



Claims and Payment Policy: Polymerase Chain Reaction Viral Panel Testing

Policy Number: CPP-161

BACKGROUND

Polymerase chain reaction (PCR) respiratory viral panels (RVP) may detect the RNA or DNA of multiple types of respiratory viruses as a single test, often through a nasal, nasopharyngeal, or oropharyngeal swab. Viral pathogens are the most common cause of respiratory tract infections. PCR testing is effective for confirming respiratory viral infections with very high sensitivity and specificity. Rhinovirus, parainfluenza virus, coronavirus, adenovirus, respiratory syncytial virus, Coxsackie virus, human metapneumovirus, and influenza virus account for most cases of viral respiratory infections.

Multiplex PCR testing can detect numerous respiratory viruses; that number varies with the type and brand of testing being performed. However, the diagnostic role and importance of these multi-pathogen panels in identifying specific viruses in the setting of a respiratory infection is quite limited because the care and management of the patient is not altered based upon the pathogen identified, if any. For example, the child with a URI, cough, and wheezing who might be positive for RSV would not be managed any differently than the child with parainfluenza virus, adenovirus, rhinovirus, human metapneumovirus, enterovirus, Coxsackie virus, or coronavirus.

Infectious Disease Society of America (IDSA)

The IDSA recommends that “clinicians should use multiplex RT-PCR assays targeting a panel of respiratory pathogens, including influenza viruses, in hospitalized immunocompromised patients.” Further, “clinicians can consider using multiplex RT-PCR assays targeting a panel of respiratory pathogens, including influenza viruses, in hospitalized patients who are not immunocompromised if it might influence care (e.g., aid in cohorting decisions, reduce testing, or decrease antibiotic use).”

POSITION STATEMENT

Policy/Criteria

- I. It is the policy of Wellcare Health Plans that respiratory viral panels (RVPs) testing for five pathogens or less are considered **medically necessary** when meeting one of the following criteria:
 - A. Performed in the outpatient setting, will influence the plan of care, and any of the following:
 1. To assess for infection by other pathogens when COVID-19 is suspected and a COVID-19-specific test result will not be available soon enough to influence the plan of care;
 2. The member is immunocompromised;
 3. The test is ordered by an infectious disease specialist, or an infectious disease specialist is not available;
 - B. Performed in a healthcare setting that cares for critically ill patients, such as the emergency



department or inpatient hospital, including those in observation status.

II. It is the policy of Wellcare Health Plans that respiratory viral panels (RVPs) testing for six pathogens or more are considered **medically necessary** in a healthcare setting that cares for critically ill patients, such as the emergency department or inpatient hospital, including those in observation status.

III. It is the policy of Wellcare Health Plans that RVPs are considered **not medically necessary** for all other indications.

CODING & BILLING

Table 1: CPT codes that support medical necessity in any place of service

CPT Codes®	Description
87631	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., 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.

Table 2: CPT codes that support medical necessity when billed with place of service codes in Table 3

CPT Codes®	Description
0098U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 14 targets (adenovirus, coronavirus, human metapneumovirus, influenza A, influenza A subtype H1, influenza A subtype H3, influenza A subtype H1-2009, influenza B, parainfluenza virus, human rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydomphila pneumoniae, Mycoplasma pneumoniae)
0099U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 20 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus, coronavirus OC43, human metapneumovirus, influenza A, influenza A subtype, influenza A subtype H3, influenza A subtype H1-2009, influenza, parainfluenza virus, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, human



	rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae)
0100U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 21 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, human metapneumovirus, human rhinovirus/enterovirus, influenza A, including subtypes H1, H1-2009, and H3, influenza B, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, respiratory syncytial virus, Bordetella parapertussis [IS1001], Bordetella pertussis [ptxP], Chlamydia pneumoniae, Mycoplasma pneumoniae)
0115U	Respiratory infectious agent detection by nucleic acid (DNA and RNA), 18 viral types and subtypes and 2 bacterial targets, amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
87632	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, 6-11 targets
87633	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, 12-25 targets

Table 3: Place of service codes supporting medical necessity for codes in Table 2



Place of Service Code	Place of Service Name	Place of Service Description
21	Inpatient Hospital	A facility other than psychiatric which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by, or under, the supervision of physicians to patients admitted for a variety of medical conditions.
22*	Outpatient Hospital (Observation)	A portion of a hospital which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
23	Emergency Room – Hospital	A portion of a hospital where emergency diagnosis and treatment of illness or injury is provided.

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**NOTE: PCR testing in an outpatient place of service is reimbursable only when performed as part of the diagnostic work-up for a patient admitted for Observation.*

Coding Implications

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this payment policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this payment policy. If State policies **do not specify coverage provisions**, then the State will follow National coverage guidelines as outlined in this policy

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs should be reviewed prior to applying the criteria set forth in this payment policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

DEFINITIONS

Deoxyribonucleic Acid (DNA)	Deoxyribonucleic acid is a molecule composed of two polynucleotide chains that coil around each other to form a double helix carrying genetic instructions for the development, functioning, growth and reproduction of all known organisms and many viruses. DNA and ribonucleic acid (RNA) are nucleic acids. Alongside proteins, lipids and complex carbohydrates, nucleic acids are one of the four major types of macromolecules that are essential for all known forms of life.
Immunocomprisation	Immunocomprisation is a state in which the immune system's ability to fight infectious diseases and cancer is compromised or entirely absent. Most cases are acquired due to extrinsic factors that affect the patient's immune system. Examples of these extrinsic factors include HIV infection and environmental factors, such as nutrition.
Pathogen	In biology, a pathogen (Greek: pathos "suffering", "passion" and genes "producer of") in the oldest and broadest sense is any organism that can produce disease. A pathogen may also be referred to as an infectious agent, or simply a germ.
Polymerase Chain Reaction	Polymerase chain reaction (PCR) is a method widely used to rapidly make millions to billions of copies of a specific DNA sample, allowing scientists to take a very small sample of DNA and amplify it to a large enough amount to study in detail.



