

Clinical Policy: Polymerase Chain Reaction Respiratory Viral Panel Testing

Reference Number: WNC.CP.152 Last Review Date: 02/2025

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[®] that respiratory viral panels (RVPs) testing for five pathogens or fewer are considered **medically necessary** when meeting all of the following¹⁻⁸:
 - **A.** The member/enrollee has one of the following clinical indications for infectious disease testing:
 - 1. The member/enrollee is immunocompetent, and the clinical indication includes a presumption of active infection or infection-associated complications (which may include exacerbation of underlying disease) that require the identification of a causative organism for appropriate management. Note: Atypical clinical presentations of disease are considered appropriate indications for special populations who may not present with classic symptoms of infection (i.e., the elderly);
 - 2. The member/enrollee is immunocompromised (i.e., those with weakened immune systems including those with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS), those who are taking immunosuppressive medications (i.e., chemotherapy, biologics, transplant-related immunosuppressive drugs, high-dose systemic corticosteroids) and those with inherited diseases that affect the immune system (i.e., congenital immunoglobulin deficiencies). Note: atypical clinical presentations of disease are considered appropriate indications for testing. In this population, testing may be performed once as part of a pre-transplant evaluation, regardless of the presence of symptoms;
 - **B.** The results of testing will impact clinical management in a manner already demonstrated in the peer-reviewed published literature to improve outcomes;
 - **C.** Testing is performed according to the intended use of the test in the intended population for which the test was developed and validated;
 - **D.** Targeted testing is not appropriate (i.e., will not provide sufficient information for the appropriate clinical management);
 - **E.** The panel performed includes at least the minimum pathogens required for clinical decision making for its intended use that can be reasonably detected by the test;



- **F.** The registered test demonstrates equivalent or superior test performance characteristics analytical validity (AV) and clinical validity (CV) to established standard-of-care (SOC) methods (i.e., culture, pathogen-specific PCR) for the majority of targets included on the panel;
- G. Documentation of the following is clearly stated in the medical record:
 - 1. Specific clinical indications for testing (i.e., clinical suspicion of a pathogen as the cause of the medical condition);
 - 2. Specific reasons for performing panel testing;
 - 3. Provider type/specialty and Place of Service.
- **II.** It is the policy of WellCare of North Carolina[®] that RVPs testing for six pathogens or more are considered **medically necessary** when meeting the following:
 - A. The criteria in section I are met, and any of the following:
 - 1. Performed in a healthcare setting that cares for critically ill individuals, such as the emergency department or inpatient hospital, and includes those in observation status;
 - 2. Member/enrollee is immunocompromised, as defined in section I.A.2.;
 - 3. Member/enrollee is immunocompetent and both of the following:
 - a. A severe and established underlying respiratory pathology is present (i.e., severe asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis, pulmonary fibrosis, radiation therapy to the lung).
 - b. Treatment with antibiotics may be indicated according to established guidelines.¹⁸⁻¹⁹

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.⁷Viral pathogens are the most common cause of respiratory tract infections.⁸ Rhinovirus, parainfluenza virus, coronavirus, adenovirus, respiratory syncytial virus (RSV), Coxsackie virus, human metapneumovirus, and influenza virus account for most cases of viral respiratory infections.¹⁰ 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.¹¹

PCR testing is generally effective for confirming respiratory viral infections with very high sensitivity and specificity^{8,12} Respiratory viral infections often have nonspecific clinical 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.^{9, 13-16} Multiplex PCR testing can detect a variety of respiratory viruses depending on the type and brand of testing being used.¹³ 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.¹⁷

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)."^{7(pg. 898)}

Coding Implications

This clinical policy references Current Procedural Terminology (CPT[®]). CPT[®] is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2025, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Table 1: CPT codes that support medical necessity in any place of service, without diagnosis code requirements

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, or a diagnosis code in both table 4 and table 5.

CPT ^{®*} Codes	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
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected



CPT ^{®*}	Description
Codes 0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
0225U	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), 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 (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

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
19	Off Campus- Outpatient Hospital	A portion of an off-campus hospital provider based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
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.



