

Reimbursement Policy:
COVID-19 Testing
(Commercial, Medicare and Medicaid)

POLICY NUMBER	EFFECTIVE DATE:	APPROVED BY
RPC20210016	<ul style="list-style-type: none"> 1/01/2022 12/01/2021- Medicaid COVID-19 Vaccine Counseling 	RPC (Reimbursement Policy Committee)

Reimbursement Guideline Disclaimer: We have policies in place that reflect billing or claims payment processes unique to our health plans. Current billing and claims payment policies apply to all our products, unless otherwise noted. We will inform you of new policies or changes in policies through postings to the applicable Reimbursement Policies webpages on emblemhealth.com and connecticare.com. Further, we may announce additions and changes in our provider manual and/or provider newsletters which are available online and emailed to those with a current and accurate email address on file. The information presented in this policy is accurate and current as of the date of this publication.

The information provided in our policies is intended to serve only as a general reference resource for services described and is not intended to address every aspect of a reimbursement situation. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to, legislative mandates, physician or other provider contracts, the member’s benefit coverage documents and/or other reimbursement, and medical or drug policies. Finally, this policy may not be implemented the same way on the different electronic claims processing systems in use due to programming or other constraints; however, we strive to minimize these variations.

We follow coding edits that are based on industry sources, including, but not limited to, CPT® guidelines from the American Medical Association, specialty organizations, and CMS including NCCI and MUE. In coding scenarios where there appears to be conflicts between sources, we will apply the edits we determine are appropriate. We use industry-standard claims editing software products when making decisions about appropriate claim editing practices. Upon request, we will provide an explanation of how we handle specific coding issues. If appropriate coding/billing guidelines or current reimbursement policies are not followed, we may deny the claim and/or recoup claim payment.

Overview

There are three main types of tests for the SARS-CoV-2 virus: diagnostic (viral) tests, antigen tests and serologic (antibody) tests. A diagnostic (molecular and antigen) test tells if you likely have a current infection by looking for parts of the virus itself in samples taken from an individual’s respiratory system secretions (such as nasal swabs). A serologic, or antibody, test tells if you have had a previous infection of the virus from a blood sample by looking at your antibody response to the infection. In general, a serologic test cannot be used for diagnostic purposes. A serological test to determine if a person has, or has had, COVID-19 may be unreliable. Antibodies may be detected in individuals who have had a distant history of infection, and antibodies may wane over time and no longer be detected in an individual with prior infection. This policy describes when SARS-CoV-2 diagnostic and serology testing may be considered medically necessary.

Diagnostic and Covered

SARS-CoV-2 Diagnostic Testing

For the purpose of this policy, molecular and antigen testing for the diagnosis of SARS-CoV-2 is informed by authoritative statements by the FDA (2021), CDC (2021, 2020) and published professional society recommendations (e.g., IDSA, 2021). COVID 19 Nucleic acid and antigen tests that are FDA approved or authorized under the FDA Emergency Use Authorization (EUA) for diagnosing and treating COVID-19 are considered medically necessary when following the above society guidelines for evaluation and laboratory testing for COVID-19.

Reimbursement Policy:

COVID-19 Testing

(Commercial, Medicare and Medicaid)

Per the CDC, “Clinicians should use their judgment to determine if a patient has signs or symptoms compatible with COVID-19 and whether the patient should be tested. Most patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough) but some infected patients may present with other symptoms as well.”

- Symptomatic individual suspected of having COVID-19.
- Testing of asymptomatic patients used as part of a pre-surgical or facility pre-admission screening, prior to an immunosuppressive procedure, or when a patient is admitted to a Skilled Nursing Facility in accordance with CMS and CDC testing guidelines.
- Known or suspected prolonged, close contact, with an individual with a laboratory confirmed case of COVID-19 as defined by CDC guidelines.
- Coronavirus COVID-19 (SARS-CoV-2) respiratory panel (up to 5 respiratory pathogens) test when member has signs and symptoms of COVID-19.

