
CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 28

Date: FEBRUARY 11, 2005

CHANGE REQUEST 3690

SUBJECT: Update of Laboratory NCDs to Reference New Screening Benefits

I. SUMMARY OF CHANGES: We are revising sections 190.20, Blood Glucose Testing, and 190.23, Lipid Testing, to include references to the lipid and glucose screening benefits.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: January 1, 2005
IMPLEMENTATION DATE: March 11, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/190.20/ Blood Glucose Testing
R	1/190.23/ Lipid Testing

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

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SUBJECT: Update of Laboratory NCDs to Reference New Screening Benefits

I. GENERAL INFORMATION

A. Background: The NCD Manual currently includes national coverage determinations (NCDs) for blood glucose and lipid testing. Some of the procedures included in these NCDs are covered, effective January 1, 2005, as diabetes and cardiovascular screening benefits, respectively, under the MMA. While instructions and system changes have already been made to implement these new benefit timely (see CR 3411, 3429, and 3637), the screening benefits are not referenced in the NCD, rendering the coverage explanation incomplete.

B. Policy: This instruction updates the language in the current NCD for blood glucose and lipid testing to reference the new diabetes and cardiovascular screening benefits.

C. Provider Education: None.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)							
		F I	R H I	C H I	D R I	Shared System Maintainers			
					F I S S	M C S	V M S	C W F	
3690.1	System requirements for implementing the screening benefits have already been issued. See CRs 3411, 3429, 3637, and 3677. This CR merely incorporates information regarding the screening benefits into the NCDs for blood glucose and lipid testing. Contractors shall note the new updates to the NCD manual.								

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date*: January 1, 2005 Implementation Date: March 11, 2005</p> <p>Pre-Implementation Contact(s): Jackie Sheridan-Moore, (410) 786-4635</p> <p>Post-Implementation Contact(s): Jackie Sheridan-Moore, (410) 786-4635</p>	<p>Medicare contractors shall implement these instructions within their current operating budgets.</p>
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190.20 - Blood Glucose Testing

(Rev.28, Issued: 02-11-05, Effective: 01-01-05, Implementation: 03-11-05)

This policy is intended to apply to blood samples used to determine glucose levels. 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 or 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.

Indications

Blood glucose values are often necessary for the management of patients with diabetes mellitus, where hyperglycemia and hypoglycemia are often present. They are also critical in the determination of control of blood glucose levels in the patient with impaired fasting glucose (FPG 110-125 mg/dL), the patient with insulin resistance syndrome and/or carbohydrate intolerance (excessive rise in glucose following ingestion of glucose or glucose sources of food), in the patient with a hypoglycemia disorder such as nesidioblastosis or insulinoma, and in patients with a catabolic or malnutrition state. In addition to those conditions already listed, glucose testing may be medically necessary in patients with tuberculosis, unexplained chronic or recurrent infections, alcoholism, coronary artery disease (especially in women), or unexplained skin conditions (including pruritis, local skin infections, ulceration and gangrene without an established cause).

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.

Effective January 1, 2005, the Medicare law expanded coverage to diabetic screening services. Some forms of blood glucose testing covered under this national coverage determination may be covered for screening purposes subject to specified frequencies. See 42 CFR 410.18 and section 90, chapter 18, of the Claims Processing Manual, for a full description of this screening benefit.

Limitations

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).

190.23 - Lipid Testing

(Rev.28, Issued: 02-11-05, Effective: 01-01-05, Implementation: 03-11-05)

Lipoproteins are a class of heterogeneous particles of varying sizes and densities containing lipid and protein. These lipoproteins include cholesterol esters and free cholesterol, triglycerides, phospholipids and A, C, and E apoproteins. Total cholesterol comprises all the cholesterol found in various lipoproteins.

Factors that affect blood cholesterol levels include age, sex, body weight, diet, alcohol and tobacco use, exercise, genetic factors, family history, medications, menopausal status, the use of hormone replacement therapy, and chronic disorders such as hypothyroidism, obstructive liver disease, pancreatic disease (including diabetes), and kidney disease.

In many individuals, an elevated blood cholesterol level constitutes an increased risk of developing coronary artery disease. Blood levels of total cholesterol and various fractions of cholesterol, especially low density lipoprotein cholesterol (LDL-C) and high density lipoprotein cholesterol (HDL-C), are useful in assessing and monitoring treatment for that risk in patients with cardiovascular and related diseases. Blood levels of the above cholesterol components including triglyceride have been separated into desirable, borderline and high-risk categories by the National Heart, Lung, and Blood Institute in their report in 1993. These categories form a useful basis for evaluation and treatment of patients with hyperlipidemia. Therapy to reduce these risk parameters includes diet, exercise and medications, and fat weight loss, which is particularly powerful when combined with diet and exercise.