Table 4: ICD-10 Diagnosis Codes that Support Medical Necessity for CPT Codes in Table 2 when Billed with a Diagnosis Code in Table 5

ICD-	Description
10-CM	Description
Code	
A37.00	Whooping cough due to Bordetella pertussis without pneumonia
A37.01	Whooping cough due to Bordetella pertussis with pneumonia
A37.10	Whooping cough due to Bordetella parapertussis without pneumonia
A37.11	Whooping cough due to Bordetella parapertussis with pneumonia
A37.80	Whooping cough due to other Bordetella species without pneumonia
A37.81	Whooping cough due to other Bordetella species with pneumonia
A37.90	Whooping cough, unspecified species without pneumonia
A37.91	Whooping cough, unspecified species with pneumonia
A41.81	Sepsis due to Enterococcus
A41.89	Other specified sepsis
A41.9	Sepsis, unspecified organism
A48.1	Legionnaires' disease
A48.2	Nonpneumonic Legionnaires' disease [Pontiac fever]
B25.0	Cytomegaloviral pneumonitis
B33.23	Viral pericarditis
B33.24	Viral cardiomyopathy
B59	Pneumocystosis
B97.21	SARS-associated coronavirus as the cause of diseases classified elsewhere
B97.29	Other coronavirus as the cause of diseases classified elsewhere
J05.0	Acute obstructive laryngitis [croup]
J06.9	Acute upper respiratory infection, unspecified
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
J10.01	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
J11.08	Influenza due to unidentified influenza virus with specified pneumonia
J11.00	Influenza due to unidentified influenza virus with other respiratory manifestations
J I I I	Intractiza dae to undertance infractiza vitas with other respiratory manifestations



ICD-10-	Description
CM	
Code	
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
J12.0	Adenoviral pneumonia
J12.1	Respiratory syncytial virus pneumonia
J12.2	Parainfluenza virus pneumonia
J12.3	Human metapneumovirus pneumonia
J12.81	Pneumonia due to SARS-associated coronavirus
J12.82	Pneumonia due to coronavirus disease 2019
J12.89	Other viral pneumonia
J12.9	Viral pneumonia, unspecified
J13	Pneumonia due to Streptococcus pneumoniae
J15.0	Pneumonia due to Klebsiella pneumoniae
J15.1	Pneumonia due to Pseudomonas
J15.20	Pneumonia due to staphylococcus, unspecified
J15.211	Pneumonia due to Methicillin susceptible Staphylococcus aureus
J15.212	Pneumonia due to Methicillin resistant Staphylococcus aureus
J15.29	Pneumonia due to other staphylococcus
J15.3	Pneumonia due to streptococcus, group B
J15.4	Pneumonia due to other streptococci
J15.61	Pneumonia due to Acinetobacter baumannii
J15.69	Pneumonia due to other Gram-negative bacteria
J15.7	Pneumonia due to Mycoplasma pneumoniae
J15.8	Pneumonia due to other specified bacteria
J15.9	Unspecified bacterial pneumonia
J16.0	Chlamydial pneumonia
J16.8	Pneumonia due to other specified infectious organisms
J18.0	Bronchopneumonia, unspecified organism
J18.1	Lobar pneumonia, unspecified organism
J18.2	Hypostatic pneumonia, unspecified organism
J18.8	Other pneumonia, unspecified organism
J18.9	Pneumonia, unspecified organism
J20.0	Acute bronchitis due to Mycoplasma pneumoniae
J20.1	Acute bronchitis due to Hemophilus influenzae
J20.2	Acute bronchitis due to streptococcus
J20.3	Acute bronchitis due to coxsackievirus



