabolism

E75.26 Sulfatase deficiency

E77.0-E79.9 Disorders of glycoprotein/lipoprotein metabolism and other lipidemias, disorders of purine and

pyrimidine metabolism

E83.10-E83.19 Disorders of iron metabolism

E86.0-E88.9 Volume depletion, other disorders of fluid, electrolyte and acid-base balance, other and

unspecified metabolic disorders

E89.1 Postprocedural hypoinsulinemia E89.3 Postprocedural hypopituitarism

F05-F09 Delirium, other mental, mood, personality and behavioral disorders due to known physiological

condition

F10.10-F10.99 Alcohol related disorders

F20.0-F21 Schizophrenia, schizotypal disorder

F25.0-F25.9 Schizoaffective disorders F31.0-F31.9 Bipolar disorder

G40.001-G40.919 Epilepsy and recurrent seizures

G56.00-G59 Mononeuropathies

G60.0-G63 Hereditary and idiopathic, inflammatory, other and unspecified polyneuropathies

G90.01-G90.A Disorders of autonomic nervous system

G93.31-G93.49 Postviral and related fatigue syndromes, other and unspecified encephalopathy

H01.001-H02.9 Blepharitis, other disorders of eyelid

H10.821-H10.829 Rosacea conjunctivitis
H25.011-H26.9 Age-related, other cataract
H35.00-H36 Other retinal disorders, retinopathy

H40.001-H42 Glaucoma

H47.331-H47.339 Pseudopapilledema of optic disc

H49.00-H49.9 Paralytic strabismus

H52.00-H53.9 Disorders of refraction and accommodation, visual disturbances

I10-I16.9Hypertensive diseasesI20.0-I25.9Ischemic heart diseaseI42.0-I43Cardiomyopathy

150.1-15A
 170.201-170.92
 Heart failure, non-ischemic myocardial injury (non-traumatic)
 Atheerosclerosis of native arteries or bypass grafts of the extremities

I73.01 Raynaud's syndrome with gangrene

195.1 Orthostatic hypotension

I96 Gangrene, not elsewhere classified

J02.0-J02.9 Acute pharyngitis
J12.0-J18.9 Pneumonia
J20.0-J20.9 Acute bronchitis

J40-J44.9 Bronchitis, emphysema, chronic obstructive pulmonary disease

K11.7 Disturbances of salivary secretion K12.0-K12.39 Stomatitis and related lesions

K29.00-K30 Gastritis and duodenitis, functional dyspepsia

K52.0-K52.9 Other and unspecified noninfective gastroenteritis and colitis

K59.31-K59.39 Megacolon, not elsewhere classified

K70.0-K77 Diseases of liver

K80.00-K87 Disorders of gallbladder, biliary tract and pancreas L00-L08.9 Infections of the skin and subcutaneous tissue

 L29.0-L29.9
 Pruritus

 L68.0-L68.9
 Hypertrichosis

 L74.4
 Anhidrosis

 L89.000-L89.96
 Pressure ulcer

L92.0-L92.9 Granulomatous disorders of skin and subcutaneous tissue
L97.101-L97.929 Non-pressure chronic ulcer of lower limb, not elsewhere classified
L98.0-L99 Other disorders of skin and subcutaneous tissue, not elsewhere classified

M04.1-M04.9 Autoinflammatory syndromes

M60.000-M60.9 Myositis

M79.0-M79.9 Other and unspecified soft tissue disorders, not elsewhere classified

M86.00-M86.9 Osteomyelitis

N10-N16 Renal tubule-interstitial diseases N28.84-N28.86 Pyelitis/pyeloureteritis/ureteritis cystica

N30.00-N30.91 Cystitis,

N34.0-N34.3 Urethritis and urethral syndrome

N35.111-N35.119 Postinfective urethral stricture, not elsewhere classified, male

N39.0 Urinary tract infection, site not specified

N45.1-N45.4 Orchitis and epididymitis

N52.01-N53.9 Male erectile dysfunction, other male sexual dysfunction

N70.01-N77.1 Inflammatory diseases of female pelvic organs

N91.0-N92.6 Absent, scanty and rare menstruation; excessive, frequent and irregular menstruation

N97 0-N97 9 Female infertility

O09.00-O09.93 Supervision of high risk pregnancy

O10.011-O16.9 Edema, proteinuria and hypertensive disorders in pregnancy, childbirth and the puerperium

