Testing for Coronavirus Disease 2019 (COVID-19)

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Overview

There are two main types of tests for the SARS-CoV-2 virus: diagnostic (viral) tests and serologic (antibody) tests. A diagnostic 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.

Medically Necessary

SARS-CoV-2 Diagnostic Testing

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 CDC guidelines for evaluation and laboratory testing for COVID-19.

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 medically necessary when any of the following criteria are met:

- Individual is hospitalized for an acute illness suspected as coronavirus disease 2019 (COVID 19) infection.
- 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).
- 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.

Not Medically Necessary

- 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.
- SARS-CoV-2 serology (antibody) testing is considered not medically necessary to evaluate current infection or contagiousness or for any other scenario than described above.
- Until more information is available about the dynamics of IgA detection in serum, testing for IgA antibodies is not recommended.
- 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.

Limitations and Exclusions (unless mandated otherwise by applicable law)

- 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 are not covered.
- Tests that have not been approved for use by the FDA or authorized per FDA EUA guidelines.

Member's medical records must document that services are medically appropriate for the care provided. EmblemHealth 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 EmblemHealth upon request. Failure to produce the requested information may result in denial or retraction of payment.

Coding/Billing Information

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 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

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])
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 Medically Necessary Procedure Codes

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
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

Covered ICD-10 Diagnosis Codes

B34.2	Coronavirus infection, unspecified
J02.8	Acute pharyngitis due to other specified organisms
J02.9	Acute pharyngitis, unspecified
J34.89	Other specified disorders of nose and nasal sinuses
M79.10	Myalgia, unspecified site
M79.11	Myalgia of mastication muscle
M79.12	Myalgia of auxiliary muscles, head and neck
M79.18	Myalgia, other site
R05	Cough
R06.02	Shortness of breath
R07.89	Other chest pain
R09.81	Nasal congestion
R11.0	Nausea
R11.10	Vomiting, unspecified
R11.11	Vomiting without nausea
R11.2	Nausea with vomiting, unspecified
R19.7	Diarrhea, unspecified
R23.0	Cyanosis
R41.82	Altered mental status, unspecified

R43.0	Anosmia
R43.1	Parosmia
R43.2	Parageusia
R43.8	Other disturbances of smell and taste
R50.9	Fever, unspecified
R51.0	Headache with orthostatic component, not elsewhere classified
R51.9	Headache, unspecified
R53.83	Other fatigue
R68.83	Chills (without fever)
U07.1	COVID-19
Z01.811	Encounter for preprocedural respiratory examination
Z01.812	Encounter for preprocedural laboratory examination
Z01.818	Encounter for other preprocedural examination
Z01.89	Encounter for other specified special examinations
Z03.818	Encounter for observation for suspected exposure to other biological agents ruled out
Z20.822	Contact with and (suspected) exposure to COVID-19 (eff. 01/01/2021)
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
Z51.11	Encounter for antineoplastic chemotherapy
Z51.12	Encounter for antineoplastic immunotherapy
Z79.52	Long term (current) use of systemic steroids

Non-Covered ICD-10 Diagnosis Codes

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
Z01.84	Encounter for antibody response examination
Z11.52	Encounter for screening for COVID-19 (eff. 01/01/2021)
Z11.59	Encounter for screening for other viral diseases

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)

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)

IDSA in their COVID-19 antibody testing primer (updated May 4, 2020) stated, "Unlike molecular tests for COVID-19 (eg, 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).".

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.

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Revision history

Jun. 11, 2021	Added text communicating that antibody testing to assess immunity after COVID-19 vaccination is not medically necessary commensurate with the FDA's safety communication
Nov. 11, 2020	New Policy