Date of Last Revision: 03/24



Coding Implications
Revision log

INFECTIOUS DISEASE: RESPIRATORY LAB TESTING

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

OVERVIEW

Respiratory illnesses cause significant morbidity and mortality within the United States and around the world. Seasonal influenza, respiratory syncytial virus (RSV), and SARS-CoV-2 infect many individuals each year, and while most will recover with no complications, a significant number will be hospitalized or die. Diagnostic testing for upper respiratory tract infections can be very useful for clinicians, as clinical signs and symptoms of these infections can have significant overlap between pathogens. Accurate and rapid testing techniques may aid clinicians, via identification of a specific pathogen, in selecting the best course of treatment for patients. Optimally, treatment is started within 48-72 hours of diagnosis. Testing methods range from culture and microscopy to immunoassays and advanced molecular diagnostic techniques; technology in this space is evolving rapidly and clinical guidelines can lag as a result.

This policy is intended for use in the outpatient setting.

POLICY REFERENCE TABLE

Criteria Sections	Example Tests (Labs)	References
Syndromic/Multiple x Respiratory Panels with 6 or	Respiratory Pathogen Panel, Quest Diagnostics	3
More Targets	ePlex Respiratory Pathogen Panel (GenMark Diagnostics, Inc)	



	Biofire FilmArray Respiratory Panel 2.1 (Biofire Diagnostics) QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN Sciences)	
	ePlex Respiratory Pathogen Panel 2 (GenMark Diagnostics, Inc)	
	Respiratory Pathogen with ABR (RPX) (Lab Genomics LLC, Thermofisher Scientific)	
	Respiratory Virus PCR Panel IV (Quest Diagnostics)	
	Respiratory Viral Panel, PCR (Quest Diagnostics)	
SARS-CoV-2, RSV, or Influenza A/B, OR Multiplex Respiratory Viral	Xpert Xpress SARS-CoV- 2/Flu/RSV for SARS-CoV-2 and Flu targets only (Cepheid)	3, 6, 7
Panels with 5 or Fewer Targets	Xpert Xpress SARS-CoV- 2/Flu/RSV for all targets (Cepheid)	
	Infectious Agent Antigen Detection by Immunoassay	
	Infectious Agent Antigen Detection by Immunoassay, Qualitative or Semiquantitative	



	Infectious Agent Antigen Detection by Immunoassay, Qualitative or Semiquantitative, SARS-CoV-2 and Flu A/B Influenza A and B and RSV RNA, Qualitative, Real-Time RT-PCR (Quest Diagnostics)	
	SARS-CoV-2 RNA (COVID-19), Qualitative NAAT (Quest Diagnostics)	
	SARS-CoV-2 RNA (COVID-19) and Influenza A and B, Qualitative NAAT (Quest Diagnostics)	
	Infectious Agent Antigen Detection by Nucleic Acid (DNA or RNA) SARS-CoV-2/Flu/RSV Multiplex Amplified Probe Technique	
	Infectious Agent Antigen Detection by Immunoassay with Direct Optical Observation	
Bacterial Respiratory Infection/Pneumoni a Panels	Infectious Agent: Chlamydia pneumoniae Detection by Nucleic Acid (DNA or RNA), Direct Probe Technique	3
	Chlamydophila pneumoniae, DNA, Qualitative, Real-Time PCR (Quest Diagnostics)	



	Infectious Agent: Chlamydia pneumoniae Detection by Nucleic Acid (DNA or RNA), Quantification	
	Legionella DNA, Qualitative, Real-Time PCR (Quest Diagnostics)	
	Infectious Agent: Mycoplasma pneumoniae Detection by Nucleic Acid (DNA or RNA), Direct Probe Technique	
	Mycoplasma pneumoniae, DNA PCR (Labcorp)	
	Infectious Agent: Mycoplasma pneumonia Detection by Nucleic Acid (DNA or RNA), Quantification	
Influenza A and B Antibody Tests	Influenza Type A and Type B Antibody, Serum (Quest Diagnostics)	1

CRITERIA

It is the policy of Ambetter of Tennessee that the specific tests noted below are **medically necessary** when meeting the related criteria:

