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Addition of the QW Modifier to Healthcare Common Procedure Coding System (HCPCS) Code U0002 and 87635

MLN Matters Number: MM11765
Related Change Request (CR) Number: 11765
Related CR Release Date: April 24, 2020
Effective Date: March 20, 2020
Related CR Transmittal Number: R10066OTN
Implementation Date: May 8, 2020

PROVIDER TYPES AFFECTED

This MLN Matters Article is for facilities having a current Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver who bill Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article informs you about the addition of the QW modifier to 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]. Medicare will permit the use of codes U0002QW and 87635QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after March 20, 2020. Make sure your billing staffs are aware of these changes.

BACKGROUND

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 codes U0002 and 87635 were also included in CR 11681. See the related MLN Matters article, MM11681, at https://www.cms.gov/files/document/mm11681.pdf.

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 Federal Food Drug & Cosmetic Act (FD&C Act), the FDA is

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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 EUAs for COVID-19 website, https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations, 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.

Note that MACs will not search their files to adjust claims already processed prior to implementation of CR 11765. They will adjust such claims that you bring to your MAC's attention.

ADDITIONAL INFORMATION

The official instruction, CR 11765, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/r10066OTN.pdf.

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

Date of Change	Description
April 27, 2020	Initial article released.