



## Updated - Respiratory Virus Panel Tests Policy

June 26, 2020

Per the Centers for Medicare & Medicaid Services guidelines, we've added the language below to our *Respiratory Virus Tests* policy.

**COVID-19 testing for surveillance or employment purposes:** testing conducted to screen for general workplace health and safety (such as employee “return to work” programs), for public health surveillance for SARS-CoV-2, or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition is not covered under the scope of section 6001 of the FFCRA<sup>5</sup> and is not covered for HAP/AHL Members.

The updated policy is attached.



## Respiratory Viral Panel Testing

### DESCRIPTION

Virus infections can be confirmed by a multitude of methods. Diagnostic virology has changed rapidly due to the advent of molecular techniques and increased clinical sensitivity of serological assays. Immunofluorescence or immunoperoxidase are laboratory testing methods commonly used to determine if a virus is present in a patient sample. Molecular testing techniques are able to assess the viral genome or nucleic acid. Tests may include: Rapid molecular assays, Reverse Transcription-Polymerase Chain Reaction (RT-PCR), and other nucleic acid amplification tests. <sup>1</sup>

Because viruses cause most URIs, the diagnostic role of laboratory investigations and radiologic studies is limited. Only after common conditions are ruled out, should uncommon viral conditions be tested. Respiratory viral panel testing in the outpatient setting may be indicated for individuals who are at high risk for complications of respiratory viral infection, including but not limited to individuals who are immunocompromised, including lung transplant recipients, when the result of testing is used to guide or alter management.

Note: These tests are not considered "Genetic tests". They are covered as "Laboratory testing or Diagnostic Laboratory testing".

### COVERED CODES - Respiratory Viral Panels

0098U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 14 targets (adenovirus, coronavirus, human metapneumovirus, influenza A, influenza A subtype H1, influenza A subtype H3, influenza A subtype H1-2009, influenza B, parainfluenza virus, human rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydomphila pneumoniae, Mycoplasma pneumoniae) [USE FOR BioFire® FilmArray® Respiratory Panel (RP) EZ]
0099U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 20 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus, coronavirus OC43, human metapneumovirus, influenza A, influenza A subtype, influenza A subtype H3, influenza A subtype H1-2009, influenza, parainfluenza virus, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, human rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydomphila pneumonia, Mycoplasma pneumoniae) [USE FOR BioFire® FilmArray® Respiratory Panel (RP)]
0100U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 21 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, human metapneumovirus, human rhinovirus/enterovirus, influenza A, including subtypes H1, H1-2009, and H3, influenza B, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, respiratory syncytial virus, Bordetella parapertussis [IS1001], Bordetella pertussis [ptxP], Chlamydia pneumoniae, Mycoplasma pneumoniae) [USE FOR BioFire® FilmArray® Respiratory Panel 2 (RP2)]
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 [USE FOR GenMark® ePlex Respiratory Pathogen (RP) Panel]
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

### COVERED CODES - Corona virus - COVID-19

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])
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
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
C9803	Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source
G2023	Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source
G2024	Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), from an individual in a skilled nursing facility or by a laboratory on behalf of a HHA, any specimen source
U0001	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC
U0003	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, making use of high throughput technologies as described by CMS-2020-01-R
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R
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 [Use for BioFire® Respiratory Panel 2.1 (RP2.1)]

## COVERAGE CRITERIA

### Multiplex PCR respiratory viral panels

1. Multiplex PCR respiratory viral panels [87631, 87632, 87633, 0098U, 099U, 0100U, 0115U] are covered for HAP/AHL Members when the following criteria are met:
  - a. Member is in a healthcare setting that is equipped to care for and routinely does care for critically ill patients and the test is billed from ONE of the following settings:
    - i. Urgent Care (place of service 20)
    - ii. Inpatient hospital (place of service 21)
    - iii. Emergency Room (place of service 23)
  - b. Test is ordered by an infectious disease specialist who is diagnosing and treating the Member.

### Novel Coronavirus /Covid-19 testing

1. Novel Coronavirus /Covid-19 testing [86328, 86769, 87635, U0001, U0002, U0003, U0004, 0202U] is covered for HAP/AHL Members as follows:
  - a. Test: The test is an FDA Emergency Use Authorization (EUA) test
    - i. Two kinds of tests are available for COVID-19:
      - A. A viral test used to diagnose a current infection, also known as Nucleic acid amplification tests (molecular tests), RNA or PCR tests.
      - B. An antibody test used to determine existence of previous infection, also known as serology testing.
  - b. Laboratory: Testing must be performed by a Clinical Laboratory Improvement Amendment (CLIA) approved laboratory as described by the CDC. <https://www.cdc.gov/coronavirus/2019-ncov/downloads/OASH-COVID-19-guidance-testing-platforms.pdf>
  - c. Order: Testing must be ordered by a qualified healthcare provider.
    - i. The qualified health professional assumes responsibility for documentation of medical necessity in the medical record.
  - d. Member eligibility:
    - i. HAP covers medically necessary testing consistent with Center for Disease Control (CDC) and State of Michigan recommendations. The priorities for testing for COVID-19 continue to change.
      - A. For the latest information on Michigan's response to COVID-19, please visit <https://www.michigan.gov/coronavirus>
      - B. For the latest information on the CDC response to COVID-19, please visit <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html>

### For any testing:

1. Coverage of services is based on the Member's subscriber documents. Please refer to those resources for information regarding eligibility for coverage, network or provider requirements. If the Member has coverage for the services discussed in this policy, then the medical criteria applies.
2. Some services require pre-authorization by a HAP Medical Director or designee, please refer to the Procedure reference list for specific code information.