ICD-10-	Description
CM	
Code	
J20.4	Acute bronchitis due to parainfluenza virus
J20.5	Acute bronchitis due to respiratory syncytial virus
J20.6	Acute bronchitis due to rhinovirus
J20.8	Acute bronchitis due to other specified organisms
J20.9	Acute bronchitis, unspecified
J21.9	Acute bronchiolitis, unspecified
J22	Unspecified acute lower respiratory infection
J44.0	Chronic obstructive pulmonary disease with (acute) lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J45.31	Mild persistent asthma with (acute) exacerbation
J45.32	Mild persistent asthma with status asthmaticus
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.42	Moderate persistent asthma with status asthmaticus
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J45.901	Unspecified asthma with (acute) exacerbation
J45.902	Unspecified asthma with status asthmaticus
J84.116	Cryptogenic organizing pneumonia
J84.117	Desquamative interstitial pneumonia
J84.2	Lymphoid interstitial pneumonia
J85.0	Gangrene and necrosis of lung
J85.1	Abscess of lung with pneumonia
J85.2	Abscess of lung without pneumonia
J85.3	Abscess of mediastinum
R05.1	Acute cough
R05.2	Subacute cough
R05.3	Chronic cough
R05.8	Other specified cough
R06.02	Shortness of breath
R06.03	Acute respiratory distress
R06.2	Wheezing
R50.9	Fever, unspecified
R65.20	Severe sepsis without septic shock
R65.21	Severe sepsis with septic shock
R78.81	Bacteremia
T86.33	Heart-lung transplant infection
T86.812	Lung transplant infection
Z03.818	Encounter for observation for suspected exposure to other biological agents ruled out



ICD-10- CM Code	Description
Z20.822	Contact with and (suspected) exposure to COVID-19
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
U07.1	COVID-19

Table 5: ICD-10 Diagnosis Codes that Support Medical Necessity for CPT codes in Table 2 when Billed with a Diagnosis Code in Table 4

ICD-10- CM Code	Description
B20	Human immunodeficiency virus [HIV] disease
C46.0	Kaposi's sarcoma of skin
C46.1	Kaposi's sarcoma of soft tissue
C46.2	Kaposi's sarcoma of palate
C46.3	Kaposi's sarcoma of lymph nodes
C46.4	Kaposi's sarcoma of gastrointestinal sites
C46.50	Kaposi's sarcoma of unspecified lung
C46.51	Kaposi's sarcoma of right lung
C46.52	Kaposi's sarcoma of left lung
C46.7	Kaposi's sarcoma of other sites
D57.01	Hb-SS disease with acute chest syndrome
D61.09	Other constitutional aplastic anemia
D61.1	Drug-induced aplastic anemia
D61.2	Aplastic anemia due to other external agents
D61.3	Idiopathic aplastic anemia
D61.810	Antineoplastic chemotherapy induced pancytopenia
D61.811	Other drug-induced pancytopenia
D61.818	Other pancytopenia
D61.82	Myelophthisis
D61.89	Other specified aplastic anemias and other bone marrow failure syndromes
D61.9	Aplastic anemia, unspecified
D64.81	Anemia due to antineoplastic chemotherapy
D64.89	Other specified anemias
D70.0	Congenital agranulocytosis
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.2	Other drug-induced agranulocytosis
D70.3	Neutropenia due to infection
D70.4	Cyclic neutropenia



ICD-10- CM Code	Description
D70.9	Neutropenia, unspecified
D80.0	Hereditary hypogammaglobulinemia
D80.1	Nonfamilial hypogammaglobulinemia
D80.2	Selective deficiency of immunoglobulin A [IgA]
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near-normal immunoglobulins or with
	hyperimmunoglobulinemia
D80.8	Other immunodeficiencies with predominantly antibody defects
D80.9	Immunodeficiency with predominantly antibody defects, unspecified
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.30	Adenosine deaminase deficiency, unspecified
D81.31	Severe combined immunodeficiency due to adenosine deaminase deficiency
D81.32	Adenosine deaminase 2 deficiency
D81.39	Other adenosine deaminase deficiency
D81.4	Nezelof's syndrome
D81.5	Purine nucleoside phosphorylase [PNP] deficiency
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.810	Biotinidase deficiency
D81.818	Other biotin-dependent carboxylase deficiency
D81.82	Activated Phosphoinositide 3-kinase Delta Syndrome [APDS]
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome
D82.2	Immunodeficiency with short-limbed stature
D82.3	Immunodeficiency following hereditary defective response to Epstein-Barr virus
D82.4	Hyperimmunoglobulin E [IgE] syndrome
D82.8	Immunodeficiency associated with other specified major defects
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified



