CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1527	**Date: May 30, 2008**
	Change Request 6021

Subject: Clinical Laboratory Fee Schedule - New Waived Tests

I. SUMMARY OF CHANGES: This Change Request (CR) will communicate the latest tests approved by the Food and Drug Administration (FDA) as waived tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). These test codes will be incorporated into the Clinical Laboratory Fee Schedule with a QW modifer so that they can be billed by facilities with a CLIA certificate at the appropriate level.

New / Revised Material
Effective Date: July 1, 2008
Implementation Date: July 7, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. 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: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
N/A	

III. FUNDING:
SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

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

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 1527	Date: May 30, 2008	Change Request: 6021

SUBJECT: Clinical Laboratory Fee Schedule – New Waived Tests

Effective Date: July 1, 2008

Implementation Date: July 7, 2008

I. GENERAL INFORMATION

A. Background: The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare pays appropriately for CLIA-waived tests under the Clinical Laboratory Fee Schedule when performed by facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level. The Clinical Laboratory Fee Schedule is updated annually with a list of new waived tests.

B. Policy: CMS has become aware of additional tests that are appropriate for inclusion on the Clinical Laboratory Fee Schedule's list of CLIA waived tests. We are updating the list at this time rather than waiting for the next annual update.

Listed below are the latest tests approved by the Food and Drug Administration (FDA) as waived tests under CLIA. The Current Procedural Terminology (CPT) codes for the following new tests must have the modifier QW to be recognized as a waived test. The following tests are being added to the clinical lab fee schedule:

CPT	CPT Code Description
80047QW	Basic Metabolic Panel (Calcium, Ionized)
80048QW	Basic Metabolic Panel (Calcium, Total)
80051QW	Electrolyte Panel
80053QW	Comprehensive Metabolic Panel
82042QW	Albumin; Urine or Other Source, Quantitative, Each Specimen
82150QW	Amylase
82247QW	Bilirubin; Total
82977QW	Glutamyltransferase, Gamma (GGT)
84075QW	Phosphatase, Alkaline
84157QW	Protein, Total, Except by Refractometry; Other Source (e.g., Synovial Fluid, Cerebrospinal Fluid)
84520QW	Urea Nitrogen; Quantitative
87808QW	Infectious Agent Antigen Detection by Immunoassay with Direct Optical Observation; Trichomonas Vaginalis
87999QW	Unlisted Microbiology Procedure

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6021.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.	X			X						
6021.2	The Medicare contractor shall permit the use of code 80047QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after January 1, 2008.	X			X					X	
6021.3	The Medicare contractor shall permit the use of code 80048QW and code 80053QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after January 16, 2008.	X			X					X	
6021.4	The Medicare contractor shall permit the use of code 80051QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after October 30, 2007.	X			X					X	
6021.5	The Medicare contractor shall permit the use of code 87999QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after July 1, 2007.	X			X					X	
6021.6	The Medicare contractor shall permit the use of code 82042QW, code 82150QW, code 82247QW, code 82977QW, code 84075QW, code 84157QW, and code 84520QW, for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after October 4, 2006.	X			X					X	
6021.7	The Medicare contractor shall permit the use of code 87808QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after January 1, 2007.	X			X					X	
6021.8	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.	X			X						

PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6021.9	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X			X						

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
N/A	

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Glenn.McGuirk@cms.hhs.gov

Post-Implementation Contact(s): Glenn.McGuirk@cms.hhs.gov

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Carriers (RHHIs)* use only one of the following statements:

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

Section B: *For Medicare Administrative Contractors (MACs)*, use the following statement:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.