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 vaccination, handwashing, wearing a mask, and maintaining social distance (especially if someone is coughing or sneezing).

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

Antibody tests may have public health value for monitoring immunity at the population level and 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 future illness from that specific disease.

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

"Anti-SARS-CoV-2 monoclonal antibodies (mAb)" are laboratory-made proteins that behave similarly to the immune system to fight off harmful antigens or pathogens such as the SARS-CoV-2 virus.

There were six anti-SARS-CoV-2 mAb products that previously received Emergency Use Authorizations (EUA) from the FDA for treating outpatients with mild to moderate COVID-19: bamlanivimab, bamlanivimab plus etesevimab, bebtelovimab, casirivimab plus imdevimab, sotrovimab, and tixagevimab plus cilgavimab. However, the FDA has revised the EUAs for these six products, and the COVID-19 Treatment Guidelines Panel (the Panel) no longer recommends their use for the treatment or prevention of COVID-19. Because the SARS-CoV-2 virus can mutate over time, monoclonal antibodies are not currently authorized for use in the U.S., as they are not expected to be effective against the circulating dominant Omicron subvariants.

However, in April 2023, the FDA 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 viral 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 depend on age and indication for the particular type of vaccine.

"Long COVID" or "post-COVID" is when individuals have been infected by COVID-19 and experience long-term effects after acute infection. According to the CDC, the Department of Health and Human Services (HHS), and other professional health organizations, long COVID is broadly defined as signs, symptoms, and conditions that persist 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 can be fatal, but with proper medical attention, people can recover.

"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 can be fatal, but with proper medical attention, people can recover.

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers COVID-19 antibody testing as appropriate when BOTH of the following criteria are met:

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

The following indications for COVID-19 antibody testing are considered NOT medically necessary by the Plan:

1. Antibody testing to diagnose active COVID-19 infection
2. Antibody testing to assess immunity after COVID-19 vaccination or to determine the need for vaccination in an unvaccinated member
3. Antibody testing to determine if a member can return to school or work
4. Antibody testing to request an exemption from personal protective equipment (PPE) at work

5. Antibody testing to group people together in correctional facilities, dormitories, or schools
6. Antibody testing for public health monitoring at the population level for immunity

Applicable Billing 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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