Indications

The medical community recognizes lipid testing as appropriate for evaluating atherosclerotic cardiovascular disease. Conditions in which lipid testing may be indicated include:

- Assessment of patients with atherosclerotic cardiovascular disease
- Evaluation of primary dyslipidemia
- Any form of atherosclerotic disease, or any disease leading to the formation of atherosclerotic disease
- Diagnostic evaluation of diseases associated with altered lipid metabolism, such as: nephrotic syndrome, pancreatitis, hepatic disease, and hypo and hyperthyroidism
- Secondary dyslipidemia, including diabetes mellitus, disorders of gastrointestinal absorption, chronic renal failure
- Signs or symptoms of dyslipidemias, such as skin lesions
- As follow-up to the initial screen for coronary heart disease (total cholesterol + HDL cholesterol) when total cholesterol is determined to be high (>240 mg/dL), or borderline-high (200-140 mg/dL) plus two or more coronary heart disease risk factors, or an HDL cholesterol, <35 mg/dL.

To monitor the progress of patients on anti-lipid dietary management and pharmacologic therapy for the treatment of elevated blood lipid disorders, total cholesterol, HDL cholesterol and LDL cholesterol may be used. Triglycerides may be obtained if the lipid fraction is also elevated or if the patient is put on drugs (for example, thiazide diuretics, beta blockers, estrogens, glucocorticoids, and tamoxifen) which may raise the triglyceride level.

When monitoring long-term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels, it may be reasonable to perform the lipid panel annually. A lipid panel at a yearly interval will usually be adequate while measurement of the serum total cholesterol or a measured LDL should suffice for interim visits if the patient does not have hypertriglyceridemia. Any one component of the panel or a measured LDL may be reasonable and necessary up to six times the first year for monitoring dietary or pharmacologic therapy. More frequent total cholesterol, HDL cholesterol, LDL cholesterol and triglyceride testing may be indicated for marked elevations or for changes to anti-lipid therapy due to inadequate initial patient response to dietary or pharmacologic therapy. The LDL cholesterol or total cholesterol may be measured three times yearly after treatment goals have been achieved.

Electrophoretic or other quantitation of lipoproteins may be indicated if the patient has a primary disorder of lipid metabolism.

Effective January 1, 2005, the Medicare law expanded coverage to cardiovascular screening services. Several of the procedures included in this NCD may be covered for screening purposes subject to specified frequencies. See 42 CFR 410.17 and section 100, chapter 18, of the Claims Processing Manual, for a full description of this benefit.

Limitations

Lipid panel and hepatic panel testing may be used for patients with severe psoriasis which has not responded to conventional therapy and for which the retinoid etretinate has been prescribed and who have developed hyperlipidemia or hepatic toxicity. Specific examples include erythrodermia and generalized pustular type and psoriasis associated with arthritis.

Routine screening and prophylactic testing for lipid disorder are not covered by Medicare. While lipid screening may be medically appropriate, Medicare by statute does not pay for it. Lipid testing in asymptomatic individuals is considered to be screening regardless of the presence of other risk factors such as family history, tobacco use, etc. Once a diagnosis is established, one or several specific tests are usually adequate for monitoring the course of the disease. Less specific diagnoses (for example, other chest pain) alone do not support medical necessity of these tests.

When monitoring long-term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels, it is reasonable to

perform the lipid panel annually. A lipid panel at a yearly interval will usually be adequate while measurement of the serum total cholesterol or a measured LDL should suffice for interim visits if the patient does not have hypertriglyceridemia.

Any one component of the panel or a measured LDL may be medically necessary up to six times the first year for monitoring dietary or pharmacologic therapy. More frequent total cholesterol, HDL cholesterol, LDL cholesterol and triglyceride testing may be indicated for marked elevations or for changes to anti-lipid therapy due to inadequate initial patient response to dietary or pharmacologic therapy. The LDL cholesterol or total cholesterol may be measured three times yearly after treatment goals have been achieved.

If no dietary or pharmacologic therapy is advised, monitoring is not necessary. When evaluating non-specific chronic abnormalities of the liver (for example, elevations of transaminase, alkaline phosphatase, abnormal imaging studies, etc.), a lipid panel would generally not be indicated more than twice per year.