ICD-10-	Description
CM Code	
D84.0	Lymphocyte function antigen-1 [LFA-1] defect
D84.1	Defects in the complement system
D84.821	Immunodeficiency due to drugs
D84.822	Immunodeficiency due to external causes
D84.89	Other immunodeficiencies
D84.9	Immunodeficiency, unspecified
D89.0	Polyclonal hypergammaglobulinemia
D89.1	Cryoglobulinemia
D89.3	Immune reconstitution syndrome
D89.41	Monoclonal mast cell activation syndrome
D89.42	Idiopathic mast cell activation syndrome
D89.43	Secondary mast cell activation
D89.44	Hereditary alpha tryptasemia
D89.49	Other mast cell activation disorder
D89.810	Acute graft-versus-host disease
D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
D89.82	Autoimmune lymphoproliferative syndrome [ALPS]
D89.89	Other specified disorders involving the immune mechanism, not elsewhere
	classified
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic
	(poly)neuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
E84.0	Cystic fibrosis with pulmonary manifestations
J44.81	Bronchiolitis obliterans and bronchiolitis obliterans syndrome
J44.89	Other specified chronic obstructive pulmonary disease
J44.9	Chronic obstructive pulmonary disease, unspecified
J45.991	Cough variant asthma
J70.1	Chronic and other pulmonary manifestations due to radiation
J84.01	Alveolar proteinosis
J84.02	Pulmonary alveolar microlithiasis
J84.03	Idiopathic pulmonary hemosiderosis
J84.10	Pulmonary fibrosis, unspecified
J84.112	Idiopathic pulmonary fibrosis
J84.114	Acute interstitial pneumonitis
J84.170	Interstitial lung disease with progressive fibrotic phenotype in diseases classified
	elsewhere



ICD-10-	Description
CM Code	
J84.178	Other interstitial pulmonary diseases with fibrosis in diseases classified elsewhere
J84.81	Lymphangioleiomyomatosis
J84.82	Adult pulmonary Langerhans cell histiocytosis
J84.89	Other specified interstitial pulmonary diseases
O98.711	Human immunodeficiency virus [HIV] disease complicating pregnancy, first trimester
O98.712	Human immunodeficiency virus [HIV] disease complicating pregnancy, second trimester
098.713	Human immunodeficiency virus [HIV] disease complicating pregnancy, third trimester
T80.82XS	Complication of immune effector cellular therapy, sequela
Z51.11	Encounter for antineoplastic chemotherapy
Z92.850	Personal history of Chimeric Antigen Receptor T-cell therapy
Z92.858	Personal history of other cellular therapy
Z92.86	Personal history of gene therapy
Z94.0	Kidney transplant status
Z94.1	Heart transplant status
Z94.2	Lung transplant status
Z94.3	Heart and lungs transplant status
Z94.4	Liver transplant status
Z94.5	Skin transplant status
Z94.6	Bone transplant status
Z94.81	Bone marrow transplant status
Z94.82	Intestine transplant status
Z94.83	Pancreas transplant status
Z94.84	Stem cells transplant status
Z94.89	Other transplanted organ and tissue status



Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original Approval date.	03/21	03/21
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. Annual review. References reviewed and updated. background with no clinical significance. Added Criteria I.A.1. The member /enrollee is immunocompromised; and 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.	03/23	05/23
Annual Review. Replaced prior criteria in sections I. and II. with current criteria. Removed policy statement III. Background updated with no impact on criteria. Updated verbiage in Table 2 description to include new diagnosis code requirements. Added Place of Service Code 19 in Table 3. Added Table 4, Table 5, and Table 6 which include ICD-10 diagnosis codes. Removed *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. References reviewed and updated.	05/23	05/23
Added 0202U, 0223U and 0225U to CPT table 2.	08/23	08/23
Annual Review. Updated description of Table 2 as Table 6 was removed. Added ICD-10 codes J15.61 and J15.69 to Table 4. Added ICD-10 codes J44.81 and J44.89 to Table 5. Deleted Table 6 from policy.	02/24	02/24
Annual review. Updated description and background with no clinical significance. Coding reviewed. References reviewed and updated.	02/25	02/25

