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SPECIAL EDITION: October Update

COVID-19 October Update

As we approach the season for influenza (flu) and respiratory syncytial virus (RSV) infections, clinicians need to be able to rapidly distinguish these two seasonal infections from infections caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Ordinarily, a test panel that evaluates these four viruses would be reported using Current Procedural Terminology (CPT®) code 87631, *Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets.*

However, as the coronavirus 2019 (COVID-19) pandemic continues to progress, the need to be able to distinguish the tests for influenza A, influenza B, and RSV that include SARS-CoV-2 from those that do not has become apparent. The CPT Editorial Panel (Panel) acknowledged that such codes would represent a fragmentation of an existing service (87631); however, the substantive need created by the unique circumstances of the SARS-CoV-2 pandemic provides justification to create specific codes to designate such respiratory viral panels.

The Panel also approved revised guidelines to correct and clarify reporting of infectious agent antigen studies in the Microbiology subsection in the Pathology and Laboratory section of the CPT code set. To address the urgent clinical need to report testing, the Panel expedited the publication of these additional codes to the AMA website on October 6, 2020, at https://www.ama-assn.org/practice-management/cpt/covid-19-coding-and-guidance. These codes are **effective immediately** for use in reporting these laboratory tests.

Infectious-Agent Detection

For a list of the new and revised codes specific to laboratory testing for SARS-CoV-2 and the new and revised parenthetical notes and guidelines to correct and clarify reporting of infectious agent antigen studies, see the following.

Immunology

86317 Immunoassay for infectious agent antibody, quantitative, not otherwise specified

►(For immunoassay techniques for non-infectious agent antigens, see 83516, 83518, 83519, 83520)◄

continued on next page

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►(For infectious agent antigen detection by immunoassay technique, see 87301-87451. For infectious agent antigen detection by immunoassay technique with direct optical [ie, visual] observation, see 87802-87899)◄

(For particle agglutination procedures, use 86403)

Microbiology

87250 Virus isolation; inoculation of embryonated eggs, or small animal, includes observation and dissection

87255 including identification by non-immunologic method, other than by cytopathic effect (eg, virus specific enzymatic activity)

►These codes are intended for primary source only. For similar studies on culture material, refer to codes 87140-87158. Infectious agents by antigen detection, immunofluorescence microscopy, or nucleic acid probe techniques should be reported as precisely as possible. The molecular pathology procedures codes (81161, 81200-81408) are not to be used in combination with or instead of the procedures represented by 87471-87801. The most specific code possible should be reported. If there is no specific agent code, the general methodology code (eg, 87299, 87449, 87797, 87798, 87799, 87899) should be used. For identification of antibodies to many of the listed infectious agents, see 86602-86804. When separate results are reported for different species or strain of organisms, each result should be coded separately. Use modifier 59 when separate results are reported for different species or strains that are described by the same code.◄

►When identifying infectious agents on primary source specimens (eg, tissue, smear) microscopically by direct/indirect immunofluorescent assay [IFA] techniques, see 87260-87300. When identifying infectious agents on primary source specimens or derivatives via non-microscopic immunochemical techniques with fluorescence detection (ie, fluorescence immunoassay [FIA]), see 87301-87451, 87802-87899. When identifying infectious agents on primary source specimens using antigen detection by immunoassay with direct optical (ie, visual) observation, see 87802-87899.◄

A new guideline for correct reporting of infectious agent antigen primary source studies using microscopic direct/indirect immunofluorescent assay (IFA) techniques vs immunoassay with direct optical (ie, visual) observation and primary source specimen or derivative studies using non-microscopic immunochemical techniques with fluorescence detection was added to the Microbiology subsection. The parenthetical note following code 86317 was revised with the addition of instructions for correct reporting of infectious agent antigen detection by immunoassay technique performed with and without direct optical observation.

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

▲87305 Aspergillus

▲87320 Chlamydia trachomatis

▲87324 Clostridium difficile toxin(s)

▲87327 Cryptococcus neoformans

(For Cryptococcus latex agglutination, use 86403)

▲87328 cryptosporidium

▲87329 giardia

▲87332 cytomegalovirus

▲87335 Escherichia coli 0157

(For giardia antigen, use 87329)

▲87336 Entamoeba histolytica dispar group

▲87337 Entamoeba histolytica group

▲87338 Helicobacter pylori, stool

▲87339 Helicobacter pylori

(For H. pylori, stool, use 87338. For H. pylori, breath and blood by mass spectrometry, see 83013, 83014. For H. pylori, liquid scintillation counter, see 78267, 78268)

▲**87340** hepatitis B surface antigen (HBsAg)

▲**87341** hepatitis B surface antigen (HBsAg) neutralization

▲**87350** hepatitis Be antigen (HBeAg)

