

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-20 One-Time Notification</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 11156</b>	<b>Date: December 10, 2021</b>
	<b>Change Request 12557</b>

**SUBJECT: Addition of the QW modifier to Healthcare Common Procedure Coding System (HCPCS) Code 86328**

**I. SUMMARY OF CHANGES:** This change informs Medicare contractors about the addition of the QW modifier to CMS Healthcare Common Procedure Coding System (HCPCS) code 86328 [Test for detection of severe acute respiratory syndrome coronavirus 2 (Covid-19) antibody, qualitative or semiquantitative]. This One Time Notification applies to Chapter 16, Section 70.9.

**EFFECTIVE DATE: September 23, 2020**

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

**IMPLEMENTATION DATE: January 3, 2022**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
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 86328 [Test for detection of severe acute respiratory syndrome coronavirus 2 (Covid-19) antibody, qualitative or semiquantitative] was included in CMS Transmittal Number R10575CP (Change Request Number: 11815).

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 Federal Food, Drug, and Cosmetic (FD&C) Act, the Food and Drug Administration (FDA) is able to issue Emergency Use Authorization (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 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.

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 the point of care under an EUA can be used by facilities having a current CLIA certificate of waiver or a CLIA certificate for provider-performed microscopy procedures. On September 23, 2020, the FDA has issued the first individual EUA for the detection of severe acute respiratory syndrome coronavirus 2 (Covid-19) antibody (qualitative or semiquantitative) for use at the point of care setting, i.e., in patient care settings operating under a CLIA Certificate of Waiver. The HCPCS code 86328 describes the testing performed by this EUA. To be recognized as a test that can be performed in a facility having a CLIA certificate of waiver or a CLIA certificate for provider-performed microscopy procedures, the modifier QW must be added.

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	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
12557.1	The Medicare contractor shall permit the use of code 86328QW for claims submitted by facilities with a valid, current CLIA certificate of waiver or a CLIA certificate for provider-performed microscopy procedures with dates of service on or after September 23, 2020.		X						X		
12557.2	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	C E D I		
		A	B	H H H				
12557.3	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.		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**