

Summary: National Coverage Determination (NCD) for Glycated Hemoglobin/Glycated Protein

NCD 190.21

National Government Services (NGS), the Medicare Administrative Contractor for Jurisdiction K, is required to implement coverage consistent with the terms of National Coverage Determinations (NCDs) developed and finalized by the Centers for Medicare & Medicaid Services. Effective November 25, 2002, CMS implemented an NCD that defines the circumstances when Medicare will (and will not) cover testing for glycated hemoglobin/glycated protein. The following language excerpts from this NCD:

Item/Service Description*

The management of diabetes mellitus requires regular determinations of blood glucose levels. Glycated hemoglobin/protein levels are used to assess long-term glucose control in diabetes. Alternative names for these tests include glycated or glycosylated hemoglobin or Hgb, hemoglobin glycated or glycosylated protein, and fructosamine.

Glycated hemoglobin (equivalent to hemoglobin A1) refers to total glycosylated hemoglobin present in erythrocytes, usually determined by affinity or ion-exchange chromatographic methodology. Hemoglobin A1c refers to the major component of hemoglobin A1, usually determined by ion-exchange affinity chromatography, immunoassay or agar gel electrophoresis. 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 in whole blood assesses glycemic control over a period of 4-8 weeks and appears to be the more appropriate test for monitoring a patient who is capable of maintaining long-term, stable control. Measurement may be medically necessary every 3 months to determine whether a patient's metabolic control has been on average within the target range. More frequent assessments, every 1-2 months, may be appropriate in the patient whose diabetes regimen has been altered to improve control or in whom evidence is present that intercurrent events may have altered a previously satisfactory level of control (for example, post-major surgery or as a result of glucocorticoid therapy). Glycated protein in serum/plasma assesses glycemic control over a period of 1-2 weeks. It may be reasonable and necessary to monitor glycated protein monthly in pregnant diabetic women. Glycated hemoglobin/protein test results may be low, indicating significant, persistent hypoglycemia, in nesidioblastosis or insulinoma, conditions which are accompanied by inappropriate hyperinsulinemia. A below normal test value is helpful in establishing the patient's hypoglycemic state in those conditions.

Indications*

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

Limitations*

It is not considered reasonable and necessary to perform glycated hemoglobin tests more often than every three months on a controlled diabetic patient to determine whether the patient's metabolic control has been on average within the target range. It is not considered reasonable and necessary for these tests to be performed more frequently than once a month for diabetic pregnant women. Testing for uncontrolled type one or two diabetes mellitus may require testing more than four times a year. The above Description Section provides the clinical basis for those situations in which testing more frequently than four times per annum is indicated, and medical necessity documentation must support such testing in excess of the above guidelines.

Many methods for the analysis of glycated hemoglobin show significant interference from elevated levels of fetal hemoglobin or by variant hemoglobin molecules. When the glycated hemoglobin assay is initially performed in these patients, the laboratory may inform the ordering physician of a possible analytical interference. Alternative testing, including glycated protein, for example, fructosamine, may be indicated for the monitoring of the degree of glycemic control in this situation. It is therefore conceivable that a patient will have both a glycated hemoglobin and glycated protein ordered on the same day. This should be limited to the initial assay of glycated hemoglobin, with subsequent exclusive use of glycated protein. These tests are not considered to be medically necessary for the diagnosis of diabetes.

Documentation Requirements

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this NCD. (See "Indications and Limitations of Coverage.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

*This language is a direct quote from the NCD.

Representative List of Covered ICD-10-CM Diagnosis Codes

The list provided below is only a subset of codes that CMS identifies as covered for this NCD. See https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/Downloads/manual201801_ICD10.pdf, at pg. 1686 (marked as pg. 1632)

ICD-10 Code	Description
E11.65	Type 2 Diabetes Mellitus with Hyperglycemia
E11.69	Type 2 Diabetes Mellitus with Other Specified Complications
E11.8	Type 2 Diabetes Mellitus with Unspecified Complications
E11.9	Type 2 Diabetes Mellitus without Complications
E79.0	Hyperuricemia without Signs of Inflammatory Arthritis and Tophaceous Disease
E83.10	Disorder of Iron Metabolism, Unspecified
E83.19	Other Disorders of Iron Metabolism
K91.2	Postsurgical Malabsorption, Not Elsewhere Classified
R73.01	Impaired Fasting Glucose
R73.9	Hyperglycemia, Unspecified
R78.89	Finding of Other Specified Substances, Not Normally Found in Blood
R79.0	Abnormal Level of Blood Mineral
R79.89	Other Specified Abnormal Findings of Blood Chemistry
R79.9	Abnormal Finding of Blood Chemistry, Unspecified
Z79.4	Long Term (Current) Use of Insulin
Z79.891	Long Term (Current) Use of Opiate Analgesic
Z79.899	Other Long Term (Current) Drug Therapy
Z86.39	Personal History of Other Endocrine, Nutritional and Metabolic Disease

The following diagnosis codes are among those identified as "ICD-10-CM Codes Covered by Medicare Program" in the CMS "National Coverage Determinations (NCD) Coding Policy Manual and Change Report (ICD-10-CM)" section that identifies covered diagnosis codes for the above-described NCD.



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