

# Clinical Policy: Polymerase Chain Reaction Respiratory Viral Panel Testing

Reference Number: WNC.CP.152 Last Review Date: 03/23

Coding Implications <u>Revision Log</u>

# See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

**Note:** When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

#### Description

Medical necessity criteria for multiplex respiratory polymerase chain reaction (PCR) testing.

#### Policy/Criteria

- **I.** It is the policy of WellCare of North Carolina<sup>®</sup> that respiratory viral panels (RVPs) testing for *five pathogens or less* are considered medically necessary when meeting **one** of the following<sup>1-7</sup>:
  - A. Performed in the outpatient setting and will influence the plan of care;
    - 1. The member/enrollee is immunocompromised;
    - 2. 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 of North Carolina<sup>®</sup> that 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 of North Carolina<sup>®</sup> that RVPs are considered **not medically necessary** for all other indications.

#### 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.<sup>6</sup> Viral pathogens are the most common cause of respiratory tract infections.<sup>8</sup> Rhinovirus, parainfluenza virus, coronavirus, adenovirus, respiratory syncytial virus (RSV), Coxsackie virus, human metapneumovirus, and influenza virus account for most cases of viral respiratory infections.<sup>1</sup> Immunocompromised patients can develop severe lower respiratory tract infections from common respiratory viral pathogens that otherwise cause mild upper respiratory tract infections in healthy patients.<sup>9</sup>

PCR testing is generally effective for confirming respiratory viral infections with very high sensitivity and specificity.<sup>7,13</sup> Respiratory viral infections often have nonspecific clinical



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presentations and, therefore, accurate and timely identification through PCR testing has the potential to optimize antiviral use when appropriate, decrease the spread of any viral infection, and to reduce the number of patients being treated with antibiotics unnecessarily.<sup>8,10-12,15</sup> Multiplex PCR testing can detect numerous respiratory viruses depending on the type and brand of testing being used.<sup>12</sup> 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 individual patient is rarely altered based upon the pathogen identified.<sup>14</sup>

#### 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)."<sup>6(pg. 898)</sup>

#### **Coding Implications**

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CPT <sup>®*</sup> Codes – Support Medical Necessity in any Place of Service	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.

<b>CPT®*</b> Codes – Support Medical Necessity when billed with Place of Service Codes in Table 3	Description
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





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CPT <sup>®*</sup> Codes – Support Medical Necessity when billed with Place of Service Codes in Table 3	Description
87632	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, 6-11 targets
87633	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, 12-25 targets

#### Place of Service Codes Supporting Medical Necessity in Table 2

<b>Place of Service Code</b>	Description
21	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*	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	A portion of a hospital where emergency diagnosis and treatment of
	illness or injury is provided.

\*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.

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original approval date	03/21	06/21
Updated background with no clinical significance. Deleted obsolete codes. Added note for POS 22. References reviewed and updated.	05/22	08/22
Annual review. References reviewed and updated. Updated background with no clinical significance. Added I.B. to criteria 1. The member /enrollee is immunocompromised;2. The test is ordered by an infectious disease specialist, or an infectious disease specialist is not available." NCHC verbiage removed from NC Guidance Verbiage.	03/22	

#### References

1. Local coverage determination. MoIDX: multiplex nucleic acid amplified tests for respiratory viral panels (L37315). Centers for Medicare and Medicaid Services Web site.



#### POLYMERASE CHAIN REACTION RESPIRATORY VIRAL PANEL TESTING http://www.cms.hhs.gov/mcd/search.asp. Published May 13, 2019 (revised October 01,

2019). Accessed February 03, 2022.

