mln MATTERS®
KNOWLEDGE • RESOURCES • TRAINING

Addition of the QW Modifier to Healthcare Common Procedure Coding System (HCPCS) Code 86328

MLN Matters Number: MM12557
Related Change Request (CR) Number: 12557
Related CR Release Date: December 10, 2021
Effective Date: September 23, 2020
Related CR Transmittal Number: R11156OTN
Implementation Date: January 3, 2022

Provider Types Affected

This MLN Matters Article is for physicians, suppliers, and other providers billing Medicare Administrative Contractors (MACs) for services they provide to Medicare patients.

Provider Action Needed

In this Article, you'll learn about:

- The addition of the QW modifier to HCPCS code 86328
- Emergency Use Authorizations (EUA) that the FDA can issue during Public Health Emergencies (PHEs)
- The first EUA issued to detect COVID-19 antibodies for use in patient care

Make sure your billing staff knows about these changes.

Background

Clinical Laboratory Improvement Amendments (CLIA) regulations require a facility be appropriately certified for each test performed. Medicare & Medicaid only pays for laboratory tests performed in certified facilities. Each claim for a HCPCS code that CMS considers a CLIA laboratory test is currently edited at the CLIA certificate level.

We included HCPCS code 86328 [Test for detection of severe acute respiratory syndrome coronavirus 2 (Covid-19) antibody, qualitative or semiquantitative] in MLN Matters Article MM11815.

The FDA doesn't categorize tests authorized under an EUA. The settings in which you may use an EUA-authorized are described in the Letter of Authorization. As discussed in the Guidance for Industry and Other Stakeholders: EUA of Medical Products and Related Authorities, when the FDA authorizes tests for use at the point of care (including COVID-19 point of care test

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

systems) under an EUA, we deem such tests as CLIA waived tests.

For the duration of the emergency declaration, you can perform such tests in a patient care setting that's qualified to have the test performed there due to operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Tests listed on the FDA's In Vitro Diagnostic EUAs website authorized by the FDA for use at the point of care under an EUA can be used by facilities that have a current CLIA Certificate of Waiver or CLIA Certificate for provider-performed microscopy procedures.

On September 23, 2020, the FDA issued the first individual EUA for the detection of severe acute respiratory syndrome coronavirus 2 (Covid-19) antibody (qualitative or semiquantitative) for use at the point of care setting, that's, in patient care settings operating under a CLIA Certificate of Waiver. The HCPCS code 86328 describes the testing you do under this EUA. You must add the QW modifier so we'll recognize this as a test a facility can do if it has:

- A CLIA certificate of waiver
- A CLIA certificate for provider-performed microscopy procedures

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

More Information

We issued CR 12557 to your MAC as the official instruction for this change.

For more information, find your MAC's website.

Document History

Date of Change	Description
December 10, 2021	Initial article released.