NCD - Glycated Hemoglobin/Glycated Protein (190.21)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Tracking Information

Publication Number

100-3

Manual Section Number

190.21

Manual Section Title

Glycated Hemoglobin/Glycated Protein

Version Number

1

Effective Date of this Version

11/25/2002

Implementation Date

01/01/2003

Description Information

Benefit Category

Diagnostic Laboratory Tests

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

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 and Limitations of Coverage

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.

Note: Scroll down for links to the quarterly Covered Code Lists (including narrative).

Cross Reference

Also see the Medicare Claims Processing Manual, Chapter 120, Clinical Laboratory Services Based on Negotiated Rulemaking.

Transmittal Information

Transmittal Number

17

Coverage Transmittal Link

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/r17ncd.pdf

Revision History

07/2002 - Implemented NCD. Effective date 11/25/02. Implementation date 1/01/03. (TN AB-02-110) (CR 2130)

07/2004 - Published NCD in the NCD Manual without change to narrative contained in PM AB-02-110. Coding guidance now published in Medicare Lab NCD Manual. Effective and Implementation dates NA. (TN 17) (CR 2130)

Other

Covered Code Lists (including narrative)

July 2022 (PDF) (ICD-10)
April 2022 (PDF) (ICD-10)
January 2022 (PDF) (ICD-10)
October 2021 (PDF) (ICD-10)
July 2021 (PDF) (ICD-10)
April 2021 (PDF) (ICD-10)
January 2021 (PDF) (ICD-10)
October 2020 (PDF) (ICD-10)
July 2020 (PDF) (ICD-10)
April 2020 (PDF) (ICD-10)
January 2020 (PDF) (ICD-10)
October 2019 (PDF) (ICD-10)
July 2019 (PDF) (ICD-10)
April 2019 (PDF) (ICD-10)
January 2019 (PDF) (ICD-10)
October 2018 (PDF) (ICD-10)
July 2018 (PDF) (ICD-10)
April 2018 (PDF) (ICD-10)
January 2018 (ICD-10)
October 2017 (ICD-10)
July 2017 (ICD-10)
April 2017 (ICD-10)
January 2017 (ICD-10)
October 2016 (ICD-10)
January 2016 (ICD-10)
October 2015 (ICD-10, ICD-9)
October 2014 (ICD-10, ICD-9)

Changes to Lab NCD Edit Software

April 2022
January 2022
October 2021
July 2021
October 2020
April 2020

January 2020
October 2019
July 2019
January 2019
October 2018
April 2018
January 2018
July 2017
April 2017
January 2017
January 2016
October 2014

Coding Analyses for Labs (CALs)

This NCD has been or is currently being reviewed under the National Coverage Determination process.The following are existing associations with CALs, from the Coding Analyses for Labs database.

- Original Consideration for Glycated Hemoglobin/Glycated Protein (Addition of ICD-9-CM 271.3, Intestinal disaccharidase deficiencies and disaccharide malabsorption) (CAG-00336N)

- Original Consideration for Glycated Hemoglobin/Glycated Protein (Addition of CPT Code 83037, Hemoglobin; glycosylated [A1c] by device cleared by FDA for home use) (CAG-00373N)

Additional Information

Other Versions

Title	Version	Effective Between
Glycated Hemoglobin/Glycated Protein	1	11/25/2002 - N/A