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BENEFIT COVERAGE GUIDELINE – 2.04.518

SARS-CoV-2 Serology (Antibody) Testing

Effective Date:	Mar. 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	Feb. 26, 2024	None
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Two kinds of tests are available for COVID-19: **viral tests**[1] and **antibody (serology) tests**[2].

- A viral test tells you if you have a current infection.
- An antibody test tells you if you had a previous infection.

"Viral tests[1] check samples from your respiratory system (such as swabs of the inside of the nose) to determine if you currently have an infection with SARS-CoV-2, the virus that causes COVID-19."

"Antibody tests[2] check your blood by looking for antibodies, which can show if you had a past infection with the virus that causes COVID-19. Antibodies are proteins that help fight off infections and usually provide protection against getting that disease again (immunity). Antibodies are disease specific. For example, measles antibody will protect a person who is exposed again to measles but will have no effect if the person is exposed to mumps."

Depending on the timing of the infection and of the test, an antibody test may not identify antibodies in someone with a current COVID-19 infection. Therefore, antibody tests should not be used as the sole test to diagnose COVID-19. A viral test is necessary to determine if you are currently infected.

COVID-19 antibody tests are covered for the purpose of supporting a COVID-19 diagnosis. The Families First Coronavirus Response Act ("FFCRA")[3] requires coverage of "in vitro diagnostic tests" for COVID-19. Federal regulatory guidance notes that antibody tests are used to detect antibodies against the SARS-CoV-2 virus, are intended for use in the diagnosis of the disease or

condition of having current or past infection with SARS-CoV-2, the virus which causes COVID-19," and references the U. S. Food and Drugs Administration's (FDA's) opinion that serological tests should not be used as the sole basis for diagnosis.[4] These services are to be provided "in accordance with accepted standards of current medical practice."[5] The Centers for Disease Control ("CDC") has published standards describing how antibody tests are used for the purposes of diagnosis.[6,7]

The purpose of this guideline is to describe the Plan's process to confirm that a serology test is used to support a diagnostic test for COVID-19. The Plan covers antibody tests used to support the diagnosis of the disease or condition of an individual. Testing performed for other purposes, such as public surveillance, is not covered. Tests performed on an inpatient basis are presumed to be for diagnostic purposes. Tests performed on an outpatient basis require confirmation that the test is for the diagnosis of the disease or condition of an individual, as described below.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Scope of Policy: Serological tests for SARS-CoV-2 performed in an outpatient place of service

Testing	Coverage Criteria
Serology testing for current/active infection with SARS-CoV-2	**In accordance with Centers for Disease Control (CDC) Interim Guidelines for COVID-19 Antibody Testing[6] issued May 23, 2020, and last updated September 21, 2021, and Overview of Testing for SARS-CoV-2[7] published on June 13, 2020, and last updated December 29, 2021:** **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 7-14 days after illness onset, serologic testing can be offered in addition to recommended direct detection methods such as polymerase chain reaction. This will

Testing	Coverage Criteria
	maximize sensitivity as the sensitivity of nucleic acid detection is decreasing and serologic testing is increasing during this time period. **Serologic testing should be offered as a method to help establish a diagnosis when individuals present with late complications of COVID-19 illness, such as multisystem inflammatory syndrome in children.** **Please note the following:** • "Serology assays do not typically replace direct detection methods as the primary tool for diagnosing an active SARS-CoV-2 infection." [6] In addition, the US Food and Drug Administration (FDA) states that serological tests should not be "used as the sole basis of diagnosis."[4] As such, serological tests will not be covered when provided as the sole basis of diagnosis for current infection with COVID-19. • The Plan relies on the Centers of Disease Control (CDC) as the source of accepted standard of medical practice for COVID-19 diagnostic testing.
Serology testing to determine past infection with SARS-CoV-2	**Serology tests to determine immune status of an individual are not covered because such testing is not in accordance with accepted standards of current medical practice.** **Please note the following:** • The Plan relies on the Centers of Disease Control (CDC) as the source of accepted standard of medical practice for COVID-19 diagnostic testing. CDC's Overview of Testing for SARS-CoV-2[7] states: "It is currently not clear whether a positive serologic test indicates immunity against SARS-CoV-2; serologic tests should not be used at this time to determine if an individual is immune."

Documentation Requirements
The individual's medical records submitted for review should document that coverage criteria are met. The record should include the following:

Documentation Requirements
• Office visit notes that contain the relevant history, physical and reason the test is being ordered **AND** • Name of the antibody test being performed **AND** • Documentation for how the test impacts the medical management of the individual

Coding

Code	Description
CPT	
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])
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])

Related Information

Definition of Terms

Diagnostic Testing: Testing to identify current infection in individuals that is performed when a person is displaying symptoms of COVID-19, or when a person is not symptomatic but has been recently exposed to SARS-CoV-2 (either a confirmed or suspected case of COVID-19).