Note: CDC guidance for COVID-19 testing may be adapted by state and local health departments to respond to rapidly changing local circumstances.

SARS-CoV-2 Serology Testing

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) serology (antibody) testing may be considered a covered service when the following criteria are met:

- An individual seeks and receives a COVID-19 diagnostic test from a licensed or authorized health care provider, **OR**
 - A licensed or authorized health care provider refers an individual for a COVID-19 diagnostic test. **AND**
- FDA approved or cleared or Emergency Use Authorization (EUA) **AND**
- Performed by a CLIA-accredited high or medium-complexity laboratory (per test Instructions for Use) **AND**

One of the following three conditions is present:

- Results of a molecular or antigen test is non diagnostic for COVID-19 and the results of the test will be used to aid in the diagnosis of a condition related to COVID-19 infection (e.g., Multisystem Inflammatory Syndrome [MIS]). **OR**
- Used as a method to support the clinical assessment of acute COVID-19 illness for persons who are being tested 3–4 weeks after illness onset, in addition to recommended direct detection methods such as polymerase chain reaction (PCR). **OR**
- Used as a method to help establish a clinical picture when patients have late complications of COVID-19 illness, such as multisystem inflammatory syndrome in children.

Reimbursement Policy:

COVID-19 Testing

(Commercial, Medicare and Medicaid)

Limitations and Exclusions (unless mandated otherwise by applicable law):

If the above criteria are not met, in vitro testing (i.e., molecular, antigen, antibody) may not be covered, including but not limited to, the following instances:

- Persons without symptoms who are prioritized by health departments or clinicians, for any reason, including but not limited to: public health monitoring, sentinel surveillance, or screening of other asymptomatic individuals according to state and local plans.
- Tests used to determine if someone can return to work or employer requested testing.
- Tests used to group people together in settings such as schools, sports, dormitories, and correctional facilities.
- Travel related testing.
- Routine and/or executive physicals.
- Over-the-Counter (OTC) tests for the diagnosis of COVID-19 infection.
- Tests that have not been approved for use by the FDA or authorized per FDA EUA guidelines.
- A high-throughput molecular or antigen in vitro diagnostic test for the diagnosis of SARS-CoV-2 (COVID19) infection will not be covered unless billed by a CLIA-accredited high-complexity laboratory.
- Respiratory Virus Panels which include COVID-19 for screening purposes or asymptomatic individuals or when more than 5 pathogens are tested regardless of the presence of symptoms.
- Antibody testing to assess immunity after COVID-19 vaccination ([FDA Safety Communication: Antibody Testing Is Not Currently Recommended to Assess Immunity After COVID-19 Vaccination](#)). While a positive antibody test result can be used to help identify people who may have had a prior SARS-CoV-2 infection, more research is needed in people who have received a COVID-19 vaccination. Currently authorized SARS-CoV-2 antibody tests have not been evaluated to assess the level of protection provided by an immune response to COVID-19 vaccination.

EmblemHealth/ConnectiCare maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to plan upon request. Failure to produce the requested information may result in denial or retraction of payment.

Coding/Billing Information

Effective 6/1/2022 – EmblemHealth and ConnectiCare will amend the billing instructions to align with CMS' instructions on how to bill for COVID-19 test related services. The plan will require the use of modifier CS when identifying services that are related to the need determination for a COVID-19 test.

Note:

- 1) This list of codes may not be all-inclusive.
- 2) Deleted codes and codes which are not effective at the time the service is rendered may not be

Reimbursement Policy:

COVID-19 Testing

(Commercial, Medicare and Medicaid)

eligible for reimbursement

- 3) COVID-19 and antigen tests must have CLIA Certificate of Compliance or Accreditation for Moderate or High Complexity Testing unless designated as a CLIA waived test (QW) by the FDA.
- 4) COVID-19 Antibody testing must have CLIA Certificate of Compliance or Accreditation for Moderate or High Complexity Testing.

