



Using
in Your Practice
Information on Coding, Reimbursement and CLIA Waiver

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Attachments: **Form HCFA-116**
 List of State Agencies

Medicare Payment for Clinical Laboratory Services

Before Medicare pays for any test or diagnostic service, two basic criteria must be met:

- (1) the service must be covered by Medicare (e.g., certain procedures such as routine screening tests are not covered) and
- (2) the service must be medically necessary or indicated.

Once these two criteria are met, Medicare pays for most clinical laboratory tests based on the Laboratory Fee Schedule. Each carrier publishes a unique laboratory fee schedule and adjusts payment levels annually on January 1st based on Congressional budget recommendation.

Medicare payment for clinical laboratory tests is always the lesser of the fee schedule amount or the actual amount billed. The provider must accept the Medicare reimbursement as payment in full for a laboratory test. Medicare patients may NOT be billed for any additional amounts. Tests must be billed directly to Medicare by the laboratory or physician performing the test. If an outside laboratory performs a test on a referral from a physician, only the reference laboratory may legally bill Medicare for the procedure.

Procedure (CPT) Codes and Modifiers

The CPT codes for Glycated Hemoglobin (A1c) determinations are:

- 83036 Hemoglobin; glycated (A1c)**
- 83036QW Hemoglobin; glycated (A1c) using CLIA waived method**

Medicare reimbursement for CPT codes 83036 and 83036QW is \$13.42 in all states except:

Idaho: \$9.66	Maryland: \$12.66	Oklahoma: \$11.95
Rhode Island: \$12.09	South Dakota: \$12.86	Wyoming: \$10.49

Diagnosis (ICD-9) Codes

An appropriate diagnosis (ICD-9) code (or narrative description) must be indicated for each service or supply billed under Medicare Part B. ICD-9-CM is an acronym for International Classification of Diseases, 9th Revision, Clinical Modification.

When a patient presents with an undiagnosed illness, the ICD-9 code is determined by the "signs and symptoms" present. Symptoms are defined as what the patient tells the physician. Signs are what the physician observes as part of his examination of the patient.

Definitive ICD-9 codes should only be assigned and recorded in the medical record after a diagnosis is clearly determined. Terms such as "rule out", "probable", and "suspected" should NOT be used since they can not be coded as such and may be interpreted as a firm diagnosis by a third party payer.

Office Visits Primarily for the Purpose of HbA1c Testing

The following evaluation and management code may be billed in addition to 83036 or 83036QW for A1c testing under certain circumstances.

99211 Office or outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician.

Physician interpretation of test results is considered to be part of the evaluation and management services provided to a patient during an office visit and is not separately billable. However, if a patient sees a nurse or other non-physician health care professional for the purpose of A1c testing (for example, to monitor insulin therapy) and the nurse takes vital signs, compares the results of the A1c test to predetermined guidelines, and advises the patient accordingly, 99211 may be billed.

Patients with abnormal results or other indications not covered by established guidelines should always be referred to a physician. The level of office visit then reported would depend on the evaluation and management services provided by the physician.

When a Metrika A1cNow test is provided to a patient by a physician for home testing at a later date, the test may be submitted for payment when the patient notifies the physician of the result and it is entered in the medical record. The date of service would be the date the test is performed, not the date the test materials are provided to the patient. If the patient fails to perform the test, the physician may bill the patient for the cost of the test materials;

however, the test itself can not be billed to Medicare or the patient since it was not performed.

Local Medical Review Policy (LMRP) and National Coverage Determinations (NCD) for Glycated Hemoglobin (A1c)

Local Medical Review Policy(LMRPs) or National Coverage Determinations (NCDs) dictate the coverage for clinical laboratory tests in regard to medical necessity issues. LMRPs and NCDs typically include: (1) Indications and Limitations of Coverage, (2) Covered ICD-9 Codes, (3) Reasons for Non-coverage, (4) Non-covered ICD-9 Codes, and (5) Documentation Requirements. Policy may be published for a single assay, disease or group of tests. Most policies connect with a single CPT code, however some apply to a group of related codes. Only a limited number of LMRPs are published by each Medicare carrier. LMRPs differ from state to state, NCDs apply uniformly to all providers throughout the country.

