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Addition of the QW Modifier to Healthcare Common Procedure Coding System (HCPCS) Code 87636

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Related Change Request (CR) Number: 12269
Related CR Release Date: April 26, 2021
Effective Date: July 1, 2021
Related CR Transmittal Number: R10732OTN
Implementation Date: July 6, 2021

PROVIDER TYPES AFFECTED

This MLN Matters® Article is for physicians, hospitals, laboratories, other providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for HCPCS code 87636 for Medicare patients.

PROVIDER ACTION NEEDED

This article informs you of the addition of the QW modifier to HCPCS code 87636 [Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique]. CMS included HCPCS code 87636 in Transmittal R10575CP (CR 12080) with an effective date of October 6, 2020. Make sure your billing staffs are aware of this change.

BACKGROUND

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

On February 4, 2020, the HHS Secretary determined there is a Public Health Emergency (PHE) due to COVID-19. During PHEs declared under Section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act, the FDA may 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 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 doesn't categorize tests authorized under an EUA. The settings in which an EUA-authorized test may be used are described in the Letter of Authorization. The Guidance for

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Industry and Other Stakeholders: Emergency Use Authorization of Medical Products and Related Authorities says when the FDA authorizes tests for use at the point of care (including COVID-19 point of care test systems) under an EUA, such tests are deemed to be CLIA waived tests. As such, throughout the COVID-19 PHE, you can perform such tests in a patient care setting 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.

Facilities possessing a current CLIA Certificate of Waiver may conduct In Vitro Diagnostic point of care tests under EUAs listed on the FDA In Virto Diagnostic EUAs website. The FDA has issued at least one EUA for infectious agent detection by nucleic acid of COVID-19 and influenza virus types A and B using a multiplex amplified probe technique that it authorized for use at the point of care setting. HCPCS code 87636 describes this EUA test.

Claims for tests you perform in facilities having a CLIA certificate of waiver must include the QW modifier. MACs won't search their files to either retract payment for claims already paid or to retroactively pay claims. However, they will adjust such claims you bring to their attention.

ADDITIONAL INFORMATION

CMS issued CR 12269 to your MAC as the official instruction for this change.

For more information, contact your MAC.

DOCUMENT HISTORY

Date of Change	Description
April 26, 2021	Initial article released.