Covered Procedure Codes*

**NY Medicaid covered codes may differ and follow NYS guidelines*

CPT/HCPCS	Description
U0001	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
U0002 (QW)	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) 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
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 and time of specimen collection. (List separately in addition to either HCPCS code U0003 or U0004)
0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed
0240U	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected (Xpert® Xpress SARSCoV-2/Flu/RSV (SARS-CoV-2 & Flu Targets only), Cepheid)
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 (Xpert® Xpress SARSCoV-2/Flu/RSV (all targets), Cepheid)
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])

Reimbursement Policy:

COVID-19 Testing

(Commercial, Medicare and Medicaid)

CPT/HCPCS	Description
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 (SARSCoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
87426	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme- linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; 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
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
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])

Not Covered Procedure Codes:

CPT/HCPCS	Description
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

Reimbursement Policy:
COVID-19 Testing
(Commercial, Medicare and Medicaid)

CPT/HCPCS	Description
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
0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum

Considered Not Covered Under Standard Benefit Plan Language:

ICD-10 Code	Description
Z02.0	Z02.0 Encounter for examination for admission to educational institution
Z02.1	Z02.1 Encounter for pre-employment examination
Z02.3	Encounter for examination for recruitment to armed forces
Z02.5	Encounter for examination for participation in sport
Z02.6	Encounter for examination for insurance purposes
Z02.71	Encounter for disability determination
Z02.79	Encounter for issue of other medical certificate
Z02.89	Encounter for other administrative examinations
Z02.9	Encounter for administrative examinations, unspecified

COVID-19 Counseling (EH MEDICAID Plans only):

Effective December 1, 2021, New York State (NYS) Medicaid provides reimbursement for Coronavirus Disease 2019 (COVID-19) vaccination counseling to unvaccinated Medicaid members/enrollees to encourage the administration of the COVID-19 vaccine.

Coding and Reimbursement:

Reimbursement for COVID-19 vaccination counseling is limited to unvaccinated individuals who have not received an initial/first dose of the COVID-19 vaccine and do not have an appointment to receive an initial/first dose of the COVID-19 vaccine, but who are eligible to receive the COVID-19 vaccination.

Reimbursement Policy:
COVID-19 Testing
(Commercial, Medicare and Medicaid)

Service	CPT Code	Modifier	ICD-10	Reimbursement
COVID-19 Vaccine Counseling	99429 – Other Preventive Medicine Services	N/A	Z71.89 – Other Specified Counseling	\$25
COVID-19 Vaccine Counseling Provided via Audio-Only (Telephonic) Telehealth	99429 – Other Preventive Medicine Services	GQ	Z71.89 – Other Specified Counseling	\$25

For complete information, including billing and documentation guidelines, please refer to [NY State Medicaid COVID-19 Vaccine Counseling Coverage](#)

Background

The American Medical Association (AMA)

The AMA (May 14, 2020) recommended the following regarding serological testing for SARSCoV-2 antibodies:

- “Serology tests should not be offered to individuals as a method of determining immune status.
- Serology tests should not be used as the sole basis of diagnosis of COVID-19 infection.”

Centers for Disease Control and Prevention (CDC)

The CDC notes that not everyone needs to be tested. Recommendations regarding testing for the SARS-CoV-2 virus using diagnostic (molecular or antigen) tests have been published by the CDC (2021):

- Molecular or antigen tests are recommended to diagnose acute infection.
- Testing for SARS-CoV-2 should be conducted in consultation with a healthcare provider
- If an individual does not have COVID-19 symptoms and has not been in close contact with someone known to have SARS-CoV-2 infection (meaning being within 6 feet of an infected person for at least 15 minutes) a test is not needed unless recommended or required by your healthcare provider or public health official.