3. Medicaid Providers should refer to:
  - a. The Michigan Medicaid Provider Manual for coverage criteria, located at: <http://www.mdch.state.mi.us/dch-medicaid/manuals/MedicaidProviderManual.pdf>
  - b. The Michigan Medicaid Fee Schedule located at: [http://www.michigan.gov/mdch/0,1607,7-132-2945\\_42542\\_42543\\_42546\\_42551-159815--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html)

## LIMITATIONS

1. Viral panels are billed with the corresponding code that best describes the test. Unit of service is one.

## EXCLUSIONS

1. Respiratory viral panel testing in the outpatient setting is not covered for HAP/AHL Members who are:
  - a. Average risk individuals
  - b. Who are not at high risk of complications (not immunocompromised)
  - c. The result of testing is unlikely to guide management
2. Respiratory viral panel testing in the outpatient setting using large panels involving 6 or more targets is not covered for HAP/AHL Members except when ordered by a provider specializing in infectious disease.
3. **COVID-19 testing for surveillance or employment purposes:** testing conducted to screen for general workplace health and safety (such as employee “return to work” programs), for public health surveillance for SARS-CoV-2, or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition is not covered under the scope of section 6001 of the FFCRA<sup>5</sup> and is not covered for HAP/AHL Members.

## REFERENCES:

1. Center for Disease Control and Prevention. Information on Rapid Molecular Assays, RT-PCR, and other Molecular Assays for Diagnosis of Influenza Virus Infection. Avail @ <https://www.cdc.gov/flu/professionals/diagnosis/molecular-assays.htm>
2. Bartlett, J.G., MD. Diagnostic approach to community-acquired pneumonia in adults. UpToDate. Literature review current through: Mar 2020. This topic last updated: Dec 02, 2019. Topic 7032 Version 55.0.
3. Flor M Munoz, F.M., MD, MSc and Flomenberg, P., MD. Diagnosis, treatment, and prevention of adenovirus infection. UpToDate. Literature review current through: Mar 2020. This topic last updated: Jan 07, 2020. Topic 8348 Version 19.0.
4. FDA. Emergency Use Authorizations. <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>
5. FAQs ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION PART 43. June 23, 2020. <https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf>

## MEDICARE REFERENCES:

1. Local Coverage Determination (LCD): MoIDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37764) <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37764>
  - a. Local Coverage Article:  
Billing and Coding: MoIDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (A57579) <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57579&ver=8&LCDId=37764&bc=AAAAAAAAAgAAA&>

## MEDICAID REFERENCES:

1. Michigan Medicaid Provider Manual. <http://www.mdch.state.mi.us/dch-medicaid/manuals/MedicaidProviderManual.pdf>
  - a. Billing & Reimbursement for Professionals
    - i. SECTION 6 - SPECIAL BILLING
      - A. 6.14 LABORATORY SERVICES - Panels
  - b. Hospital
    - i. SECTION 3 – COVERED SERVICES
      - A. 3.20 LABORATORY
  - c. Laboratory
    - i. SECTION 1 - GENERAL INFORMATION
    - ii. SECTION 5 - PROCEDURE GUIDELINES
      - A. 5.3 TEST REPORTS - Panel tests
  - d. Practitioner
    - i. SECTION 3 – GENERAL PRACTICE
      - A. 3.14 LABORATORY
        - I. 3.14.C. NON-COVERED SERVICES

subscriber documents and are subject to all terms and conditions including specific exclusions and limitations. This type of document includes the following: Subscriber contract and associated riders; Member Benefit Guide; or an Evidence of Coverage document (for Medicare Advantage Members).

**HAP HMO/POS and AHL EPO/PPO Members:**

If there is a discrepancy between this policy and coverage described in the subscriber documents, the Member's subscriber documents will apply.

**ASO Members:**

Coverage as discussed in this policy may not apply to employer groups that are self-funded (referred to as an ASO group [Administrative Services Only]). Each ASO group determines the coverage available to their members which is found in the ASO Benefit Guide and associated riders. If a member has coverage for the type of service covered by this policy, then the medical criteria as discussed in this policy applies to those services.

**Medicare Advantage Plan Members:**

Coverage is based on Medicare (CMS) regulations and guidelines which include the NCDs (National Coverage Decision) and LCDs (Local Coverage Decision) for our area. When no coverage determination has been made by CMS, then this policy will apply.

**Medicaid Plan Members:**

For Medicaid/Healthy Michigan Plan members coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located

at: [http://www.michigan.gov/mdch/0,1607,7-132-2945\\_42542\\_42543\\_42546\\_42551-159815--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html). If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: [http://www.michigan.gov/mdch/0,1607,7-132-2945\\_5100-87572--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html), the Michigan Medicaid Provider Manual will apply.

**EFFECTIVE DATE**

04/01/2020

**REVISED DATE**

06/26/2020

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04/13/2020

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