A new NCD for A1c will become effective **November 25, 2002**. Until then, existing LMRPs will apply. After November 25th the following ICD-9 codes and frequency limits will apply in all states.

ICD-9 Codes Covered by Medicare

211.7	Benign neoplasm of islets of Langerhans
250.00-250.93	Diabetes mellitus and related codes
251.0	Hypoglycemic coma
251.1	Other specified hypoglycemia
251.2	Hypoglycemia, unspecified
251.3	Post-surgical hypoinsulinemia
251.4	Abnormal secretion of glucagon
251.8	Other specified disorders of pancreatic internal secretion
251.9	Unspecified disorder of pancreatic internal secretion
258.0-258.9	Polyglandular dysfunction and related disorders
271.4	Renal glycosuria
275.0	Disorders of iron metabolism (hemochromatosis)
577.1	Chronic pancreatitis
579.3	Other and unspecified post-surgical nonabsorption
648.00	Diabetes mellitus complicating pregnancy, unspecified episode
648.03	Diabetes mellitus complicating pregnancy, antipartum complication
648.04	Diabetes mellitus complicating pregnancy, postpartum complication
648.80	Abnormal glucose tolerance complicating pregnancy, unspecified episode
648.83	Abnormal glucose tolerance complicating pregnancy, antipartum complication
648.84	Abnormal glucose tolerance complicating pregnancy, postpartum complication
790.2	Abnormal glucose tolerance test
790.6	Other abnormal blood chemistry (hyperglycemia)
962.3	Poisoning by insulin and antidiabetic agents
V12.2	Personal history of endocrine, metabolic, and immunity disorders
V58.69	Long term current use of other medication

Frequency of testing considered medically necessary

Every 3 months to monitor a diabetic patient's metabolic control

Every 1-2 months when treatment regimen is altered to improve control

Every month for diabetic pregnant women

Patients with uncontrolled type I or II diabetes may be tested more frequently, however, the medical record must support such increased testing.

Billing Medicare Patients for Services Which May Be Denied

Medicare patients may be billed for services that are clearly not covered. For example, routine physicals or screening tests such as total cholesterol are not covered when there is no indication that the test is medically necessary. However, when a Medicare carrier is likely to deny payment because of medical necessity policy (either as stated in their written Medical Review Policy or upon examination of individual claims) the patient must be informed and consent to pay for the service before it is performed. Otherwise, the patient has no obligation to pay for the test.

An **Advance Beneficiary Notice (ABN)**, sometimes called a patient waiver form, is used to document that the patient is aware that Medicare may not pay for a test or procedure and has agreed to pay the provider in the event payment is denied. Each ABN must be specific to the service provided and the reason that Medicare may not pay for the service. Blanket waivers for all Medicare patients are not allowed.

Since both LMRPs as well as the new NCD for A1c include frequency limits, an ABN is appropriate any time the possibility exists that the frequency of testing may be in excess of stated policy. For example, if an A1c test may have been performed by another provider less than three months ago for a patient with uncomplicated diabetes, it would be prudent to obtain a signed ABN.

The CPT code modifier, -GA (Waiver of Liability Statement on File), is used to indicate that the provider has notified the Medicare patient that the test performed may not be reimbursed by Medicare and may be billed to the patient.

An ABN must: (1) be in writing; (2) be obtained prior to the beneficiary receiving the service; (3) clearly identify the particular service; (4) state that the provider believes Medicare is likely to deny payment for the service; (5) give the reason(s) that the provider believes that Medicare is likely to deny payment for the specific service, and (6) include the beneficiary's signature and date. Routine notices to beneficiaries which do nothing more than state that Medicare denial of payment is possible, or that the provider never knows whether Medicare will pay for a service, are not considered acceptable evidence of advance notice.

In the near future Medicare will issue a standard ABM form, in the mean time the following sample ABN meets the above requirements.

Medicare will only pay for services that it determines to be reasonable and necessary under Section 1862(a)(1) of the Medicare law. If Medicare determines that a particular service, although it would otherwise be covered, is not reasonable and necessary under Medicare program standards, Medicare will deny payment for that service.

