CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-20 One-Time Notification	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10066	**Date: April 24, 2020**
	Change Request 11765

SUBJECT: Addition of the QW modifier to Healthcare Common Procedure Coding System (HCPCS) code U0002 and 87635

I. SUMMARY OF CHANGES: This change informs Medicare contractors about the addition of the QW modifier to Healthcare Common Procedure Coding System (HCPCS) codes U0002 (2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC) and 87635 [Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique]. This One Time Notification applies to Chapter 16, Section 70.9.

EFFECTIVE DATE: March 20, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 8, 2020

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

Pub. 100-20	Transmittal: 10066	Date: April 24, 2020	Change Request: 11765

SUBJECT: Addition of the QW modifier to Healthcare Common Procedure Coding System (HCPCS) code U0002 and 87635

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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 U0002 [2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC], and 87635 [Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique] were included in CMS transmittal IU7670, change request 11681.

On February 4, 2020, the Secretary of the Department of Health and Human Services (HHS) determined, pursuant to section 564 of the Federal Food, Drug and Cosmetic (FD&C) Act, that there is a significant potential for 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 a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV). The virus is now named SARS-CoV-2, which causes the illness COVID-19.

Currently there is no Food and Drug Administration (FDA)-approved or cleared test to diagnose or detect COVID-19. The FDA has issued several Emergency Use Authorizations (EUAs) for the use of new diagnostic test to detect the SARS-CoV-2 virus. During public health emergencies declared under section 564 of the FD&C Act, the FDA is able to issue 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.

FDA does not categorize tests authorized under an EUA. Instead, the settings in which an EUA authorized test may be used are described in the Letter of Authorization and, as discussed in the Guidance for Industry and Other Stakeholders: Emergency Use Authorization of Medical Products and Related Authorities, the FDA may determine that a test shall be deemed to be in a particular category. The terms "patient care settings outside of the clinical laboratory environment," "near patient testing," and "point of care" are mentioned in some EUAs, Policy for Diagnostic Tests for Coronavirus Disease-2019, and generally refer to settings that are equipped with the instrumentation and appropriately trained personnel necessary to perform the test, and may include settings such as hospitals, physician offices, urgent care, outreach clinics, and temporary patient care settings. In cases where these terms are used in EUAs, FDA has deemed such test to be appropriate for use in a CLIA waived setting for the time period of the emergency. These terms generally do not apply to home specimen collection or at home testing unless otherwise specified.

Those tests listed on the FDA's Emergency Use Authorizations for COVID-19 website under the Test Kit Manufacturers and Commercial Laboratories Table that include the terms "patient care settings outside of the clinical laboratory environment," "near patient testing," or "point of care" in the EUA can be used by facilities having a current CLIA certificate of waiver. On March 20, 2020, FDA issued the first EUA containing the previous terms. HCPCS code U0002 and 87635 must have the modifier QW to be recognized as a test that can be performed in a facility having a CLIA certificate of waiver.

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			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
11765.1	The Medicare contractor shall permit the use of code U0002QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after March 20, 2020.		X							
11765.2	The Medicare contractor shall permit the use of code 87635QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after March 20, 2020.		X							
11765.3	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			DME MAC	CEDI
		A	B	HHH		
11765.4	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:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

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).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
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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.

ATTACHMENTS: 0