O24.011-O24.93 Pre-existing, gestational or unspecified diabetes in pregnancy

O30.001-O48.1 Maternal care related to the fetus and amniotic cavity and possible delivery problems

Obesity complicating pregnancy, childbirth and the puerperium O99.210-O99.215 O99.810-O99.815

Abnormal glucose complicating pregnancy, childbirth and the puerperium

P05.00-P07.39 Disorders of newborn related to slow fetal growth and fetal malnutrition, short gestation and low

birth weight

P37.0 Congenital tuberculosis

P78 84 Gestational alloimmune liver disease

R00.0-R00.9 Abnormalities of heart beat R06.00-R06.9 Abnormalities of breathing R07.0-R07.9 Pain in throat and chest

Fecal incontinence, hepatomegaly and splenomegaly, jaundice, ascites, other symptoms and R15.0-R19.8

signs involving the digestive system and abdomen

R20.0-R20.9 Disturbances of skin sensation

Abnormal involuntary movements, abnormalities of gait, other lack of coordination R25.0-R27.9 R29.0-R29.91 Other symptoms and signs involving the nervous and musculoskeletal systems

R35.0-R35.89 Polyuria

R40.0-R42 Somnolence, stupor and coma, other symptoms and signs involving cognitive function and

awareness, dizziness and giddiness

R45.0-R45.89 Symptoms and signs involving emotional state

R53.0-R56.9 Malaise and fatigue, age-related physical debility, syncope and collapse, convulsions

R61 Generalized hyperhidrosis

R62.0-R62.59 Delayed milestone/other and unspecified lack of expected normal physiological development in

childhood

R63.0-R64 Symptoms and signs concerning food and fluid intake, cachexia

R68.2 Dry mouth, unspecified R73.01-R73.9 Elevated blood glucose level

Finding of abnormal level of heavy metals in blood R78.71-R78.79 R79 89-R79 9 Abnormal findings of blood chemistry, other or unspecified

R80.0-R81 Proteinuria, glycosuria S02.0XXA-S02.92XS Fracture of skull and facial bones S92.001A-S92.919S Fracture of foot and toe, except ankle

S99.001A-S99.929S Other and unspecified injuries of ankle and foot

T38.3X1A-T38.3X4S Poisoning by insulin and oral hypoglycemic [antidiabetic] drugs T43.3X5A-T43.3X5S Adverse effect of phenothiazine antipsychotics and neuroleptics T43.505A-T43.505S Adverse effect of unspecified antipsychotics and neuroleptics T43.595A-T43.595S Adverse effect of other antipsychotics and neuroleptics

T46.6X5A-T46.6X5S Adverse effect of antihyperlipidemic and antiarteriosclerotic drugs T82.855A-T82.856S Stenosis of coronary artery stent, peripheral vascular stent

U07.1 COVID-19

Z13.1

U09.9 Post COVID-19 condition, unspecified

Z05.0-Z05.9 Encounter for observation and evaluation of newborn for suspected diseases and conditions ruled

Z08-Z09 Encounter for follow-up examination after completed treatment for malignant neoplasms, for

conditions other than malignant neoplasm Encounter for screening for diabetes mellitus Z19.1-Z19.2 Hormone sensitivity malignancy status Z68.23-Z68.45 Body mass index [BMI] 23.0-70 or greater, adult

Z68.53-Z68.54 Body mass index [BMI] pediatric, 85<sup>th</sup> percentile to greater than or equal to 95<sup>th</sup> percentile for age

779 01-779 899 Long term (current) drug therapy Z83.3 Family history of diabetes mellitus

Z83.430-Z83.438 Family history of other disorder of lipoprotein metabolism and other lipidemias

Z84.82 Family history of sudden infant death syndrome

Z86.31-Z86.39 Personal history of endocrine, nutritional and metabolic diseases

### When services are Not Medically Necessary:

For the procedure codes listed above for all other indications.

## **Discussion/General Information**

Glucose is the most important source of cellular energy in the human body. Blood levels of glucose are tightly controlled through the interaction of several hormones and peptides produced in the brain, pancreas, liver, intestines, muscles, and adipose tissue. Disturbance in this regulatory system results in diabetes mellitus (DM), 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. 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 and optimal DM treatment can prevent or delay development of these complications.

