CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-20 One-Time Notification	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 653	**Date: March 19, 2010**
	Change Request 6852

SUBJECT: Clinical Laboratory Fee Schedule (CLFS) - Special Instructions for Specific Test Codes (CPT Code 80100, CPT Code 80101, CPT Code 80101QW, G0430, G0430QW, and G0431QW)

I. SUMMARY OF CHANGES: This Change Request (CR) provides special instruction for the proper use of CPT Code 80100, CPT Code 80101, CPT Code 80101QW, G0430, G0430QW, G0431, and G0431QW.

EFFECTIVE DATE: April 1, 2010
IMPLEMENTATION DATE: April 5, 2010

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

Pub. 100-20	Transmittal: 653	Date: March 19, 2010	Change Request: 6852

SUBJECT: Clinical Laboratory Fee Schedule (CLFS) – Special Instructions for Specific Test Codes (CPT Code 80100, CPT Code 80101, CPT Code 80101QW, G0430, G0430QW, G0431, and G0431QW)

Effective Date: April 1, 2010

Implementation Date: April 5, 2010

I. GENERAL INFORMATION

A. Background:

Each year, the Centers for Medicare and Medicaid Services (CMS) hosts an Annual Public Meeting concerning new test codes that have been established by the Common Procedural Terminology (CPT) committee and that will be covered by Medicare and paid based on the CLFS.

During CY 2009, effective for January 1, 2010, two new G codes were established – G0430 and G0431 – as it had come to CMS' attention that some companies were using questionable billing practices concerning CPT Code 80100 and CPT Code 80101. Therefore, CMS created two new G codes to operate in place of and alongside existing CPT Code 80100 and existing CPT Code 80101.

In addition, those clinical laboratories that require a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver had been utilizing CPT Code 80101QW. In order to ensure that clinical laboratories that require a CLIA certificate of waiver are also billing correctly whether the drug screen test performed is for a single drug class or multiple drug classes, effective April 1, 2010, two additional G codes are being established – G0430QW and G0431QW.

Therefore, this Change Request (CR) provides special instructions for the proper use of CPT Code 80100, CPT Code 80101, CPT Code 80101QW, G0430, G0430QW, G0431, and G0431QW as of April 1, 2010.

B. Policy: Each test code discussed in this CR is currently described as follows by the American Medical Association (AMA) (CPT Codes) and CMS (G Codes):

CPT Code 80100 – Drug screen, qualitative; multiple drug classes chromatographic method, each procedure

CPT Code 80101 – Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class

CPT Code 80101QW – Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class

G0430 – Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure

G0430QW – Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure

G0431 – Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class

G0431QW – Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class

For purposes of the Clinical Laboratory Fee Schedule (CLFS), beginning April 1, 2010, when performing a qualitative drug screening test for multiple drug classes that uses chromatographic methods, CPT Code 80100 is the appropriate code to bill. New test code G0430 was created to limit the billing to one time per procedure and to remove the limitation of the method (chromatographic) when this method is not being used in the performance of the test. As a result, when a clinical laboratory that does not require a CLIA certificate of waiver performs a qualitative drug screening test for multiple drug classes that does not use chromatographic methods, new test code G0430 is the appropriate code to bill. When a clinical laboratory that does require a CLIA certificate of waiver performs a qualitative drug screening test for multiple drug classes that does not use chromatographic methods, new test code G0430QW is the appropriate code to bill.

New test code G0431 is a direct replacement for CPT Code 80101. For purposes of the CLFS, beginning April 1, 2010, new test code G0431 should be utilized by those clinical laboratories that do not require a CLIA certificate of waiver. Those clinical laboratories that do require a CLIA certificate of waiver should utilize new test code G0431QW.

Effective April 1, 2010, CPT Code 80101 will no longer be covered by Medicare, and CPT Code 80101QW will be deleted.

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	
6852.1	Carriers shall retrieve the CY 2010 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY10APR.V0401) from the CMS mainframe on or after April 1, 2010.	X			X						
6852.1.1	Carriers shall notify CMS of successful receipt via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., carrier name and number).	X			X						
6852.2	Intermediaries shall retrieve the CY 2010 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.CY10APR.V0401.FI) from the CMS mainframe on or after April 1, 2010.	X		X							

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	
6852.2.1	Intermediaries shall notify CMS of successful receipt via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., fiscal intermediary name and number).	X		X							
6852.3	Contractors shall manually remove Code 80101QW from the Clinical Laboratory Fee Schedule (CLFS) beginning April 1, 2010.	X			X						
6852.4	Contractors shall permit the use of Code G0430QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after April 1, 2010.	X			X						
6852.5	Contractors shall permit the use of Code G0431QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after April 1, 2010.	X			X						
6852.6	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	X						

III. 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	
6852.7	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	X		X	X						

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	
	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.										

IV. SUPPORTING INFORMATION

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

Use "Should" to denote a recommendation.

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 at glenn.mcguirk@cms.hhs.gov

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

VI. FUNDING

Section A: 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.

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.