Respiratory Viral Panel	Respiratory Viral Panel, PCR - The detection and identification of specific viral nucleic acids from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection.
Ribonucleic Acid (RNA)	Ribonucleic acid (RNA) is a polymeric molecule essential in various biological roles in coding, decoding, regulation and expression of genes. RNA and DNA are nucleic acids. Along with lipids, proteins, and carbohydrates, nucleic acids constitute one of the four major macromolecules essential for all known forms of life. Like DNA, RNA is assembled as a chain of nucleotides, but unlike DNA, RNA is found in nature as a single strand folded onto itself, rather than a paired double strand.

REFERENCES

- Hill AT, et al. and the CHEST Expert Cough Panel. Adult Outpatients with Acute Cough Due to Suspected Pneumonia or Influenza: CHEST Guideline and Expert Panel Report. CHEST 2019; Volume 155, Issue 1, Pages 155–167.
- Noridian Local Coverage Determination. L37315 MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels. Revision effective 10/1/2019.
- Hayes. Molecular Test Assessment: “Film Array Respiratory Panel (Bio Fire Diagnostics LLC),” May 2020.
- Hayes. Molecular Test Assessment: “Film Array Respiratory Panel 2 (Bio Fire Diagnostics LLC),” March 2020.
- Uyeki TM, et al. Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza. Clin Inf Dis 2019; Volume 68, Issue 6, Pages e1–e47, <https://doi.org/10.1093/cid/ciy866>.
- Ralston SL, et al. Clinical practice guideline: the diagnosis, management, and prevention of bronchiolitis. American Academy of Pediatrics. Pediatrics 2014; Volume 134, Issue 5, Pages e1474- 502. doi: 10.1542/peds.2014-2742.
- Esposito S, et al. Multiplex Platforms for the Identification of Respiratory Pathogens: Are They Useful in Pediatric Clinical Practice? Front Cell Infect Microbiol. 2019 Jun 4; 9:196. Doi: 10.3389/fcimb.2019.00196.
- Busson L, et al. Contribution of the FilmArray Respiratory Panel in the management of adult and pediatric patients attending the emergency room during 2015–2016 influenza epidemics: An interventional study. Int J Infect Dis. 2019 Jun;83:32-39. doi: 10.1016/j.ijid.2019.03.027.
- Echavarría M, et al. Clinical impact of rapid molecular detection of respiratory pathogens in patients with acute respiratory infection. J Clin Virol. 2018 Nov;108:90-95. doi: 10.1016/j.jcv.2018.09.009.
- Ramirez JA, Musher DM, Evans SE, et al. Treatment of Community-Acquired Pneumonia in Immunocompromised Adults: A Consensus Statement Regarding Initial Strategies. Chest. 2020



Jun 16 doi: 10.1016/j.chest.2020.05.598.

11. Sberna G, Amendola A, Valli MB, et al. Trend of respiratory pathogens during the COVID-19 epidemic. J Clin Virol. 2020 Aug; 129: 104470. Published online 2020 May 26.
12. Lai C, Wang C, Hsueh P. Co-infections among patients with COVID-19: The need for combination therapy with non-anti-SARS-CoV-2 agents? J Microbiol Immunol Infect. 2020 Aug; 53(4): 505–512.

IMPORTANT INFORMATION ABOUT THIS DOCUMENT

Claims and Payment Policies (CPPs) are policies regarding claims or claim line processing and/or reimbursement related to the administration of health plan benefits. They are not recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for diagnosing, treating, and making clinical recommendations to the member. CPPs are subject to, but not limited to, the following:

- State and federal laws and regulations;
- Policies and procedures promulgated by the Centers for Medicare and Medicaid Services, including National Coverage Determinations and Local Coverage Determinations;
- The health plan’s contract with Medicare and/or a state’s Medicaid agency, as applicable;
- Other CPPs and clinical policies as applicable.
- The provisions of the contract between the provider and the health plan; and
- The terms of a member’s particular benefit plan, including those terms outlined in the member’s Evidence of Coverage, Certificate of Coverage, and other policy documents.

In the event of a conflict between a CPP and a member’s policy documents, the terms of a member’s benefit plan will always supersede the CPP. The use of this policy is neither a guarantee of payment, nor a prediction of how a specific claim will be adjudicated. Any coding information is for informational purposes only. No inference should be made regarding coverage or provider reimbursement as a result of the inclusion, or omission, in a CPP of a CPT, HCPCS, or ICD-10 code. Always consult the member’s benefits that are in place at time of service to determine coverage or non-coverage. Claims processing is subject to a number of factors, including the member’s eligibility and benefit coverage on the date of service, coordination of benefits, referral/authorization requirements, utilization management protocols, and the health plan’s policies. Services must be medically necessary in order to be covered. References to other sources and links provided are for general informational purposes only, and were accurate at the time of publication. CPPs are reviewed annually but may change at any time and without notice, including the lines of business for which they apply. CPPs are available at www.Wellcare.com.

RULES, PRICING & PAYMENT COMMITTEE HISTORY AND REVISIONS

Date	Action
MM/DD/YYYY	<ul style="list-style-type: none"> • Approved by RGC