References

- Local coverage determination. Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L38988). Centers for Medicare and Medicaid Services Web site. <u>http://www.cms.hhs.gov/mcd/search.asp. Published April 17</u>, 2022 (revised June 09, 2022). Accessed February 22, 2024.
- Local coverage article. Billing and coding: MoIDX: molecular syndromic panels for infectious disease pathogen identification testing (A58710). Centers for Medicare and Medicaid Services Web site. <u>http://www.cms.hhs.gov/mcd/search.asp. Published</u> <u>April 17</u>, 2022 (revised January 01, 2024). Accessed February 22, 2024.
- Local coverage article. Billing and coding: MolDX: molecular syndromic panels for infectious disease pathogen identification testing (A58720). Centers for Medicare and Medicaid Services Web site. <u>http://www.cms.hhs.gov/mcd/search.asp</u>. Published April 17, 2022 (revised January 01, 2024). Accessed February 22, 2024.
- 4. Local coverage article. Billing and coding: MolDX: molecular syndromic panels for infectious disease pathogen identification testing (A58726). Centers for Medicare and Medicaid Services Web site. <u>http://www.cms.hhs.gov/mcd/search.asp</u>. Published



April 17, 2022 (revised January 01, 2024). Accessed February 22, 2024.

- Local coverage article. Billing and coding: MolDX: molecular syndromic panels for infectious disease pathogen identification testing (A58747). Centers for Medicare and Medicaid Services Web site. <u>http://www.cms.hhs.gov/mcd/search.asp</u>. Published April 17, 2022 (revised January 01, 2024). Accessed February 22, 2024.
- Local coverage article. Billing and coding: MoIDX: molecular syndromic panels for infectious disease pathogen identification testing (A58761). Centers for Medicare and Medicaid Services Web site. <u>http://www.cms.hhs.gov/mcd/search.asp</u>. Published April 17, 2022 (revised January 01, 2024). Accessed February 22, 2024.
- 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 to 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
- 9. 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 to 95. doi:10.1016/j.jcv.2018.09.009
- 10. Weston S, Frieman MB. Respiratory Viruses. *Encyclopedia of Microbiology*. 2019;85 to -101. doi:10.1016/B978-0-12-801238-3.66161-5
- 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 to 1911. doi:10.1016/j.chest.2020.05.598
- 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 to 2016 influenza epidemics: An interventional study. *Int J Infect Dis*. 2019;83:32 to 39. doi:10.1016/j.ijid.2019.03.027
- 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 to 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 May 08, 2023). Accessed February 22, 2024.
- 15. Molecular Test Assessment. FilmArray respiratory panel 2 (BioFire Diagnostics LLC). Hayes. <u>www.hayesinc.com</u>. Published March 10, 2020 (annual review March 31, 2023). Accessed February 22, 2024.
- 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 to 202. doi:10.1007/s10096-021-04375-3



- 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 to e1502. doi:10.1542/peds.2014-2742
- 18. Metlay JP, Waterer GW, Long AC, et al. Diagnosis and treatment of adults with community-acquired pneumonia. An official clinical practice guideline of the American Thoracic Society and Infectious Diseases Society of America. *Am J Respir Crit Care Med.* 2019;200(7):e45-e67. doi:10.1164/rccm.201908-1581ST
- 19. Global Initiative for Asthma[®]. Global strategy for asthma management and prevention. <u>https://ginasthma.org/wp-content/uploads/2018/04/wms-GINA-2018-report-tracked_v1.3.pdf</u>. Published 2015. Updated 2018.

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 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: <u>https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html</u> 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) 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: <u>https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan</u>

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 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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

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