

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2443	Date: April 6, 2012
	Change Request 7766

SUBJECT: Clinical Laboratory Fee Schedule - New Waived Tests

I. SUMMARY OF CHANGES: CMS has become aware of an additional test that is appropriate for inclusion on the CLFS list of CLIA waived tests. We are updating the list at this time rather than waiting for the next annual update. The following code is the latest test approved by the Food and Drug Administration (FDA) as a waived test under CLIA. The Current Procedural Terminology (CPT) code for the following test must have the modifier QW to be recognized as a waived test. The following test is being added to the CLFS: 86386QW Nuclear Matrix Protein 22 (NMP22), qualitative

EFFECTIVE DATE: January 1, 2012

IMPLEMENTATION DATE: July 2, 2012

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:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:

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

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:

One-Time Notification

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

Attachment – One-Time Notification

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SUBJECT: Clinical Laboratory Fee Schedule – New Waived Tests

Effective Date: January 1, 2012

Implementation Date: July 2, 2012

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 & Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level. The Clinical Laboratory Fee Schedule (CLFS) is updated annually with a list of new waived tests.

B. Policy:

CMS has become aware of an additional test that is appropriate for inclusion on the CLFS’ list of CLIA waived tests. We are updating the list at this time rather than waiting for the next annual update.

Listed below is the latest test approved by the Food and Drug Administration (FDA) as a waived test under CLIA. The Current Procedural Terminology (CPT) code for the following test must have the modifier QW to be recognized as a waived test. The following test is being added to the CLFS:

<u>CPT</u>	<u>CPT Code Description</u>
86386QW	Nuclear Matrix Protein 22 (NMP22), qualitative

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an “X” in each applicable column)									
		A / B M A C	D M M A C	F I I E R	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
						F S S	M S S	V M S	C W F		
7766.1	The Medicare contractor shall manually include the new test listed above in CLIA-covered code files with the QW modifier.	X			X						
7766.2	The Medicare contractor shall permit the use of code 86386QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after January 1, 2012.	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / B	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers			
		M A C	M A C			I S S	M S S	V S S	C W F	
7766.3	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					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / B	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers			
		M A C	M A C			I S S	M S S	V S S	C W F	
7766.4	<p>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.</p> <p>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.</p>	X			X					

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s): Glenn McGuirk (410) 786-5723

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs) 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.