Proactive management of DM requires regular determinations of blood glucose levels, and blood glucose testing can also be used to screen for or to diagnose prediabetes and DM. Effective January 1, 2005. Medicare expanded coverage to diabetic screening services. According to the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination for blood glucose testing:

Blood glucose determination may be done using whole blood, serum or plasma. It may be sampled by capillary puncture, as in the fingerstick method, or by vein puncture or arterial sampling. The method for assay may be by color comparison of an indicator stick, by meter assay of whole blood or a filtrate of whole blood, using a device approved for home monitoring, or by using a laboratory assay system using serum or plasma. The convenience of the meter or stick color method allows a patient to have access to blood glucose values in less than a minute or so and has become a standard of care for control of blood glucose, even in the inpatient setting.

Many medical conditions may be a consequence of a sustained elevated or depressed glucose level. These include comas, seizures or epilepsy, confusion, abnormal hunger, abnormal weight loss or gain, and loss of sensation. Evaluation of glucose may also be indicated in patients on medications known to affect carbohydrate metabolism.

Frequent home blood glucose testing by diabetic patients should be encouraged. In stable, non-hospitalized patients who are unable or unwilling to do home monitoring, it may be reasonable and necessary to measure quantitative blood glucose up to four times annually. Depending upon the age of the patient, type of diabetes, degree of control, complications of diabetes, and other co-morbid conditions, more frequent testing than four times annually may be reasonable and necessary.

In some patients presenting with nonspecific signs, symptoms, or diseases not normally associated with disturbances in glucose metabolism, a single blood glucose test may be medically necessary. Repeat testing may not be indicated unless abnormal results are found or unless there is a change in clinical condition. If repeat testing is performed, a specific diagnosis code (e.g., diabetes) should be reported to support medical necessity. However, repeat testing may be indicated where results are normal in patients with conditions where there is a confirmed continuing risk of glucose metabolism abnormality (e.g., monitoring glucocorticoid therapy) (CMS, 2005).

Some forms of blood glucose screening covered under this national coverage determination may be subject to specified frequencies.

According to CMS, additional conditions may predispose to hyperglycemic and hypoglycemic states including:

- 1. Impaired fasting glucose (FPG 110-125 mg/dL);
- 2. Insulin resistance syndrome;
- 3. Carbohydrate intolerance (excessive rise in glucose following ingestion of glucose or glucose sources of food);
- 4. Hypoglycemia disorders, such as nesidioblastosis or insulinoma;
- 5. Catabolic or malnutrition states;
- 6. Tuberculosis;
- 7. Unexplained chronic or recurrent infections;
- 8. Alcoholism:
- 9. Coronary artery disease;
- 10. Unexplained skin conditions (including pruritis, local skin infections, ulceration and gangrene without an established cause).

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<sub>1c</sub> 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, 2023).

Populations at Increased Risk to Develop Diabetes Mellitus.

The development of diabetes is influenced by multiple factors (ADA, 2023). Among these factors, being overweight or having obesity are the strongest risk factors for developing prediabetes and type 2 DM in adults. Obesity has been shown to play a major role in the development of diabetes, with one study finding a 100-fold increase in risk for individuals with a BMI >35 kg/m² (36). This risk increases with age (Biggs, 2010). Other significant factors include smoking, with active smokers having an average 1.5-fold increased risk of developing diabetes. There is a direct correlation between the frequency of smoking and risk, with more frequent smokers having increased risk (Willi, 2007). Family history is also a significant risk factor. Having a first degree relative with diabetes is associated with a two to three-fold increased risk of developing diabetes. Individuals with both maternal and paternal family history of diabetes have a 5-to-6-fold increase in their risk of developing diabetes. (InterAct Consortium, 2015; Meigs, 2000). Ethnicity may also significantly increase risks for the development of diabetes. Individuals of Asian, Hispanic, and Black heritage have an almost 2-fold increase in risk. (Menke, 2015; Shai, 2006). Many medications impair glucose tolerance and place individuals at increased risk for developing complications include statins, antipsychotics, corticosteroids, and others (ADA, 2023; Brooks, 2009; Bobes, 2003; Cooper, 2016; Elena, 2018; Holt, 2019; Leslie, 2004; Sattar, 2023). Periodic blood glucose monitoring is indicated for these individuals to detect and manage their risks for diabetes and its complications.

Measurement and monitoring of blood glucose in populations at increased risk of developing diabetes mellitus is considered a key metric in quality healthcare. The National Committee for Quality Assurance (NCQA), an organization responsible for the accreditation of most U.S. health plans, includes blood glucose measurement as a key quality indicator in the Healthcare Effectiveness Data and Information Set (HEDIS) measures (NCQA, 2023). The HEDIS measures specifically evaluate the use of blood glucose testing measurement in individuals with schizophrenia or bipolar disorder who are treated with antipsychotic medications.

