COVID-19 Testing Guidance

BlueCross BlueShield of Western New York

COVID-19 TESTING GUIDELINES

Health insurance covers medically necessary services, tests, and procedures that maintain or improve a member's health. Testing for purposes of employment or public health surveillance are not covered health insurance benefits. The cost for such tests may be covered by employers, or local, state, or federal government entities.

Please note: During the state of emergency, state and federal governments are issuing frequent COVID-19-related guidance. Our Health Plan's guidelines and communications are subject to change accordingly.

CLINICAL GUIDELINES

MOLECULAR OR ANTIGEN TESTING

Molecular or antigen testing for SARS-CoV-2 is considered **medically necessary** in the following circumstances when ordered by a healthcare provider or pharmacist who is allowed by state regulation to order and/or perform the test:

- Members with symptoms of COVID-19 (see Background below for details)
- Members without symptoms of COVID-19 who have been in close contact with and potentially exposed to an individual known to have a documented SARS-CoV-2 infection (see Background below for details)
- Members who require pre-admission or pre-procedure COVID-19 testing when ordered by a PCP or healthcare provider involved in the admission or procedure

Molecular or antigen testing for SARS-CoV-2 is considered **not medically necessary** in all other circumstances, including, but not limited to:

- No symptoms of COVID-19
- No close contact with an individual known to have a documented SARS-CoV-2 infection
- Targeted group screening after attending a public or private gathering of more than 10 people (without universal mask wearing and/or physical distancing)
- General population, work, or school screening for SARS-CoV-2
- Testing for return to work or school
- Testing related to travel without meeting the above medically necessary criteria

ANTIBODY TESTING

Antibody testing may be considered **medically necessary** to support the clinical assessment of a person who presents late in their COVID-19 illness when used in conjunction with viral detection tests.

Antibody testing may be considered **medically necessary** if a person is suspected to have a post-infectious syndrome caused by SARS-CoV-2 infection (e.g., Multisystem Inflammatory Syndrome in Children; MIS-C).

Antibody testing is considered **not medically necessary** in all other circumstances, including, but not limited to:

- Testing for the diagnosis of an acute infection when criteria above are not met
- Testing for diagnosis of a past infection in a person who had an undiagnosed acute illness compatible with COVID-19 and has completely recovered
- General population screening for the presence of antibodies to SARS-CoV-2
- Testing to confirm the presence of antibodies to SARS-CoV-2 for purposes of determining need for or efficacy of vaccinations in the general population (**Note**: this does not apply to immune deficient members whose clinical needs should be determined by the treating provider)

BACKGROUND

SYMPTOMS OF INFECTION

The signs and symptoms of COVID-19 present at the onset of the illness vary, but many people with COVID-19 will experience the following over the course of the disease:

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

Symptoms may differ with severity of disease. This list does not include all possible symptoms.

Emergency warning signs* of COVID-19 that indicate a person will need to **seek emergency medical care immediately:**

- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion
- Inability to wake or stay awake
- Bluish lips or face

*This list does not include all possible symptoms.

DEFINITION OF EXPOSURE/CONTACT

A **contact** or **exposure** is defined by the Centers for Disease Control and Prevention (CDC) as someone who had any contact with an infected person (probable or confirmed COVID-19 case) while they were infectious – starting from two (2) days before illness onset (or, for asymptomatic clients, two (2) days prior to positive specimen collection) until the time the individual is isolated.

Close contact is defined by New York State (NYS) Department of Health (DOH) as someone who was within six feet of an infected person for at least ten (10) minutes cumulative during the period beginning 48 hours before either the individual's onset of symptoms or before a positive test, until the individual was isolated. Individuals who are unsure of the extent of their contact with someone suspected or confirmed to have COVID-19 are instructed to contact their local health department (CDC and DOH) for clarification.

Proximate contact is defined by the NYS DOH as being in the same enclosed environment, such as a classroom, office, or gathering, for at least ten (10) minutes cumulative over 24 hours (but greater than six feet) from a person who has tested positive for COVID-19 or who is displaying symptoms of COVID-19.