- Local coverage determination. MoIDX: multiplex nucleic acid amplified tests for respiratory viral panels (L37301). Centers for Medicare and Medicaid Services Web site. <u>http://www.cms.hhs.gov/mcd/search.asp</u>. Published May 13, 2019 (revised October 01, 2019). Accessed February 07, 2022.
- Local coverage determination. MoIDX: multiplex nucleic acid amplified tests for respiratory viral panels (L37348). Centers for Medicare and Medicaid Services Web site. <u>http://www.cms.hhs.gov/mcd/search.asp</u>. Published December 03, 2018 (revised November 30, 2020). Accessed February 08, 2022.
- Local coverage determination. MoIDX: multiplex nucleic acid amplified tests for respiratory viral panels (L37713). Centers for Medicare and Medicaid Services Web site. <u>http://www.cms.hhs.gov/mcd/search.asp</u>. Published November 12, 2018 (revised November 11, 2019). Accessed February 08, 2022.
- Local coverage determination. MoIDX: multiplex nucleic acid amplified tests for respiratory viral panels (L37764). Centers for Medicare and Medicaid Services Web site. <u>http://www.cms.hhs.gov/mcd/search.asp</u>. Published December 17, 2018 (revised October 10, 2020). Accessed February 08, 2022.
- Uyeki TM, Bernstein HH, Bradley JS, et al. Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenzaa. *Clin Infect Dis*. 2019;68(6):895-902. doi:10.1093/cid/ciy874
- Esposito S, Mencacci A, Cenci E, Camilloni B, Silvestri E, Principi N. Multiplex Platforms for the Identification of Respiratory Pathogens: Are They Useful in Pediatric Clinical Practice? *Front Cell Infect Microbiol*. 2019;9:196. Published 2019 Jun 4. doi:10.3389/fcimb.2019.00196
- Echavarría M, Marcone DN, Querci M, et al. Clinical impact of rapid molecular detection of respiratory pathogens in patients with acute respiratory infection. *J Clin Virol*. 2018;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; 158(5):1896-1911. doi:10.1016/j.chest.2020.05.598
- Hill AT, Gold PM, El Solh AA, et al. Adult Outpatients with Acute Cough Due to Suspected Pneumonia or Influenza: CHEST Guideline and Expert Panel Report. *Chest*. 2019;155(1):155-167. doi:10.1016/j.chest.2018.09.016
- Molecular Test Assessment. FilmArray Respiratory Panel (BioFire Diagnostics LLC). Hayes. <u>www.hayesinc.com</u>. Published May 21, 2020 (annual review June 28, 2021). Accessed February 07, 2022.
- Molecular Test Assessment. FilmArray Respiratory Panel 2 (BioFire Diagnostics LLC). Hayes. <u>www.hayesinc.com</u>. Published March 10, 2020 (annual review February 24, 2021). Accessed February 07, 2022.
- Busson L, Bartiaux M, Brahim S, 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;83:32-39. doi:10.1016/j.ijid.2019.03.027



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- Ralston SL, Lieberthal AS, Meissner HC, et al. Clinical practice guideline: the diagnosis, management, and prevention of bronchiolitis [published correction appears in Pediatrics. 2015 Oct;136(4):782]. *Pediatrics*. 2014;134(5):e1474-e1502. doi:10.1542/peds.2014-2742
- 15. Wils J, Saegeman V, Schuermans A. Impact of multiplexed respiratory viral panels on infection control measures and antimicrobial stewardship: a review of the literature. *Eur J Clin Microbiol Infect Dis.* 2022;41(2):187-202. doi:10.1007/s10096-021-04375-3

#### North Carolina Guidance

Eligibility Requirements

- a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
- b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

- 1. that is unsafe, ineffective, or experimental or investigational.
- 2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as



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long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

#### **EPSDT and Prior Approval Requirements**

- 1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
- IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below: NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html EPSDT provider page: https://medicaid.ncdhhs.gov/

#### Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- a. meet Medicaid qualifications for participation;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

#### Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

#### Claims-Related Information

Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

- a. Claim Type as applicable to the service provided: Professional (CMS-1500/837P transaction) Institutional (UB-04/837I transaction) Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
- b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s)



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shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

#### Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service

- d. Modifiers Providers shall follow applicable modifier guidelines.
- e. Billing Units Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
- f. Co-payments -

For Medicaid refer to Medicaid State Plan: https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: <u>https://medicaid.ncdhhs.gov/</u>.

#### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering



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benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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