



REIMBURSEMENT POLICY STATEMENT OHIO MEDICAID

Original Issue Date		Next Annual Review		Effective Date	
12/01/2018		12/01/2019		12/01/2018	
Policy Name				Policy Number	
Molecular Diagnostic Testing for Influenza Virus Infection				PY-0450	
Policy Type					
Medical	Administrative	Pharmacy	REIMBURSEMENT		

Reimbursement Policies prepared by CSMG Co. and its affiliates (including CareSource) are intended to provide a general reference regarding billing, coding and documentation guidelines. Coding methodology, regulatory requirements, industry-standard claims editing logic, benefits design and other factors are considered in developing Reimbursement Policies.

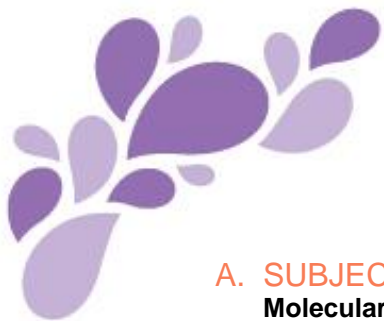
In addition to this Policy, Reimbursement of services is subject to member benefits and eligibility on the date of service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification and utilization management guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

This Policy does not ensure an authorization or Reimbursement of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced herein. If there is a conflict between this Policy and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

CSMG Co. and its affiliates may use reasonable discretion in interpreting and applying this Policy to services provided in a particular case and may modify this Policy at any time.

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A. SUBJECT

Molecular Diagnostic Testing for Influenza Virus Infection

B. BACKGROUND

Molecular testing, following a diagnosis or suspected diagnosis can help guide appropriate therapy by identifying specific therapeutic targets and appropriate pharmaceutical interventions. Molecular diagnostic testing utilizes Polymerase Chain Reaction (PCR), a genetic amplification technique that only requires small quantities of DNA, for example, 0.1 mg of DNA from a single cell, to achieve DNA analysis in a shorter laboratory processing time. Knowing the gene sequence, or at minimum the borders of the target segment of DNA to be amplified, is a prerequisite to a successful PCR amplification of DNA.

Molecular diagnostic testing for Influenza Virus can detect influenza viral RNA or nucleic acids in respiratory specimens with high sensitivity and specificity. The detection of influenza viral RNA or nucleic acids is not necessarily indicative of a viable or ongoing influenza viral replication. In cases where there is known active influenza virus and the clinical picture of the patient shows signs and symptoms of the influenza virus, molecular diagnostic testing is not needed.

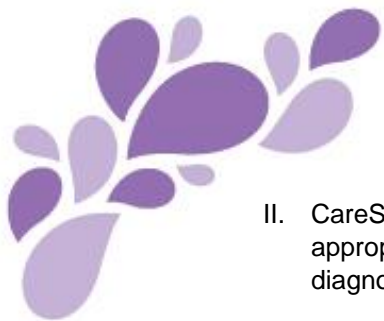
All facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Waived tests include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria. Although CLIA requires that waived tests must be simple and have a low risk for erroneous results, this does not mean that waived tests are completely error-proof. CareSource may periodically require review of a provider's office testing policies and procedures when performing CLIA-waived tests.

C. DEFINITIONS

- **Polymerase Chain Reaction (PCR)** - a genetic amplification technique also known as a Nucleic Acid Amplification Test (NAAT)
- **Medically Necessary**- Health care services or supplies needed to diagnosis or treat an illness, injury, condition, disease or its symptoms and that meet the accepted standards of medicine.

