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Addition of the QW Modifier to Healthcare Common Procedure Coding System (HCPCS) Code 87426

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Related Change Request (CR) Number: 11927
Related CR Release Date: July 24, 2020
Effective Date: June 25, 2020
Related CR Transmittal Number: R10231OTN
Implementation Date: October 5, 2020

PROVIDER TYPES AFFECTED

This MLN Matters Article is for clinical laboratories and other providers submitting claims to 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 87426 [(Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]]. Please make sure your billing staffs are aware of this modifier addition to code 87426.

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.

HCPCS code 87426 was included in the Centers for Medicare & Medicaid Services' (CMS') CR 11815. You can review the related MLN Matters Article (MM11815) at https://www.cms.gov/files/document/mm11815.pdf. In addition, CR 11815 mentioned the effective date for code 87426 as being June 25, 2020.

On February 4, 2020, the HHS Secretary determined that there is 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 the virus that causes Coronavirus disease 2019. During public health emergencies declared under section 564 of the FD&C Act, the FDA is able

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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. Currently there is no Food and Drug Administration (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 does not 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 (POC) (including SARS-CoV-2 POC test systems) under an EUA, such tests are deemed to be CLIA waived tests. Accordingly, for the duration of the PHE declaration, such tests can be performed in a patient-care setting that is operating at that setting under a CLIA Certificate Waiver, Certification of Compliance, or Certificate of Accreditation.

Facilities possessing a current CLIA certificate of waiver can use tests listed on the FDA's In Vitro Diagnostic EUA website if such tests are authorized by the FDA for use at the POC. As of July 2, 2020, the FDA has issued two individual EUAs for antigen diagnostic tests for SARS-CoV-2 that are authorized for use at the POC (the inpatient care settings operating under a CLIA Certificate of Waiver). HCPCS code 87426 describes the testing performed by these two EUA antigen SARS-CoV-2 tests. To be recognized as a test that can be performed in a facility possessing a CLIA Certificate of Waiver, the modifier QW must be added (87426QW).

Note: Providers should be aware that MACs will not search their files to either retract payment for claims already paid or to retroactively pay claims. However, MACs will adjust claims that you bring to their attention.

ADDITIONAL INFORMATION

The official instruction, CR 11927, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/r10231OTN.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
July 24, 2020	Initial article released.