## 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<sub>1c</sub> 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 2023 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  $\ge$  25 kg/m2 or  $\ge$  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 HbAc level. (Evidence grade B; ADA, 2023)

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<sub>1c</sub> can be used for early pregnancy type-2 DM screening, but that HbA<sub>1c</sub> 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 ≥ 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, 2023). 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<sub>1c</sub> 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<sub>1c</sub> level done at 15 weeks gestation or later is not a reliable indicator of gestational DM or of preexisting DM.

The American Academy of Child and Adolescent Psychiatry (AACAP) published a practice parameter for the use of atypical antipsychotic medications in children and adolescents in 2011. That document stated the following:

Recommendation 12. Careful attention should be given to the increased risk of developing diabetes with the use of AAA, and blood glucose levels and other parameters should be obtained at baseline and monitored at regular intervals [CS].

Adult studies have found an association between the development of diabetes/abnormal glucose regulation and the use of AAAs. There is also evidence to suggest that the development of diabetes is not only directly related to weight gain. Therefore, careful monitoring for diabetes, through close attention to the clinical signs and symptoms of diabetes, and regular monitoring of blood glucose levels and, as needed, hemoglobin A1C is warranted.

The AACAP also published their practice parameter for the assessment and treatment of children and adolescents with schizophrenia in 2013, which cite and support the ADA guidelines (McClellan, 2013).

#### Diagnosis of Prediabetes and DM

A DM diagnosis can be confirmed in the presence of classic symptoms and a random plasma glucose level  $\geq$  200 mg/dL (ADA, 2023 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 <u>)*</u>	≥6.5% (48 mmol/mol) <b>±</b>
Fasting plasma glucose	100-125 mg/dL (5.6-6.9 mmol/L)*	≥126 mg/dL (7.0 mmol/L) <u>†</u>
2-hour plasma glucose during 75-g		
pral		
glucose tolerance test	140-199 mg/dL (7.8-11.0 mmol/L)*	≥200 mg/dL (11.1 mmol/L) <u>†</u>
Random plasma glucose	_	≥200 mg/dL (11.1 mmol/L) <u>‡</u>

<sup>\*</sup>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.

‡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 2023 ADA Standards of Medical Care in Diabetes (ADA, 2023) provides recommendations for monitoring glycemic control in individuals with DM. Options for this monitoring include measurement of HbA<sub>1c</sub>, 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<sub>1c</sub> as the measure of that control.

The ADA notes several issues that can affect the reliability of  $HbA_{lc}$  testing in pregnancy. Pregnancy is associated with faster RBC turnover. This can artifactually lower the  $HbA_{lc}$  level. As a measure of glycemic control over long periods of time,  $HbA_{lc}$  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.  $HbA_{lc}$  levels can be used as a secondary measure of glycemic control (ADA 2023). 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, 2023; 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.

Insulin resistance syndrome: A condition where tissues have a diminished ability to respond to the action of insulin. To compensate for resistance, the pancreas secretes more insulin. Insulin-resistant persons, therefore, have high plasma insulin levels. The syndrome can be defined as a cluster of abnormalities, including obesity, hypertension, dyslipidemia and type 2 diabetes, that are associated with insulin resistance and compensatory hyperinsulinemia.

Insulinoma: A pancreatic tumor comprised of beta cells that secrete insulin.

Nesidioblastosis: A rare hypoglycemia syndrome related to pancreatic beta cell hypertrophy and an increase in the size and number of pancreatic islets. Also known as noninsulinoma pancreaticogenous hypoglycemia syndrome (NIPS).

<sup>†</sup>In the absence of unequivocal hyperglycemia, diagnosis requires two abnormal test results from the same sample or in two separate samples.

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, 2023).

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 A1C test is used to monitor the glucose levels of patients who have been diagnosed with diabetes.

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.

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### Index

Blood glucose testing Hemoglobin, Hyperglycemia

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
	01/03/2024	Revised note regarding populations at high risk for diabetes. Updated Description,
		Discussion, and References sections. Updated Coding section, added ICD-10-CM
		codes F20.0-F21, F25.0-F25.9, F31.0-F31.9, T43.3X5A-T43.3X5S, T43.505A-
		T43.505S, T43.595A-T43.595S, T46.6X5A-T46.6X5S.
New	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC review. Initial
		document development.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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