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SPECIAL EDITION: November Update

COVID-19 November Update

As the flu season approaches and the coronavirus disease 2019 (COVID-19) pandemic persists, the necessity for a single test that measures antigens for severe acute respiratory syndrome (SARS) coronavirus (CoV) (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) as well as influenza virus types A and B has become apparent.

During the November Current Procedural Terminology (CPT®) Editorial Panel (Panel) meeting, the Panel approved an additional code for the Microbiology subsection of the Pathology and Laboratory section of the CPT code set. To address the ongoing clinical need to report COVID-19 testing, the Panel expedited the publication of this additional code to the AMA website on November 10, 2020, at https://www.ama-assn.org/delivering-care/public-health/covid-19-2019-novel-coronavirus-resource-center-physicians. This code is effective immediately for use in reporting this laboratory test.

Microbiology

▲**87301** 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; adenovirus enteric types 40/41

▲**87426** severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])

#●**87428** severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B

Background

Currently, there are two existing CPT codes to report antigen testing using immunoassay technique for influenza type A or B (87400) and SARS-CoV-2 (87426). However, there is no code that describes multiplex immunoassay antigen testing for these three viral targets, ie, SARS-CoV, SARS-CoV-2 [COVID-19], and influenza virus types A and B. A code to report a multiplex viral pathogen panel using an antigen immunoassay technique would facilitate reporting SARS-CoV-2 testing, along with influenza types A and B in the differential diagnosis.

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Analogous codes have been adopted for multiplex viral pathogen panels using molecular methods for detecting nucleic acids (eg, 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*; 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 following clinical example and procedural description reflect a typical clinical situation for which this new code would be appropriately reported. Because of the early deployment and utilization of these tests, clinical indications are subject to further refinement as knowledge of the novel coronavirus evolves. The Panel will continue to review and may clarify these indications as more information becomes available.

Clinical Example (87428)

A 50-year-old female presents with fever, cough, and shortness of breath. A nasopharyngeal swab is collected for SARS CoV-2, influenza A, and influenza B antigen testing.

Description of Procedure (87428)

Place the swab and swirl it in a supplied reagent tube to disrupt and release viral nucleoprotein antigens; transfer an aliquot of that sample to the test cassette sample well; and place it in the analyzer. Report the qualitative results to the ordering health care professional.

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The *CPT Assistant* Special Edition information is designed to provide accurate, up-to-date coding information. We continue to make every reasonable effort to ensure the accuracy of the material presented. However, this publication does not replace the CPT codebook; it serves only as a guide.

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KNOWLEDGE • RESOURCES • TRAINING

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

MLN Matters Number: MM11927
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.