

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10529	Date: December 23, 2020
	Change Request 12093

SUBJECT: Addition of the QW modifier to Healthcare Common Procedure Coding System (HCPCS) Codes 87811 and 87428

I. SUMMARY OF CHANGES: This change request informs Medicare contractors about the addition of the QW modifier to CMS Healthcare Common Procedure Coding System (HCPCS) code 87811 [Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])] and code 87428 [Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B]. This One Time Notification applies to Chapter 16, Section 70.9.

EFFECTIVE DATE: October 6, 2020

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

IMPLEMENTATION DATE: April 5, 2021

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	N/A

III. FUNDING:

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

Attachment - One-Time Notification

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I. GENERAL INFORMATION

A. Background: The Clinical Laboratory Improvement Amendments (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid only pay for laboratory tests performed in certified facilities, each claim for a HCPCS code that is considered a CLIA laboratory test is currently edited at the CLIA certificate level.

The Healthcare Common Procedure Coding System (HCPCS) code 87811 [Infectious agent antigen detection by immunoassay with direct optical (i.e., visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])] was mentioned in change request 12080 with an effective date of October 6, 2020.

The HCPCS code 87428 [Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B] was mentioned in change request 12080 with an effective date of November 10, 2020.

On February 4, 2020, the HHS Secretary determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus disease 2019. During public health emergencies declared under section 564 of the FD&C Act, the FDA is able to issue Emergency Use Authorizations (EUAs) when certain criteria are met that allows for the use and distribution of potentially life-saving medical products to diagnose, treat, or prevent the disease, which can include diagnostic tests. Currently, there is no Food and Drug Administration (FDA)-approved or cleared test to diagnose or detect Coronavirus disease 2019. The FDA has issued several In Vitro Diagnostic EUAs for SAR-CoV-2 and Coronavirus disease 2019.

The FDA does not categorize tests authorized under an EUA. The settings in which an EUA-authorized test may be used are described in the Letter of Authorization. As discussed in the Guidance for Industry and Other Stakeholders: Emergency Use Authorization of Medical Products and Related Authorities, when the FDA authorizes tests for use at the point of care (including SARS-CoV-2 point of care test systems) under an EUA, such tests are deemed to be CLIA waived tests. Accordingly, for the duration of the emergency declaration, such tests can be performed in a patient care setting that is qualified to have the test performed there as a result of operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The tests listed on the FDA's In Vitro Diagnostic EUAs website authorized by the FDA for use at point of care under an EUA can be used by facilities having a current CLIA certificate of waiver. To be recognized as a test that can be performed in a facility having a CLIA certificate of waiver, the modifier QW must be added.

As of December 2, 2020, the FDA issued 2 individual EUAs for antigen detection by immunoassay with direct optical (i.e., visual) observation for SARS-CoV-2 that are authorized for use at the Point of Care (POC) setting, i.e., in patient care settings operating under a CLIA Certificate of Waiver. The HCPCS code 87811QW describes the testing performed by these 2 EUA antigen detection by immunoassay with direct optical observation SARS-CoV-2 tests.

In addition, the FDA issued one individual EUA for infectious agent antigen detection by immunoassay technique, qualitative or semiquantitative for SARS-CoV-2 and influenza virus types A and B that is authorized for use at the POC setting. The HCPCS code 87428QW describes this EUA test.

This One Time Notification applies to Chapter 16, Section 70.9.

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 in a facility with a valid, current CLIA certificate, 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	Shared- System Maintainers				Other	
		A	B		F I S S	M C S	V M S	C W F		
12093.1	The Medicare contractor shall permit the use of code 87811QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after October 6, 2020.		X						X	
12093.2	The Medicare contractor shall permit the use of code 87428QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after November 10, 2020.		X						X	
12093.3	Contractors need not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors shall adjust claims brought to their attention.		X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E D I	C M E D I
		A	B	H H H		
12093.4	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.		X			

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, kathleen.todd@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

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ATTACHMENTS: 0