

Reimbursement Policy

Diagnostic Testing of Influenza

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I. Policy Description

Influenza is an acute respiratory illness caused by influenza A or B viruses resulting in upper and lower respiratory tract infection, fever, malaise, headache, and weakness. It mainly occurs in outbreaks and epidemics during the winter season, and is associated with increased morbidity and mortality in certain high-risk populations (Dolin, 2024b).

Rapid influenza diagnostic tests (RIDTs) refer to clinical laboratory improvement amendments (CLIA) waived immunoassays that can detect influenza viruses during the outpatient visit, giving results in a clinically relevant time period to inform treatment decisions (CDC, 2017). Besides RIDTs, influenza can be detected using polymerase chain reaction (PCR)-based assays as well as culture testing; however, the former is not often used in initial clinical management due to time constraints. Serologic testing is not used in outpatient settings for diagnosis (Dolin, 2024a).

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

- 1) For symptomatic individuals (see Note 1) (when influenza activity has been documented in the community or geographic area), **one**, but **not both**, of the following **MEETS COVERAGE CRITERIA**:
 - a) One single rapid flu test (**either** a point-of-contact rapid nucleic acid amplification test (NAAT) **or** a rapid antigen test).
 - b) One single traditional NAAT.
- 2) Viral culture testing for influenza **DOES NOT MEET COVERAGE CRITERIA**.
- 3) For asymptomatic individuals, influenza testing (e.g., rapid antigen flu tests, rapid NAAT or RT-PCR tests, traditional RT-PCR tests, viral culture testing) **DOES NOT MEET COVERAGE CRITERIA**.
- 4) Serology testing for influenza **DOES NOT MEET COVERAGE CRITERIA**.

NOTES:

Note 1: Typical Influenza Signs and Symptoms (CDC, 2023a):

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- Fever: A 100.4°F or higher temperature or feeling feverish/chills AND one or more:
 - Cough
 - Sore throat
 - Headaches and/or body aches
 - Difficulty breathing or shortness of breath
 - Fatigue
 - Runny or stuffy nose

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: <https://www.cms.gov/medicare-coverage-database/search.aspx>. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

On January 12, 2017, the FDA released the following concerning the reclassification of influenza testing systems: “The Food and Drug Administration (FDA) is reclassifying antigen based rapid influenza virus antigen detection test systems intended to detect influenza virus directly from clinical specimens that are currently regulated as influenza virus serological reagents from class I into class II with special controls and into a new device classification regulation” (Kux, 2017). The effective date is February 13, 2017. This reclassification now requires new minimum standards and annual reactivity testing. “Consequently, many previously available RIDTs can no longer be purchased in the United States” (Azar & Landry, 2018).

A list of tests granted waived status under CLIA (Clinical Laboratory Improvement Amendments of 1988) according to CPT codes is maintained by the Centers for Medicare & Medicaid Services (CMS) website (CMS, 2018). As of August 14, 2023, 27 different influenza tests are listed with the 87804 CPT code for influenza immunoassay with direct optical observation.

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

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IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
86710	Antibody; influenza virus
87254	Virus isolation; centrifuge enhanced (shell vial) technique, includes identification with immunofluorescence stain, each virus
87275	Infectious agent antigen detection by immunofluorescent technique; influenza B virus
87276	Infectious agent antigen detection by immunofluorescent technique; influenza A virus
87400	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; Influenza, A or B, each
87501	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, includes reverse transcription, when performed, and amplified probe technique, each type or subtype
87502	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or sub-types
87503	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, each additional influenza virus type or sub-type beyond 2 (List separately in addition to code for primary procedure)
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
87804	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Influenza

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Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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