RESPIRATORY PATHOGEN PANEL TESTS

Syndromic/Multiplex Respiratory Panels with 6 or More Targets

- I. Syndromic Multiplex Respiratory Panels with 6 or more targets may be considered **medically necessary** when:
 - A. The member/enrollee presents in the outpatient setting with <u>signs or symptoms of</u> an acute respiratory infection, **AND**



- 1. The member/enrollee meets at least one of the following criteria:
 - a) Immunocompromised, OR
 - b) Has severe pneumonia, OR
 - c) Has exacerbations of airway disease, AND
- B. Results of the testing will influence the member's/enrollee's clinical management.
- II. Current evidence does not support the use of Syndromic Multiplex Respiratory Panels with 6 or more targets for all other indications.

SARS-CoV-2, RSV, or Influenza A/B, OR Multiplex Respiratory Viral Panels with 5 or Fewer Targets

- I. SARS-CoV-2, RSV, or Influenza A/B, **OR** Multiplex Respiratory Viral Panels with 5 or fewer targets, may be considered **medically necessary** when:
 - A. The member/enrollee presents in the outpatient setting with <u>signs or symptoms of</u> an acute respiratory infection, **AND**
 - B. Results of the testing will influence the member's/enrollee's clinical management.
- II. Current evidence does not support the use of SARS-CoV-2, RSV, or Influenza A/B, **OR** Multiplex Respiratory Viral Panels with 5 or fewer targets, for all other indications.

Bacterial Respiratory Infection/Pneumonia Panels

- I. Bacterial Respiratory Infection/Pneumonia Panels may be considered **medically necessary** when:
 - A. The member/enrollee presents in the outpatient setting with signs or symptoms of an acute respiratory infection, AND
 - B. The member/enrollee meets any of the following criteria:
 - 1. New or worsening lung infiltrates, **OR**
 - 2. Moderate to severe upper respiratory illness, **OR**
 - 3. Has received empiric antibiotics before obtaining cultures, **OR**
 - 4. Has possible multidrug-resistant bacteria or polymicrobial infection, AND



- C. Results of the testing will influence the member's clinical management.
- II. Current evidence does not support the use of Bacterial Respiratory Infection/Pneumonia Panels for all other indications.

Influenza A and B Antibody Tests

I. Current evidence does not support the use of Influenza A and B Antibody Tests for the purpose of diagnosing influenza.

NOTES AND DEFINITIONS

- 1. **Moderate to severe upper upper respiratory illness** includes one or more clinical findings of lower respiratory illness (e.g., pneumonia, severe cough/bronchitis, shortness of breath, difficulty breathing).
- 2. **Severe pneumonia** is defined by the Infectious Diseases Society of America/American Thoracic Society Criteria as: the presence of one major criterion or at least three minor criteria.

Minor criteria: respiratory rate \geq 30 breaths/min, PaO2/FiO2 ratio \leq 250, multilobar infiltrates, confusion/disorientation, uremia (blood urea nitrogen level \geq 20 mg/dl), leukopenia (white blood cell count < 4,000 cells/µl), thrombocytopenia (platelet count < 100,000/µl), hypothermia (core temperature < 36°C), and hypotension requiring aggressive fluid resuscitation.

Major criteria: septic shock with need for vasopressors and respiratory failure requiring mechanical ventilation.

- 3. **Airway disease** is a nonspecific clinical term for a heterogeneous group of conditions including chronic obstructive pulmonary disease (COPD), emphysema, cystic fibrosis, asthma, and bronchiectasis.
- 4. **Signs and symptoms of acute respiratory infection** include upper or lower respiratory tract symptoms (cough, runny nose, sore throat, bronchitis, pneumonia, bronchiolitis), with or without fever, influenza-like illness (ILI) (fever and either cough or sore throat), and respiratory distress (difficulty in breathing; often characterized by increased respiratory rate and use of accessory muscles of breathing).

Date of Last Revision: 03/24



BACKGROUND AND RATIONALE

Syndromic/Multiplex Respiratory Panels with 6 or More Targets

Infectious Diseases Society of America

The IDSA published clinical and diagnostic recommendations in 2020 regarding molecular testing for acute respiratory tract infections (RTIs). These recommendations state the following:

"Multiplex viral NAAT [nucleic acid amplification tests] (potentially combined with bacterial NAAT) also make clinical sense for immunocompromised and critically ill patients with pneumonia as well as for those with exacerbations of airway disease." (p. 2748).