DIAGNOSTIC TESTS

Point-of-Care Testing

Several SARS-CoV-2 diagnostic tests are authorized to be conducted entirely at the **point-of-care (POC)** without a sample being sent to a laboratory for analysis. The term "point-of-care" refers to a patient care setting, such as any of the following locations that meet certain requirements:

- Doctors' offices
- Nursing homes
- Urgent care centers
- Pharmacies
- School nurse offices
- Workplace health clinics

There are regulatory considerations that must guide the use of POC instruments for SARS-CoV-2 diagnostic purposes. Testing sites operating a POC diagnostic instrument must have a current certificate via the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

During the COVID-19 public health emergency, the Centers for Medicare & Medicaid Services (CMS) will permit a Certificate of Waiver laboratory to extend its existing certificate to operate a temporary COVID-19 testing site in an off-site location, such as a long-term care facility.

The temporary COVID-19 testing site is only permitted to perform waived tests, consistent with the laboratory's existing certificate and must be under the direction of the existing lab director.

See the US Food and Drug Administration (FDA) website for a list of the SARS-CoV-2 POC tests that have received Emergency Use Authorization (EUA). Tests that have been authorized for use in a POC setting will have a W, for Waived, in the Authorized Settings column of the FDA table. The laboratory or testing site must use a test authorized for POC use by FDA and must follow the manufacturer's instructions for each POC test.

Rapid POC Tests

These tests use a mucus sample from the nose or throat but can be analyzed at the doctor's office or clinic where the sample is collected, and results may be available in minutes. These may be molecular or antigen tests.

Tests Intended for At-Home Testing

Tests intended for at-home testing (including tests where the individual performs self-collection of a specimen at home), when the test is ordered by an attending health care provider who has determined that the test is medically necessary for the individual based on current accepted standards of medical practice. The FDA has authorized COVID-19 tests for use with at-home collection of samples — such as from the nose or saliva — and is also aware of developers who are conducting Institutional Review Board (IRB)-approved studies of COVID-19 tests that use at-home collection of test samples. All tests that have received an EUA, including any authorizations for home collection of a specimen, can be found on the FDA's Emergency Use Authorizations page.

Collection and Handling of Clinical Specimens

Proper collection of specimens is the most important step in the laboratory diagnosis of infectious diseases. A specimen that is not collected correctly may lead to false negative test results. All testing for SARS-CoV-2, including rapid antigen testing, is directly impacted by the integrity of the specimen, which depends on specimen collection and handling. Improper specimen collection may cause some swabs to have limited amounts of viral genetic or antigenic material for detection. Inadequate quality assurance procedures could result in cross contamination of the specimen, which could cause inaccurate test results. Delays from sample collection to testing should be minimized. Biosafety measures and instructions for use should be followed precisely to ensure accurate testing and safety of those who perform the testing.

TYPES OF ANTIGEN TESTING

Antigen tests can be used in a variety of testing strategies to respond to the COVID-19 pandemic.

Definition of Diagnostic Testing

Diagnostic testing for SARS-CoV-2 is intended to identify current infection in individuals and is performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has had recent known or suspected exposure to SARS-CoV-2. Examples of diagnostic testing include testing symptomatic persons, testing persons identified through contact tracing, and testing those who indicate that they were exposed to someone with a confirmed or suspected case of COVID-19.

Definition of Screening Testing

Screening testing for SARS-CoV-2 is intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. Screening testing is performed to identify persons who may be contagious so that measures can be taken to prevent further transmission. Examples of screening include testing in congregate settings, such as a long-term care facility or a correctional facility, a workplace testing its employees, or a school testing its students, faculty, and staff.

Definition of Surveillance Testing

Public health surveillance is the ongoing, systematic collection, analysis, and interpretation of health-related data essential to planning, implementation, and evaluation of public health practice. Surveillance testing does not involve returning a diagnostic test result to an individual, or for individual decision-making. An example of surveillance testing is a plan developed by a state public health department to randomly select and sample a percentage of all persons in a city on a rolling basis to assess local infection rates and trends.

For additional information, please review the resources on the following page.

RESOURCES

- American Medical Association's Serological Testing for SARS-CoV-2 Antibodies
- CDC Appendices
- CDC Symptoms of Coronavirus
- CDC Interim Guidelines for COVID-19 Antibody Testing
- CDC Guidance for SARS-CoV-2 Point-of-Care Testing
- Families First Coronavirus Response Act (FFCRA)
  Home Based Testing
- FDA Guidance for Point-of-Care Testing
- New York State Department of Health Guidance on Close or Proximate Contacts
- New York State Travel Advisory