

Glycated Hemoglobin/Glycated Protein

Hemoglobin A1c

CPT: 82985, 83036

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity

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 accepted as medically necessary for management and control of diabetes and 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 useful in patients with abnormalities of erythrocytes such as hemolytic anemia or hemoglobinopathies.

Limitations

It is not reasonable and necessary to perform glycated hemoglobin tests more often than every three months on a controlled diabetic patient to determine if the patient's metabolic control has been on average within the target range. It is not 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 analytical methods of glycated hemoglobin show 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 monitoring the degree of glycemic control. 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.

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The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. **If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.**

***Note—Bolded diagnoses below have the highest utilization**

There is a frequency associated with this test. Please refer to the Limitations or Utilization Guidelines section on previous page(s).

| Code | Description |
|----------------|--|
| E11.21 | Type 2 diabetes mellitus with diabetic nephropathy |
| E11.22 | Type 2 diabetes mellitus with diabetic chronic kidney disease |
| E11.29 | Type 2 diabetes mellitus with other diabetic kidney complication |
| E11.40 | Type 2 diabetes mellitus with diabetic neuropathy, unspecified |
| E11.42 | Type 2 diabetes mellitus with diabetic polyneuropathy |
| E11.59 | Type 2 diabetes mellitus with other circulatory complications |
| E11.65 | Type 2 diabetes mellitus with hyperglycemia |
| E11.69 | Type 2 diabetes mellitus with other specified complication |
| 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 |
| R73.01 | Impaired fasting glucose |
| R73.02 | Impaired glucose tolerance (oral) |
| R73.03 | Prediabetes |
| R73.09 | Other abnormal glucose |
| R73.9 | Hyperglycemia, unspecified |
| 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 |
| Z79.899 | Other long term (current) drug therapy |

To view the complete policy and the full list of codes, please refer to the CMS website reference

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