SARS-CoV-2, RSV, or Influenza A/B, OR Multiplex Respiratory Viral Panels with 5 or Fewer Targets

Infectious Diseases Society of America

The IDSA published clinical and diagnostic recommendations in 2020 regarding molecular testing for acute respiratory tract infections (RTIs). These recommendations state the following:

"Molecular testing for multiple respiratory viruses simultaneously may also be more costeffective than traditional antigen- or culture-based methods from a laboratory perspective, especially given certain thresholds of disease prevalence." (p. 2744)

Centers for Disease Control and Prevention

The CDC states the following on their website discussing RSV: "Healthcare providers should consider RSV in patients with respiratory illness, particularly during the RSV season."

The CDC states the following on their website discussing COVID-19: "Key times to get tested: if you have symptoms, test immediately."

Bacterial Respiratory Infection/Pneumonia Panels

Infectious Diseases Society of America

The IDSA published clinical and diagnostic recommendations in 2020 regarding molecular testing for acute respiratory tract infections (RTIs). These recommendations state the following:

"...bacterial NAAT may prove most useful in situations where patients have new or worsening lung infiltrates, are moderately to severely ill, have received empiric antibiotics before obtaining

Date of Last Revision: 03/24



cultures, and/or there is concern for multidrug-resistant bacteria or a polymicrobial infection." (p. 2747)

Influenza A and B Antibody Tests

Infectious Diseases Society of America

The IDSA published clinical practice guidelines in 2018 which addressed testing criteria for seasonal influenza A and B viruses. These guidelines state that serologic testing for the diagnosis of influenza should not be used by clinicians, because the results from a single serum specimen cannot be reliably interpreted. (p. 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 2023, 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 or exclusion 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.

CPT® Code	Description
86060	Antistreptolysin 0; titer
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single-step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])
86408	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]); screen
86409	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]); titer
86413	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) antibody, quantitative
86710	Antibody; influenza virus
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])



CPT® Code	Description
87040	Culture, bacterial; blood, aerobic, with isolation and presumptive identification of isolates (includes anaerobic culture, if appropriate)
87070	Culture, bacterial; any other source except urine, blood or stool, aerobic, with isolation and presumptive identification of isolates
87071	Culture, bacterial; quantitative, aerobic with isolation and presumptive identification of isolates, any source except urine, blood or stool
87073	Culture, bacterial; quantitative, anaerobic with isolation and presumptive identification of isolates, any source except urine, blood or stool
87075	Culture, bacterial; any source, except blood, anaerobic with isolation and presumptive identification of isolates
87076	Culture, bacterial; anaerobic isolate, additional methods required for definitive identification, each isolate
87077	Culture, bacterial; aerobic isolate, additional methods required for definitive identification, each isolate
87081	Culture, presumptive, pathogenic organisms, screening only;
87084	Culture, presumptive, pathogenic organisms, screening only; with colony estimation from density chart
87101	Culture, fungi (mold or yeast) isolation, with presumptive identification of isolates; skin, hair, or nail
87102	Culture, fungi (mold or yeast) isolation, with presumptive identification of isolates; other source (except blood)
87103	Culture, fungi (mold or yeast) isolation, with presumptive identification of isolates; blood
87106	Culture, fungi, definitive identification, each organism; yeast
87107	Culture, fungi, definitive identification, each organism; mold
87109	Culture, mycoplasma, any source
87116	Culture, tubercle or other acid-fast bacilli (eg, TB, AFB, mycobacteria) any source, with isolation and presumptive identification of isolates
87118	Culture, mycobacterial, definitive identification, each isolate



CPT® Code	Description
87140	Culture, typing; immunofluorescent method, each antiserum
87143	Culture, typing; gas liquid chromatography (GLC) or high pressure liquid chromatography (HPLC) method
87147	Culture, typing; immunologic method, other than immunofluorescence (eg, agglutination grouping), per antiserum
87158	Culture, typing; other methods
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 (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; Influenza, A or B, each
87420	Infectious agent antigen detection by immunoassay technique (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; respiratory syncytial virus
87426	Infectious agent antigen detection by immunoassay technique (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])
87428	Infectious agent antigen detection by immunoassay technique (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B
87480	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique
87481	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique



CPT [®] Code	Description
87482	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, quantification
87485	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia pneumoniae, direct probe technique
87486	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia pneumoniae, amplified probe technique
87487	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia pneumoniae, quantification
87498	Infectious agent detection by nucleic acid (DNA or RNA); enterovirus, amplified probe technique, includes reverse transcription when performed
87500	Infectious agent detection by nucleic acid (DNA or RNA); vancomycin resistance (eg, enterococcus species van A, van B), amplified probe technique
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)
87540	Infectious agent detection by nucleic acid (DNA or RNA); Legionella pneumophila, direct probe technique
87541	Infectious agent detection by nucleic acid (DNA or RNA); Legionella pneumophila, amplified probe technique
87542	Infectious agent detection by nucleic acid (DNA or RNA); Legionella pneumophila, quantification
87550	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria species, direct probe technique
87551	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria species,



CPT® Code	Description
	amplified probe technique
87552	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria species, quantification
87555	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria tuberculosis, direct probe technique
87556	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria tuberculosis, amplified probe technique
87560	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria avium-intracellulare, direct probe technique
87561	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria avium-intracellulare, amplified probe technique
87580	Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma pneumoniae, direct probe technique
87581	Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma pneumoniae, amplified probe technique
87582	Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma pneumoniae, quantification
87631	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, 3-5 targets
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



CPT [®] Code	Description
87634	Infectious agent detection by nucleic acid (DNA or RNA); respiratory syncytial virus, amplified probe technique
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), amplified probe technique
87636	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique
87637	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique
87640	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, amplified probe technique
87641	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique
87650	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, direct probe technique
87651	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, amplified probe technique
87652	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, quantification
87653	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group B, amplified probe technique
87797	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; direct probe technique, each organism
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism
87799	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; quantification, each organism
87800	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms;



CPT [®] Code	Description
	direct probe(s) technique
87801	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique
87804	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Influenza
87807	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; respiratory syncytial virus
87811	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])
87913	Infectious agent genotype analysis by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), mutation identification in targeted region(s)
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogenspecific 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 (For additional PLA code with identical clinical descriptor, see 0223U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment)
0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogenspecific 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 (For additional PLA code with identical clinical descriptor, see 0202U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment)
0225U	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARSCoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
0240U	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2],



CPT® Code	Description
	influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected
0241U	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected
U0001	CDC Test
U0002	Non-CDC Viral identification test, amplified probe
U0003	High throughput Viral identification test, amplified probe
U0004	High throughput Viral identification test, other than amplified probe
U0005	Infectious agent detection by nucleic acid (dna or rna); severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), amplified probe technique, cdc or non-cdc, making use of high throughput technologies, completed within 2 calendar days from date of specimen collection (list separately in addition to either hcpcs code u0003 or u0004) as described by cms-2020-01-r2

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Reviewed by external specialist.	11/23	02/24
Added "Lab" to policy title. Removed CPT and ICD-10 codes from policy reference table. Added CPT code table and moved the "coding implications" section.	02/24	
Updated CPT code table- corrected to change code descriptions. Removed code 0373U.	03/24	
Created TN Ambetter-specific version, HIM.TN.CG.CP.MP.01: Removed criteria and background information regarding Group A Streptococcus Pharyngitis Tests, Pharyngitis Cultures and Antibody Tests. Removed code 87880 from CPT table.	03/24	

Date of Last Revision: 03/24



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- 3. Hanson KE, Azar MM, Banerjee R, et al. Molecular Testing for Acute Respiratory Tract Infections: Clinical and Diagnostic Recommendations From the IDSA's Diagnostics Committee. *Clin Infect Dis.* 2020;71(10):2744-2751. doi:10.1093/cid/ciaa508
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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,

Date of Last Revision: 03/24



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.

Note: For Medicaid members/enrollees, 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.

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

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HIM.TN.CG.CP.MP.01 Infectious Disease: Respiratory Lab Testing

2024.1

Date of Last Revision: 03/24



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