

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.¹

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.² 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.¹

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), **one** (see Note 2), but **not both**, of the following **MEETS COVERAGE CRITERIA**:
 - a) One single rapid flu test (**either** a point-of-care 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**.

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NOTES:

Note 1: Typical Influenza Signs and Symptoms:³

- Fever or feeling feverish/chills
- Cough
- Sore throat
- Headaches
- Muscle or body aches
- Fatigue
- Runny or stuffy nose
- Vomiting and/or diarrhea (more common in children than adults)

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)

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.

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.”⁴⁹ 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.”⁵⁰

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A list of tests granted waived status under CLIA (Clinical Laboratory Improvement Amendments of 1988) according to CPT codes is maintained by CMS website.⁵¹ As of August 14, 2023, 27 different influenza tests are listed with the 87804 CPT code for influenza immunoassay with direct optical observation.

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, (e.g., 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)
87804	Infectious agent antigen detection by immunoassay with direct optical (i.e., 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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VI. Revision History

Revision Date	Summary of Changes
09/04/2025	Reviewed and Updated: Updated background, guidelines, and evidence-based scientific references. Literature review necessitated the following changes in coverage criteria: CC1, edited for clarity, added reference to new note 2 Note 1, updated signs and symptoms of the flu to align with the CDC New Note 2: “Note 2: One influenza test may detect influenza A and/or influenza B. When both influenza A and influenza B are detected by a test represented by CPT codes 87400, 87501, or 87804, up to two units may be billed at a single visit.” Removed CPT code 87631 (respiratory infection panels that include flu testing are addressed in AHS-G2149 Pathogen Panel testing)