▲**87380** hepatitis, delta agent

▲**87385** Histoplasma capsulatum

▲**87389** HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result

▲**87390** HIV-1

▲**87391** HIV-2

▲**87400** Influenza, A or B, each

▲**87420** respiratory syncytial virus

▲**87425** rotavirus

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

▲**87427** Shiga-like toxin

▲**87430** Streptococcus, group A

▲**87449** not otherwise specified, each organism

►(87450 has been deleted. For infectious agent antigen detection by immunoassay technique, see 87301-87451. For infectious agent antigen detection by immunoassay technique with direct optical [ie, visual] observation, see 87802-87899)◄

▲**87451** polyvalent for multiple organisms, each polyvalent antiserum

87471 Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella quintana, amplified probe technique

●**87635** severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique

●**87636** 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** 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

►(For nucleic acid detection of multiple respiratory infectious agents, not including severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] [Coronavirus disease {COVID-19}], see 87631, 87632, 87633)◄

►(For nucleic acid detection of multiple respiratory infectious agents, including severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] [Coronavirus disease {COVID-19}] in conjunction with additional target[s] beyond influenza virus types A and B and respiratory syncytial virus, see 87631, 87632, 87633)◄

▲**87802** Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Streptococcus, group B

▲87803	Clostridium difficile toxin A
#▲87806	HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies
▲87804	Influenza
87806	Code is out of numerical sequence. See 87802-87903
▲87807	respiratory syncytial virus
#●87811	severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
▲87808	Trichomonas vaginalis
▲87809	adenovirus
▲87810	Chlamydia trachomatis
▲87850	Neisseria gonorrhoeae
▲87880	Streptococcus, group A
▲87899	not otherwise specified

New Codes and Updated Microbiology Guidelines

With the creation of the three new Category I codes by the Panel, code 87636 may now be used to report combined respiratory virus multiplex testing for either SARS-CoV-2 with influenza A and influenza B, and code 87637 may be reported for SARS-CoV-2 with influenza A, influenza B, and RSV.

Code 87811 describes antigen detection of SARS-CoV-2 by direct optical (ie, visual) observation. In order to create the new codes to report the evolving methods of SARS-CoV-2 antigen testing, the Panel also reviewed the guidelines and definitions in the Immunology and Microbiology subsections.
In the Panel's review of these guidelines, it was discovered that there was overlap and confusion in certain terms that are used to describe the methodologies employed in infectious agent antigen testing, specifically the concepts surrounding immunofluorescent technique, direct optical observation, and use of single-step versus multiple-step techniques. See the following discussion on these three concepts.

Immunofluorescent Technique

Immunofluorescence is generally defined as a procedure to detect antigens in cellular contexts using antibodies and tagged fluorescent markers. It is also typically further clarified to indicate that fluorescence is identified using microscopy.

A review of the creation of these codes and subsequent codes in the family identified a lack of clarification on the type of "immunofluorescent technique" and the lack of specification regarding the use of microscopy in the CPT code set. After careful consideration of the historical information available, it was determined that non-microscopic immunofluorescent technique(s) should not be included in this code family.

Direct Optical Observation

In contrast to the differentiation of work performed based on detection methodologies (ie, by immunofluorescence vs other immunologic techniques), the direct optical observation codes distinguished the differences in the service provided based on how results are observed. Although not specifically stated, when the CPT codes for these tests were initially created, the general understanding was that these immunoassays were more akin to single-step methods and conducive to point-of-care (POC) applications or testing (POCT) (the prototype used was POCT rapid Strep screening).

The May 2009 issue of *CPT® Assistant* provided some guidance regarding this in the article, "Coding Brief: Rapid Influenza Virus A and B Testing (Code 87804)." The coding brief noted that direct optical observation "is a testing platform that yields a typically qualitative result by producing a signal on the reaction chamber that can be interpreted visually, such as a colored band." Note that this clarification only applies to primary source infectious disease codes, ie, it does not apply to drug testing codes.

Single-Step vs Multiple-Step Techniques

A historical review of the concepts of "single-step" vs "multiple-step" methodologies for immunoassays revealed a differentiation characterized primarily by the amount of laboratory technologist manipulation required. If a test required little in the way of manipulation (eg, put the sample and reagent[s] together in a single step), it was considered as a single-step process. If it required multiple touch points, it was considered as a multiple-step process. The advent of automation and matrix processes (eg, lateral flow) that allow multiple steps to occur within the analysis and testing equipment, despite the fact that the operator had a single touch point, has diminished the utility of characterizing immunoassays into only one of these categories. Although the concept of single-step and multiple-step methodologies exists beyond the CPT codes for primary source infectious disease, the Panel felt that only these codes should be addressed at this time due to the urgency to incorporate testing for the COVID-19 pandemic.

Changes Related to the Three Concepts

As a result of the findings regarding the three concepts discussed above, the Panel also approved a series of changes to several parenthetical notes, revised and added new guidelines in the Microbiology subsection, and created new code 87811.

Codes 87301-87430 were revised with the addition of "fluorescence immunoassay" and removal of the reference to a multiple-step method. Because code 87301 is a parent code and the changes were made to its descriptor, the changes resulted in a revision of all of its associated child codes. Code 87426, which was approved for the CPT 2020 code set, was revised as well.

