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Addition of the QW Modifier to Healthcare Common Procedure Coding System (HCPCS) Codes 87811 and 87428

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Related Change Request (CR) Number: 12093
Related CR Release Date: December 23, 2020
Effective Date: October 6, 2020
Related CR Transmittal Number: R10529OTN
Implementation Date: April 5, 2021

PROVIDER TYPES AFFECTED

This MLN Matters Article is for physicians, providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article informs you of the addition of the QW modifier to the following CMS HCPCS codes:

- 87811 [Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])] and code
- 87428 [Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B].

Make sure your billing staffs are aware of these changes.

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.

We discussed HCPCS code 87811 in MLN Matters article MM12080 with an effective date of October 6, 2020. We discussed HCPCS code 87428 in the same article with an effective date of November 10, 2020.

On February 4, 2020, the HHS Secretary determined that there is a public health emergency

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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 COVID-19. During public health emergencies declared under Section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act, the FDA is able to 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 COVID-19. The FDA has issued several In Vitro Diagnostic EUAs for SAR-CoV-2 and COVID-19.

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. 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. For the duration of the emergency declaration, you can perform such tests 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 point of care under an EUA can be used by facilities having a current CLIA certificate of waiver. To be recognized as a test that can be performed in a facility having a CLIA certificate of waiver, the modifier QW must be added.

As of December 2, 2020, the FDA issued 2 individual EUAs for antigen detection by immunoassay with direct optical (that is, visual) observation for SARS-CoV-2 that are authorized for use at the Point of Care setting, that is, in patient care settings operating under a CLIA Certificate of Waiver. The HCPCS code 87811QW describes the testing performed by these 2 EUA antigen detection by immunoassay with direct optical observation SARS-CoV-2 tests.

The FDA issued one individual EUA for infectious agent antigen detection by immunoassay technique, qualitative or semiquantitative for SARS-CoV-2 and influenza virus types A and B that is authorized for use at the POC setting. The HCPCS code 87428QW describes this EUA test.

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.

- The use of code 87811QW for claims submitted by facilities with a valid, current CLIA certificate of waiver is permitted with dates of service on or after October 6, 2020.
- The use of code 87428QW for claims submitted by facilities with a valid, current CLIA certificate of waiver is permitted with dates of service on or after November 10, 2020.

MACs won't search their files to either retract payment for claims already paid or to retroactively pay claims. However, your MAC will adjust claims that you bring to their attention.

ADDITIONAL INFORMATION

The official instruction, CR 12093, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/R10529OTN.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
December 23, 2020	Initial article released.