Coronavirus Disease (COVID-19) Antibody Testing

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Coronavirus disease (COVID-19) is an infectious disease caused by the SARS-CoV-2 virus that can spread quickly. People may experience mild, moderate, or severe respiratory symptoms. Most people have mild symptoms, and some may have no symptoms at all. However, some people may become severely ill and require acute care. It is important to be well-informed about how to prevent getting sick or becoming seriously ill with COVID-19 by taking precautionary measures such as vaccines, washing hands, wearing a mask, or keeping social distance (especially if someone is coughing, sneezing, etc.,).

Antibodies are proteins produced by the immune system to help fight infection and protect against getting sick in the future. An antibody test for COVID-19 can help detect whether a member has been vaccinated for COVID-19 or was sick with COVID-19 in the past; however, there is a delayed response as tests can detect the presence of antibodies anywhere from a few days to weeks post infection or vaccination. The antibodies provide protection, but only for a limited period of time and the length of time may change per member. Antibody tests do not diagnose current cases of COVID-19 infection. As per Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA), antibody tests are not recommended for the purpose of assessing immunity after COVID-19 vaccine or the need for vaccine in an unvaccinated member. They should not be used to determine if a member can return to school or work, exempt a member to wear personal protective equipment (PPE) at work, or group people together in correctional facilities, dormitories, or schools.

Antibody tests can have value for public health monitoring at the population level for immunity, support the diagnosis of multisystem inflammatory syndrome in children (MIS-C) and in adults (MIS-A).

Please refer to the CDC's website, the FDA's website, or the WHO's website for COVID-19 antibody testing information.

Definitions

"Antibodies" are proteins produced by the immune system to help fight infection and protect against getting sick in the future from that specific disease.

"Antigens" are any foreign substance, such as the SARS-CoV-2 virus, that invades the body and induces the immune system to produce antibodies.

"Anti-SARS-CoV-2 Monoclonal Antibodies" are laboratory-made proteins that behave similar to the immune system to fight off harmful antigens or pathogens such as the SARS-CoV-2 virus.

There were 6 previously approved anti-SARS-CoV-2 mAb products that have received Emergency Use Authorizations (EUA) from the FDA for the treatment of outpatients with mild to moderate COVID-19: bamlanivimab, bamlanivimab plus etesevimab, bebtelovimab, casirivimab plus imdevimab, sotrovimab, tixagevimab plus cilgavimab). However, the FDA revised the EUA use of these 6 drugs and are not recommended for the treatment or prevention of COVID-19 by the COVID-19 Treatment Guidelines Panel (the Panel). The SARS-CoV-2 virus can mutate over time and are not currently authorized for use in the U.S. because the monoclonal antibodies are not expected to work effectively for the circulating dominant Omicron subvariants.

However, in April 2023, the FDA has issued an EUA approval for Gohibic (vilobelimab) for the treatment of coronavirus disease 19 (COVID-19) in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV), or extracorporeal membrane oxygenation (ECMO). The COVID-19 Treatment Guidelines Panel has insufficient evidence to recommend either for or against the use of vilobelimab for the treatment of COVID-19. The federal COVID-19 Public Health Emergency ended in May 2023.

"COVID-19 vaccine" is an inactivated or weakened virus or protein that mimics the behavior of COVID-19 and can be formulated based on the original (ancestral) strain of SARS-CoV-2 and the Omicron BA.4 and BA.5 (BA.4/BA.5) variants of SARS-CoV-2. Dosage and administration depends on age and indication for the particular type of vaccine.

"Long COVID, Post-Covid" is when individuals have been infected by COVID-19 and experience long-term effects after the infection. As per CDC, HHS and other partners, Long COVID is broadly defined as signs, symptoms, and conditions that continue or develop after acute COVID-19 infection.

"Multisystem inflammatory syndrome in adults (MIS-A)" is a rare condition associated with SARS-CoV-2 infection in adults and less common than MIS-C. An adult may initially appear to have mild or no

symptoms after exposure, but then multiple organs may become inflamed such as the brain, eyes, gastrointestinal tract, heart, kidneys, lungs, or skin. This syndrome is serious and at times fatal, but with proper medical attention the member can get better.

"Multisystem inflammatory syndrome in children (MIS-C)" is a rare condition associated with SARS-CoV-2 infection in children and adolescents. A child may initially appear to have mild or no symptoms after exposure, but then multiple organs may become inflamed such as the brain, eyes, gastrointestinal tract, heart, kidneys, lungs, or skin. This syndrome is serious and at times fatal, but with proper medical attention the member can get better.

Clinical Indications

The plan considers COVID-19 antibody testing as appropriate when the member meets ALL of the following criteria:

1. The health care provider has ordered the test in an acute/emergent facility setting (emergency room, observation level of care, or inpatient level of care); *and*
2. The test has FDA Emergency Use Authorization (EUA), 510(k) clearance, or De Novo classification.

Please see this FDA EUA list for antibody tests. For a list of all SARS-CoV-2 serology tests that have been 510(k) cleared or granted de novo classification, see devices with product code QVP in the FDA's medical devices databases for 510(k) and De Novo.

Experimental or Investigational / Not Medically Necessary

Any of the following indications for COVID-19 antibody testing is considered NOT medically necessary by the Plan:

- Antibody tests to diagnose active COVID-19 infection.
- Antibody tests for the purpose of assessing immunity after COVID-19 vaccine or the need for vaccine in an unvaccinated member.
- Antibody tests to determine if a member can return to school or work.
- Antibody tests to request exemption for personal protective equipment (PPE) at work.
- Antibody tests to group people together in correctional facilities, dormitories, or schools.
- Antibody tests submitted to the Plan for public health monitoring at the population level for immunity

Applicable Billing Codes (HCPCS/CPT Codes)

Table 1. COVID-19 Antibody Testing	
CPT/HCPCS Codes considered appropriate if criteria are met:	
Code	*Description*
0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), includes titer(s), when performed
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
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])

Table 2. COVID-19 Antibody Testing		
Place of Service codes considered appropriate if criteria are met:		
Code	*Place of Service Name*	*Place of Service Description*
19	Off Campus-Outpatient Hospital	A portion of an off-campus hospital provider based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Effective January 1, 2016)
21	Inpatient Hospital	A facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by, or under, the supervision of physicians to patients admitted for a variety of medical conditions.
22	On Campus-Outpatient Hospital	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Description change effective January 1, 2016)

23	Emergency Room – Hospital	A portion of a hospital where emergency diagnosis and treatment of illness or injury is provided.

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Clinical Guideline Revision / History Information

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