Reimbursement Policy:

COVID-19 Testing

(Commercial, Medicare and Medicaid)

- If an individual is symptomatic the healthcare provider may advise a SARS-CoV-2 test be performed
- If a test is positive, it does not need to be repeated for at least 3 months.
- Testing should be performed for an individual who has had close contact (within 6 feet for a total of 15 minutes or more) with someone with confirmed COVID-19.

Centers for Disease Control and Prevention (CDC) On May 4, 2020, the CDC published an initial evaluation of the performance of commercial antibody tests. The Center stated, “Antibody test results should not be used to diagnose someone with an active SARS-CoV-2 infection.” The CDC notes that depending on when someone is infected and when they obtain an antibody test, the test may not accurately find antibodies in someone who actually has an active infection. The CDC indicates that a test that will detect the SARS-CoV-2 virus should be used to test for active infection.

On May 23, 2020, the CDC issued interim guidelines for COVID-19 antibody testing with the following recommendations for the use of serologic tests, which included the following:

- “Serologic testing can be offered as a method to support diagnosis of acute COVID-19 illness for persons who present late. For persons who present 9-14 days after illness onset, serologic testing can be offered in addition to recommended direct detection methods such as polymerase chain reaction.”
- “Serologic testing should be offered as a method to help establish a diagnosis when patients present with late complications of COVID-19 illness, such as multisystem inflammatory syndrome in children.”

Infectious Diseases Society of America (IDSA)

Infectious Disease Society of America (IDSA, 2020): The IDSA published practice guidelines regarding testing for COVID-19, including the following indications where testing is suggested or recommended:

- A SARS-CoV-2 nucleic acid amplification test (NAAT) is recommended in symptomatic individuals in the community suspected of having COVID-19, even when the clinical suspicion for COVID-19 is low (strong recommendation, very low certainty of evidence).
- A single viral RNA test and not repeating testing is suggested in symptomatic individuals with a low clinical suspicion of COVID-19 (conditional recommendation, low certainty of evidence).
- Repeating viral RNA testing when the initial test is negative (versus performing a single test) is suggested in symptomatic individuals with an intermediate or high clinical suspicion of COVID-19 (conditional recommendation, low certainty of evidence). Intermediate/high clinical suspicion typically applies to the hospital setting and is based on the severity, numbers and timing of compatible clinical signs/symptoms.
- Using either rapid RT-PCR or standard laboratory based NAAT over rapid isothermal NAATs in symptomatic individuals suspected of having COVID-19 is suggested (conditional recommendation, low certainty of evidence).

Reimbursement Policy:

COVID-19 Testing

(Commercial, Medicare and Medicaid)

