

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2804	Date: October 28, 2013
	Change Request 8439

Transmittal 2779, dated September 6, 2013, is being rescinded and replaced by Transmittal 2804, dated October 28, 2013, to correct the name of the test in the seventh bullet in the background section from "Premier Integrity Solutions P/Tox Druf Screen Cup" to "Premier Integrity Solutions P/Tox Drug Screen Cup". All other information remains the same.

SUBJECT: New Waived Tests

I. SUMMARY OF CHANGES: This change will inform contractors of new CLIA waived tests approved by the Food and Drug Administration. Since these tests are marketed immediately after approval, CMS must notify its contractors of the new tests so that the contractors can accurately process claims. There are 10 newly added waived complexity tests. The initial release of this Recurring Update Notification applies to Chapter 16, section 70.8 of the IOM.

EFFECTIVE DATE: January 1, 2014

IMPLEMENTATION DATE: January 6, 2014

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; Contractors activities are to be carried out with 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 obliged 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: 2804	Date: October 28, 2013	Change Request: 8439
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SUBJECT: New Waived Tests

EFFECTIVE DATE: January 1, 2014

IMPLEMENTATION DATE: January 6, 2014

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.

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. However, the tests mentioned on the first page of the attached list (i.e., CPT codes: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

The CPT code, effective date and description for the latest tests approved by the FDA as waived tests under CLIA are the following:

1. G0434QW, January 23, 2008, Phamatech At Home 12 Drug Test (Model 9308T);
2. G0434QW, January 23, 2008, Phamatech At Home 12 Drug Test (Model 9308Z);
3. 81003QW, January 29, 2013, Henry Schein Urispec Plus Urine Analyzer;
4. G0434QW, February 27, 2013, CLIAwaived, Inc. Rapid Drug Test Cup;
5. G0434QW, February 27, 2013, Clinical Reference Laboratory, Inc. Intelligent Transport Cup;
6. G0434QW, February 27, 2013, Noble Medical Inc. Noble 1 Step Cup;
7. G0434QW, February 27, 2013, Premier Integrity Solutions P/Tox Drug Screen Cup;
8. G0434QW, February 27, 2013, US Diagnostics ProScreen Drugs of Abuse Cup;
9. 84443QW, March 5, 2013, BTNX Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette (Whole Blood);

10. 86308QW, March 11, 2013, Henry Schein OneStep Pro+ Mono {Whole Blood};
11. G0434QW, May 15, 2013, UCP Biosciences, Inc. UCP Home Drug Screening Test Cups;
12. G0434QW, May 17, 2013, Alere Toxicology Services, Inc. Tox Screen Drugs of Abuse Test Cup;
13. G0434QW, June 24, 2013, Advin Multi-Drug Screen Test; and
14. 87880QW, July 3, 2013, Henry Schein OneStep Pro+ Strep A Cassette.

B. Policy: The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and 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.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility											
		A/B MAC			D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				Other
		A	B	H H H					F I S S	M C S S	V M S S	C W F	
8439.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.		X				X						
8439.2	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						
8439.3	Contractors shall not use the explanatory information under the "Use" column in the attachment as the reason for rejecting a claim.		X				X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility							
		A/B MAC			D M E M A C	F I	C A R R I E R	R H I	Other
		A	B	H H H					
8439.4	MLN Article : A provider education article related to this instruction will be available at		X				X		

Number	Requirement	Responsibility							
		A/B MAC			D M E	F I	C A R R I E R	R H H I	Other
		A	B	H H H	M A C				
	http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/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 sites 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 the contractor's 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.								

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Kathleen Todd, 410-786-3385 or Kathleen.todd@cms.hhs.gov

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

VI. FUNDING

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

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

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(Attachment)