I believe that, in your case, Medicare is likely to deny payment for the following service(s) for the reasons(s) stated below:

Procedure or Service: _____

Date of Service: _____

Reason for likely Medicare denial: _____

I have been notified by my provider that he/she believes, in my case, Medicare is likely to deny payment for the service(s) identified above, for the reasons stated. If Medicare denies payment, I agree to be personally and fully responsible for payment.

Beneficiary Signature _____ Date _____

Notes on Private Insurance/Managed Care

Where lab agreements or capitation does not exist, insurance plans generally follow Medicare rules except reimbursement rates vary greatly e.g. \$9 to \$42. Additionally, some plans may also reimburse for the fingerstick/venipuncture under CPT code 36415.

Securing a CLIA Certificate of Waiver

The Metrika A1cNow is classified as a CLIA Waived Category test by the FDA. A CLIA certificate is required any time a clinical laboratory test is performed; however, waived category tests require only a CLIA **Certificate of Waiver**. Certificate of Waiver labs must register with Medicare, pay a \$150.00 fee every two years and agree to follow manufacture's instructions. No inspections or other CLIA regulations apply.

Who Can Apply for a Certificate of Waiver.

Anyone can apply for a Certificate of Waiver unless your state has imposed additional restrictions. Under CLIA, there are no personnel qualifications for the Laboratory Director or individuals who perform waived tests. For example, Pharmacists may be granted a Certificate of Waiver in all states except NY and PA. However, a number of states require them to comply with additional requirements (AL, AZ, FL, ME, MD, MA, NJ, OR, TN and RI). Always check with your State Agency if the Director for the Certificate of Waiver laboratory is not an MD or other licensed health care provider.

To apply for a Certificate of Waiver, go to the internet at www.hcfa.gov/medicaid/clia and download a CLIA application form (HCFA-116) and follow the instructions provided, or complete the attached application form and send it to the appropriate state agency. A list of State Agency addresses is attached and is also available on the internet at www.hcfa.gov/medicaid/clia/saaddres.

How to Apply for a Certificate of Waiver.

PART I: GENERAL INFORMATION For a new application, leave the **CLIA identification number blank. The number will be assigned when the application is processed.** Be specific when indicating the name of your facility, particularly when it is a component of a larger entity, for example The Diabetes Clinic in XYZ Hospital. For a physician's office, you can use the name of the physician. The information provided is the name that will appear on your certificate. The Director should be the individual who is responsible for testing operations.

Facility street address must be the **actual_physical location** where testing is performed, including floor, suite and/ or room, if applicable. **DO NOT USE A POST OFFICE BOX NUMBER OR A MAIL DROP ADDRESS FOR THE NUMBER AND STREET OF THE ADDRESS.** If the laboratory has a separate mailing or billing address, complete that section of the application.

PART II: TYPE OF CERTIFICATE REQUESTED: Check “**Certificate of Waiver**”

PART III: TYPE OF LABORATORY: Select the type of laboratory designation that is most appropriate for your facility from the list provided. If you cannot find your designation within the list, contact your State agency for assistance.

PART IV: HOURS OF LABORATORY TESTING: Provide only the times when actual laboratory testing is performed in your facility.

PART V: MULTIPLE SITES: Only hospitals or government labs are allowed to have multiple sites. You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA regulatory exceptions outlined on the form. In general, each testing site must have an individual Certificate of Waiver unless it is a mobile lab or all are located on the same hospital campus.

PART VI: WAIVED TESTING: Indicate the total annual volume of waived tests you perform. If you are not currently performing any tests, estimate the number you will perform during the coming 12 months.

PART VII: NONWAIVED TESTING: Leave blank

PART VIII: TYPE OF CONTROL: Control means “ownership” in most cases. Select the code which most appropriately describes your facility. Proprietary/for profit entities must choose “04”.

PART VIX: DIRECTOR AFFLIATION WITH OTHER LABORATORIES: List all other facilities for which the director is responsible.

PART X. INDIVIDUALS INVOLVED IN LABORATORY TESTING: Complete part A only.

Enter the total number of individuals who perform waived tests. Do not count individuals who only collect specimens or perform clerical duties.

Once the completed FORM HCFA-116 has been returned to the applicable State agency and processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate (\$150 for a Certificate of Waiver). The CLIA identification number must be included on all Medicare claims you submit for waived tests. If you need additional information concerning CLIA, or completion the form, contact your State agency.

M  T R I K A

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