- SARS-CoV-2 RNA testing in asymptomatic individuals who are either known or suspected to have been exposed to COVID-19 is suggested (conditional recommendation, very low certainty of evidence). Known exposure was defined as direct contact with a laboratory confirmed case of COVID-19.
- SARS-CoV-2 RNA testing in asymptomatic individuals with no known contact with COVID-19 who are being hospitalized in areas with a low prevalence of COVID-19 in the community is suggested (conditional recommendation, very low certainty of evidence). Asymptomatic individuals are defined as those with no symptoms or signs of COVID-19. A low prevalence of COVID-19 in the community was considered communities with a prevalence of <2%.
- Direct SARS-CoV-2 RNA testing in asymptomatic individuals with no known contact with COVID-19 who are being hospitalized in areas with a high prevalence of COVID-19 in the community (i.e., hotspots) is recommended (conditional recommendation, very low certainty of evidence). Asymptomatic individuals are defined as those with no symptoms or signs of COVID-19. A high prevalence of COVID-19 in the community was considered communities with a prevalence of less than or equal to 10%.
- SARS-CoV-2 RNA testing in immunocompromised asymptomatic individuals who are being admitted to the hospital regardless of exposure to COVID-19 is recommended (strong recommendation, very low certainty of evidence). Immunosuppressive procedures are defined as cytotoxic chemotherapy, solid organ or stem cell transplantation, long acting biologic therapy, cellular immunotherapy, or high-dose corticosteroids.
- SARS-CoV-2 RNA testing (versus no testing) in asymptomatic individuals before immunosuppressive procedures regardless of a known exposure to COVID-19 is recommended (strong recommendation, very low certainty of evidence). Immunosuppressive procedures are defined as cytotoxic chemotherapy, solid organ or stem cell transplantation, long acting biologic therapy, cellular immunotherapy, or high-dose corticosteroids.
- The IDSA panel makes no recommendations for or against SARS-CoV-2 RNA testing before initiating immunosuppressive therapy in asymptomatic individuals with cancer (evidence gap).
- The IDSA panel makes no recommendations for or against SARS-CoV-2 RNA testing before the initiation of immunosuppressive therapy in asymptomatic individuals with autoimmune disease (evidence gap).
- SARS-CoV-2 RNA testing in asymptomatic individuals (without known exposure to COVID-19) who are undergoing major time-sensitive surgeries is suggested (conditional recommendation, very low certainty of evidence). Time-sensitive surgery is defined as medically necessary surgeries that need to be done within three months. Testing should ideally be performed as close to the planned surgery as possible (e.g. within 48-72 hours).
- SARS-CoV-2 RNA testing in asymptomatic individuals without a known exposure to COVID-19 who are undergoing a time-sensitive aerosol generating procedure (e.g., bronchoscopy) when PPE is available is not suggested (conditional recommendation, very low certainty of evidence). Time-sensitive procedures defined as medically necessary procedures that need to be done within three months. Procedures considered to be aerosol generating (i.e., bronchoscopy, open suctioning of airways, sputum induction, cardiopulmonary resuscitation, endotracheal intubation and extubation, non-invasive ventilation (e.g., BiPAP, CPAP), bronchoscopy, manual ventilation).

Reimbursement Policy:

COVID-19 Testing

(Commercial, Medicare and Medicaid)

- SARS-CoV-2 RNA testing in asymptomatic individuals without a known exposure to COVID-19 who are undergoing a time-sensitive aerosol generating procedure (e.g., bronchoscopy) when PPE is limited, and testing is available is suggested (conditional recommendation, very low certainty of evidence). Time sensitive procedures are defined as medically necessary procedures that need to be done within three months. Testing should be performed as close to the planned procedure as possible (e.g. within 48-72 hours). Decisions about PPE will be dependent on test results because of limited availability of PPE. However, there is a risk for false negative test results, so caution should be exercised for those who will be in close contact with/exposed to the patient's airways. Procedures considered to be aerosol generating (i.e., bronchoscopy, open suctioning of airways, sputum induction, cardiopulmonary resuscitation, endotracheal intubation and extubation, non-invasive ventilation (e.g., BiPAP, CPAP), bronchoscopy, manual ventilation). The decision to test asymptomatic patients will be dependent on the availability of testing resources. This recommendation does not address the need for repeat testing if patients are required to undergo.

The IDSA also notes potential utility of antibody (serology) testing in SARS-CoV-2 includes:

- Detection of PCR-negative cases, especially for patients who present late with a very low viral load below the detection limit of RT-PCR assays, or when lower respiratory tract sampling is not possible;
- Identification of convalescent plasma donors;
- Epidemiologic studies of disease prevalence in the community;

IDSA in their COVID-19 antibody testing primer (updated May 4, 2020) stated, "Unlike molecular tests for COVID-19 (e.g. PCR), antibody tests may be better suited for public health surveillance and vaccine development than for diagnosis. The current antibody testing landscape is varied and clinically unverified, and these tests should not be used as the sole test for diagnostic decisions"

The U.S. Food and Drug Administration (FDA)

Revised guidance from the FDA issued May 11, 2020, stated that the terms "serological" or "antibody" tests "are generally used to refer to tests that detect antibodies to the SARS-CoV-2 virus. Because the antibodies are part of the body's immune response to exposure and not the virus itself, such testing cannot be used for diagnosis of infection." In information to patients and consumers current as of July, 29, 2020, the FDA stated: "An antibody test does not detect the presence of the SARS-CoV-2 virus to diagnose COVID-19. These tests can return a negative test result even in infected patients (for example, if antibodies have not yet developed in response to the virus) or may generate false positive results (for example, if antibodies to another coronavirus type are detected), so they should not be used to evaluate if you are currently infected or contagious (ability to infect other people)."