Code 87449, previously a parent code, was revised with the removal of the reference to a multiple-step method. In addition, codes 87449 and 87451 are now child codes under code 87301.

Code 87450 was deleted. In a review of the recent utilization of this code, it appeared to be rarely used, which led to the belief that it may have been reported incorrectly. A parenthetical note was added following code 87449 to clarify the appropriate reporting of infectious agent antigen detection by immunoassay technique and by immunoassay technique with direct optical observation.

Codes 87802-87899 were revised with the addition of "(ie, visual)" to the code descriptor to clarify the definition of direct optical observation. Because code 87802 is a parent code and the changes were made to its descriptor, the changes resulted in a revision of all of its associated child codes.

All of these new and/or revised codes will continue to be valid and active after the Public Health Emergency declaration is lifted. These codes are intended to address the needs of payers, researchers, and public health officials, so that they can specifically identify SARS-CoV-2 testing. Note that even if a laboratory procedure produces multiple reportable test results, only a single CPT code may be reported for the procedure. If there is no CPT code that describes the procedure, the laboratory should report an unlisted procedure code with a single unit of service.

Proprietary Laboratory Analyses

●0240U Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected

●0241U Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected

Two PLA Codes Established

Two PLA codes were established to report proprietary POC testing for simultaneous qualitative

detection and differentiation of SARS-CoV-2, influenza A, influenza B, and RSV viral RNA that are performed in the office by a physician or other qualified health care professional (QHP). It is important to note that the tests represented by these two PLA codes employ the same cartridge and the assay is performed with or without RSV, and the code selection is differentiated by the number of targets tested.

Per standard CPT convention, in addition to listing codes 0240U and 0241U in the Pathology and Laboratory section, these new PLA codes will be included with the procedure's proprietary name in Appendix O in the CPT code set. To report a PLA code, the analysis performed must fulfill the code descriptor and must be the test represented by the proprietary name listed in Appendix O. Codes 0240U and 0241U will be listed in Appendix O as follows:

Proprietary Name and Clinical Laboratory or Manufacturer	Alpha-Numeric Code	Code Descriptor
►Xpert® Xpress SARS-CoV-2/Flu/RSV (SARS-CoV-2 & Flu targets only), Cepheid◄	●0240U	►Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected◄
►Xpert® Xpress SARS-CoV-2/Flu/RSV (all targets), Cepheid◄	●0241U	►Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected◄

The following clinical examples and procedural descriptions reflect typical clinical scenarios for which it would be appropriate to report these codes.

Clinical Example (87636)

A 25-year-old female calls her health care professional's health line after 2 days of fever, coughing, runny nose, and muscle aches. The health care professional recommends collecting a nasal swab to test for influenza and COVID-19 because of the overlapping symptoms.

Description of Procedure (87636)

Perform a multiplex reverse transcription polymerase chain reaction (RT-PCR) assay for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B using a sample of the collected specimen. Provide the results to the health care professional.

Clinical Example (87637)

A mother calls her health care professional's health line after her 2-year-old child has been having 2 days of fever, coughing, runny nose, and muscle aches. The health care professional recommends collecting a nasal swab to test for influenza A, influenza B, respiratory syncytial virus (RSV), and COVID-19 because of the overlapping symptoms.

Description of Procedure (87637)

Perform a multiplex reverse transcription polymerase chain reaction (RT-PCR) assay for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, influenza B, and RSV using a sample of the collected specimen. Provide the results to the health care professional.

Clinical Example (87811)

A 25-year-old female calls her health care professional's health line after 2 days of fever, coughing, runny nose, and muscle aches. The health care professional recommends collecting a nasal swab to test for COVID-19.

Description of Procedure (87811)

Following the manufacturer's instructions, add a nasal swab specimen from the patient to a lateral flow test system to detect SARS-CoV-2 antigen using an immunochromatographic immunoassay. The operator

who visually inspects the test cartridge reads the result, noting the internal control and patient result. Report the qualitative result to the ordering health care professional.

Clinical Example (0240U)

A 14-year-old female, who has no underlying conditions, presents with a two-day history of fever, sore throat, and fatigue. The physician collects a nasopharyngeal swab and submits it for simultaneous evaluation of SARS-CoV-2, influenza A, and influenza B.

Description of Procedure (0240U)

Add a sample of the collected specimen to the test cartridge and load it onto the instrument for the RT-PCR detection of viral RNA from SARS-CoV-2, influenza A, and influenza B, if present. Report all positive and negative results for each pathogen to the ordering health care professional.

Clinical Example (0241U)

A 2-year-old child presents with a two-day history of fever, sore throat, and fatigue. The physician collects a nasopharyngeal swab and orders testing for simultaneous evaluation of SARS-CoV-2, influenza A, influenza B, and RSV.

Description of Procedure (0241U)

Add a sample of collected specimen to a test cartridge and load it onto the automated instrument for the RT-PCR detection of viral RNA from SARS-CoV-2, influenza A, influenza B, and RSV, if present. Report the qualitative results for the four targets to the ordering health care professional.

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