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Addition of the QW Modifier to Healthcare Common Procedure Coding System (HCPCS) Codes 0240U, 0241U, and 87637

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Related Change Request (CR) Number: 12318
Related CR Release Date: June 11, 2021
Effective Date: October 6, 2020
Related CR Transmittal Number: R10827OTN
Implementation Date: July 6, 2021

Provider Types Affected

This MLN Matters Article is for physicians, other providers, and clinical diagnostic laboratories that submit claims to Medicare Administrative Contractors (MACs) for laboratory services for Medicare patients.

Provider Action Needed

This Article tells you of the addition of the QW modifier to certain CMS HCPCS codes (0240U, 0241U, and 87637).

Background

CMS included the following HCPCS codes in CR 12080 (see related Article MM12080):

- 0240U - [Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2[SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected]
- 0241U [Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected]
- 87637 [Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique]

The effective date of these 3 codes is October 6, 2020.

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On February 4, 2020, the HHS Secretary determined there is a public health emergency due to the virus that causes Coronavirus disease 2019. Currently, there isn't an FDA approved or cleared test to diagnose or detect Coronavirus disease 2019. The FDA has issued several In Vitro Diagnostic Emergency Use Authorizations (EUAs) for SAR-CoV-2 and Coronavirus disease 2019.

The FDA has issued at least 1 EUA for infectious agent detection by nucleic acid for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), influenza virus types A and B, and respiratory syncytial virus using multiplex and amplified probe technique. The FDA authorized the test for use at the point of care setting, that is, in patient care settings operating under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. The HCPCS codes 0240U, 0241U and 87637 describe the testing you perform with this EUA.

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, you can perform such tests in a patient care setting that qualified to have the test performed there by operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

For Medicare to recognize these tests you perform under a CLIA certificate of waiver or a CLIA certificate for provider-performed microscopy procedures, you must add the modifier QW to HCPCS codes 0240U, 0241U, and 87637.

More Information

We issued CR 12318 to your MAC as the official instruction for this change.

For more information, contact your MAC.

Document History

Date of Change	Description
June 11, 2021	Initial article released.

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