The FDA (2020) also notes that antigen tests should not be used as the sole basis for treatment or for patient management decisions and should be treated as presumptive and confirmed with a molecular assay if necessary, for patient management (FDA, 2020). The analytic sensitivity, specificity and positive and negative predictive values of individual tests that have received an FDA EUA designation can also be accessed on the FDA website at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policyframework/emergency-use-authorization#covid19euas>. The CDC (2020) notes evaluating the results of an antigen test for SARS-CoV-2 should take into account the performance characteristics (e.g., sensitivity, specificity) and the instructions for use of the FDA-authorized assay, the prevalence of SARS-CoV-2 infection

Reimbursement Policy:

COVID-19 Testing

(Commercial, Medicare and Medicaid)

in that particular community (positivity rate over the previous 7–10 days or the rate of cases in the community), and the clinical and epidemiological context of the person who has been tested.

Large Respiratory Viral Panels

Large respiratory panel testing conducted on a series of 1206 patients with suspected COVID-19 during the 2020 pandemic found modest rates of co-infection between severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and other respiratory pathogens (20%). However, the authors found that testing for non-SARS-CoV-2 respiratory pathogens (influenza A/B, respiratory syncytial virus, non-SARS-CoV-2 Coronaviridae, adenovirus, parainfluenza 1-4, human metapneumovirus, rhinovirus/ enterovirus, Chlamydia pneumoniae, Mycoplasma pneumonia) did not change disease management unless co-infection indicated the presence of virus amenable to targeted therapy (for example, neuraminidase inhibitors for influenza in appropriate patients) (Kim, 2020).

At this time, the evidence supporting RVP testing in the outpatient setting is limited to individuals who are at high risk for complications of respiratory viral infection, including immunocompromised individuals as well as including lung transplant recipients, when the result of testing is used to guide or alter management. Evidence does not demonstrate clinical utility in average risk individuals; use of these tests have not been shown to change treatment decisions and improve subsequent clinical outcomes. Large viral panels containing 6 or more pathogen targets have not demonstrated clinical utility as compared to targeted viral panels containing 5 or less pathogen targets in the outpatient setting.

References

1. Centers for Disease Control and Prevention (CDC). Coronavirus Disease 2019 (COVID-19): Evaluating and Reporting Persons Under Investigation (PUI). Centers for Disease Control and Prevention. Updated March 17, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html>. Accessed April 12, 2021.
2. Centers for Medicare and Medicaid Services (CMS). Public Health News Alert: CMS Develops New Code for Coronavirus Lab Test. CMS.gov. Feb. 13, 2020. <https://www.cms.gov/newsroom/press-releases/public-health-news-alert-cms-develops-new-code-coronavirus-lab-test>. Accessed April 12, 2021.
3. CDC. ICD-10-CM Official Coding Guidelines -Supplement Coding encounters related to COVID-19 Coronavirus Outbreak. Centers for Disease Control and Prevention. April 1, 2020 through September 30, 2020. <https://www.cdc.gov/nchs/data/icd/COVID-19-guidelines-final.pdf>. Accessed April 12, 2021.
4. McIntosh, K. Coronavirus disease 2019 (COVID-19). UpToDate. Hirsch MS, Bloom A (Eds.). <https://www.uptodate.com/landing/covid19?search=Coronavirus%20disease%202019>. Accessed April 12, 2021.
5. Wu Z, McGoogan JM. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention. JAMA 2020.
6. CDC. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19). Centers for Disease Control and Prevention. Updated Feb. 26, 2021. <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>. Accessed April 12, 2021.