D. POLICY

- I. No Prior Authorization is required for the Molecular Diagnostic Testing by PCR addressed in this policy when the following criteria are met:
 - a. Conventional testing, such as a nasal swab has been performed with a negative result on the same date of service as the requested molecular diagnostic test, AND;
 - b. The member presents with cardinal influenza virus infection symptoms to include but not limited to:
 - i. Fever over 100.4 F
 - ii. Aching muscles
 - iii. Chills and sweats
 - iv. Headache
 - v. Dry, persistent cough
 - vi. Fatigue and weakness
 - vii. Nasal congestion
 - viii. Sore throat

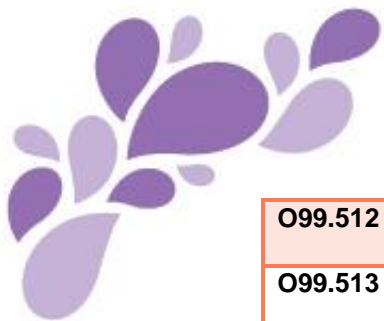


II. CareSource considers Molecular Diagnostic Testing by PCR for Influenza Virus Infection appropriate as the first line testing only when submitted with any combination of the CPT and diagnosis codes listed in the Conditions of Coverage in this policy

IV. Conventional testing, such as nasal swabs and nasopharyngeal swabs, are viewed as low cost and should be utilized before the higher cost Molecular Diagnostic Testing by PCR.

E. CONDITIONS OF COVERAGE

CODE	DESCRIPTION
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
J09.X1	Influenza due to identified novel influenza A virus with pneumonia
J09.X2	Influenza due to identified novel influenza A virus with other respiratory manifestations
J09.X3	Influenza due to identified novel influenza A virus with gastrointestinal manifestations
J09.X9	Influenza due to identified novel influenza A virus with other manifestations
J10.00	Influenza due to other identified influenza virus with unspecified type of pneumonia
J10.01	Influenza due to other identified influenza virus with the same other identified influenza virus pneumonia
J10.08	Influenza due to other identified influenza virus with other specified pneumonia
J10.1	Influenza due to other identified influenza virus with other respiratory manifestations
J10.2	Influenza due to other identified influenza virus with gastrointestinal manifestations
J10.81	Influenza due to other identified influenza virus with encephalopathy
J10.82	Influenza due to other identified influenza virus with myocarditis
J10.83	Influenza due to other identified influenza virus with otitis media
J10.89	Influenza due to other identified influenza virus with other manifestations
J11.00	Influenza due to unidentified influenza virus with unspecified type of pneumonia
J11.08	Influenza due to unidentified influenza virus with specified pneumonia
J11.1	Influenza due to unidentified influenza virus with other respiratory manifestations
J11.2	Influenza due to unidentified influenza virus with gastrointestinal manifestations
J11.81	Influenza due to unidentified influenza virus with encephalopathy
J11.82	Influenza due to unidentified influenza virus with myocarditis
J11.83	Influenza due to unidentified influenza virus with otitis media
J11.89	Influenza due to unidentified influenza virus with other manifestations
O99.511	Diseases of the respiratory system complicating pregnancy, first trimester



O99.512	Diseases of the respiratory system complicating pregnancy, second trimester
O99.513	Diseases of the respiratory system complicating pregnancy, third trimester
O99.519	Diseases of the respiratory system complicating pregnancy, unspecified trimester
O99.52	Diseases of the respiratory system complicating childbirth
O99.53	Diseases of the respiratory system complicating the puerperium

F. RELATED POLICIES/RULES

N/A

G. REVIEW/REVISION HISTORY

DATE		ACTION
Date Issued	12/01/2018	
Date Revised	11/07/2018	Corrected O00.519 to O99.519; corrected the next review date to 12/01/2019
Date Effective	12/01/2018	
Archive Date	02/02/2021	

H. REFERENCES

1. Information on Rapid Molecular Assays, RT-PCR, and other Molecular Assays for Diagnosis of Influenza Virus Infection | Seasonal Influenza (Flu) | CDC. (2018, February 20). Retrieved July 16, 2018, from www.cdc.gov/flu/professionals/diagnosis/molecular-assays.htm.

The Reimbursement Policy Statement detailed above has received due consideration as defined in the Reimbursement Policy Statement Policy and is approved.