Reimbursement Policy:

COVID-19 Testing

(Commercial, Medicare and Medicaid)

7. CDC. FAQs on Testing for SARS-CoV-2: Serology/Antibody Test FAQs. Centers for Disease Control and Prevention. Updated November, 2020. <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#serology>. Accessed November 11, 2020.
8. Echavarría M, Marcone DN, Querci M, et al. Clinical impact of rapid molecular detection of respiratory pathogens inpatients with acute respiratory infection. J Clin Virol. 2018; 108:90-95.
9. Babady NE, England MR, Jurcic Smith KL, et al. Multicenter evaluation of the ePlex respiratory pathogen panel for the detection of viral and bacterial respiratory tract pathogens in nasopharyngeal swabs. J Clin Microbiol. 2018; 56(2). pii:e01658-17.
10. Kim D, Quinn J, Pinsky B, et al. Rates of Co-infection between SARS-CoV-2 and other respiratory pathogens. JAMA. 2020Apr 15; [Epub ahead of print]. Available at: <https://jamanetwork.com/journals/jama/fullarticle/2764787>. Accessed April 12, 2021.
11. FDA. Policy for Coronavirus Disease – 2019 Tests During the Public Health Emergency (Revised). Updated May 11, 2020. Accessed October 14, 2020. <https://www.fda.gov/media/135659/download>. Accessed April 12, 2021.
12. FDA. Antibody (Serology) Testing for COVID-19; Information for Patients and Consumers. <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/antibody-serology-testing-covid-19-information-patients-and-consumers>. Current as of July 29, 2020. Accessed April 12, 2021.
13. Infectious Diseases Society of America. Guidelines on the Diagnosis of COVID-19: Serologic Testing <https://www.idsociety.org/practice-guideline/covid-19-guideline-serology/>. Updated 8/18/2020. Accessed August 12, 2021.
14. Centers for Disease Control and Prevention (CDC). Information for healthcare professionals about coronavirus (COVID-19). Overview of testing for SARS-CoV-2. Updated Oct 21, 2020. Accessed August 16, 2021. Available at URL address: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>
15. Centers for Disease Control and Prevention (CDC). COVID-19 Pandemic planning scenarios. Updated Sep 10, 2020. Accessed August 16, 2021. Available at URL address: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html#box>
16. Infectious Disease Society of America (IDSA). Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19. May 6, 2020. Accessed August 16, 2021. Available at URL address: <https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics/>
17. Centers for Disease Control and Prevention (CDC). Information for healthcare professionals about coronavirus (COVID-19). Overview of testing for SARS-CoV-2. Updated Oct 21, 2020. Accessed August 16, 2021. Available at URL address: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>

Revision History

Company(ies)	DATE	REVISION
EmblemHealth ConnectiCare	March 16, 2022	<ul style="list-style-type: none"> • Updated policy to align with CMS; Modifier CS must be appended to services related to determining the need for COVID test effective 6/01/2022

Reimbursement Policy:
COVID-19 Testing
(Commercial, Medicare and Medicaid)

Company(ies)	DATE	REVISION
EmblemHealth	Jan 13, 2022	<ul style="list-style-type: none"> Added content regarding NY State Medicaid reimbursement for COVID-19 Vaccine Counseling effective 12/01/2021. <i>Applicable only to EH Medicaid Plans.</i>
EmblemHealth ConnectiCare	Nov 19, 2021	<ul style="list-style-type: none"> Reformatted and reorganized policy, transferred content to new template. Clarified when test is considered covered.
EmblemHealth ConnectiCare	Jun. 11, 2021	<ul style="list-style-type: none"> Added text communicating that antibody testing to assess immunity after COVID-19 vaccination is not covered commensurate with the FDA’s safety communication
EmblemHealth ConnectiCare	Nov. 11, 2020	<ul style="list-style-type: none"> New Policy