Screening Testing: Testing to identify individuals who are not exhibiting symptoms of COVID-19 and who have not had a known or suspected exposure to SARS-CoV-2. Screening testing is used to identify individuals who may be contagious so that measures can be taken to prevent

further transmission of the virus (e.g., testing of a skilled nursing facility, correctional facility, employer testing employees, or schools testing students, faculty and staff).

Surveillance Testing: Testing for public health surveillance is an ongoing, systematic collection, analysis, and interpretation of health-related data for planning, implementation, and evaluation of public health practice. Surveillance testing for SARS-CoV-2 is used to monitor community or population level infection and disease rather than that of an individual, or to gain the incidence and prevalence of disease. Surveillance testing results are returned in aggregate to the requesting institution as the testing is performed only on de-identified specimens. Surveillance testing is not used to return a diagnostic test result to an individual or for individual decision-making (e.g., a public health department randomly selects and samples a percentage of all individuals in a city at intervals to assess local infection rates and trends).

Source: Centers for Disease Control and Prevention (National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases) Updated September 4, 2020.

Guidelines Review

Background

The purpose of this guideline is to describe the process that the Plan uses to determine if a service is a diagnostic test for COVID-19 in compliance with the relevant sections of the Families First Coronavirus Response Act (FFCRA)[3], Coronavirus Aid, Relief, and Economic Security (CARES) Act[8], and FAQs on Frequently Asked Questions (FAQ) on FFCRA and CARES Act, Part 42[4,5].

The Plan relies on the Centers of Disease Control (CDC) as the source of accepted standard of medical practice for COVID-19 diagnostic testing[6,7].

Practice Guidelines and Position Statements

Centers for Disease Control and Prevention (CDC)

Tests Used to Diagnose COVID-19

The CDC provides that two kinds of tests are available for COVID-19: viral tests and antibody tests.[7,9]

- "A viral test tells you if you have a current infection.
- An antibody test tells you if you had a previous infection."

The CDC Website states:

"**Viral tests**[1] check samples from your respiratory system (such as swabs of the inside of the nose) to tell you if you currently have an infection with SARS-CoV-2, the virus that causes COVID-19."[1]

"**Antibody tests**[2] check your blood by looking for antibodies, which can show if you had a past infection with the virus that causes COVID-19. Antibodies are proteins that help fight off infections and usually provide protection against getting that disease again (immunity). Antibodies are disease specific. For example, measles antibody will protect a person who is exposed again to measles but will have no effect if the person is exposed to mumps."

Depending on when someone was infected and the timing of the test, the test may not find antibodies in someone with a current COVID-19 infection. Antibody tests should not be used to diagnose COVID-19. To see if you are currently infected, you need a **viral test**.[1] Viral tests identify the virus in samples from your respiratory system, such as swabs from the inside of your nose.

Families First Coronavirus Response Act (FFCRA)[3]

Section 6001 of FFCRA Enacted March 18, 2020

This section requires private health insurance to cover testing for COVID-19 without imposing cost-sharing (e.g., deductibles, coinsurance, or copayments) for the duration of the public health emergency declared on January 31, 2020. This coverage includes the cost of administering such approved tests and related visits to health care providers. The public health emergency end date was May 11, 2023.

Coronavirus Aid, Relief, and Economic Security (CARES) Act[8]

Section 3201 of CARES Act Enacted March 27, 2020

This section expands the scope of available diagnostic testing for COVID-19 (i.e., coronavirus disease 2019) that private health insurance plans must cover. Specifically, it requires coverage of tests that have not been approved by the US Food and Drug Administration (FDA) if:

- The developer of such a test requests, or intends to request, emergency use authorization, unless such request is denied or is not submitted within a reasonable time;
- The test is developed and authorized in a state that has notified HHS that the state intends to review such tests; or
- HHS has issued guidance that such test is appropriate.

Frequently Asked Questions (FAQ) on FFCRA and CARES Act, Part 42[4.5]

Issued on April 11, 2020, this set out frequently asked questions (FAQs) regarding implementation of the Families First Coronavirus Response Act (the FFCRA)[3], the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act)[8], and other health coverage issues related to Coronavirus Disease 2019 (COVID-19).[4,5] These FAQs answer questions from stakeholders to help individuals understand the law and benefit from it, as intended.

Families First Coronavirus Response Act Enacted March 18, 2020[3]

- Section 6001 generally requires that Plans must provide services related to diagnostic testing for detection of SARS-CoV-2 or the diagnosis of COVID-19 from March 18, 2020, through applicable emergency period. The public health emergency end date was May 11, 2023.
- This coverage must be provided without cost-sharing, prior authorization, or other medical management requirements.

CARES Act Enacted March 27, 2020[8]

- Section 3201 of CARES Act amended section 6001 of FFCRA to include a broader range of diagnostic items and other services that Plans must cover without cost-sharing, prior authorization (PA) or medical management requirements.

Question Four from FAQ[4]:

Do "in vitro diagnostic tests" described in section 6001(a)(1) of the FFCRA, as amended by section 3201 of the CARES Act, include serological tests for COVID-19?

> Yes. Serological tests for COVID-19 are used to detect antibodies against the SARS-CoV-2 virus and are intended for use in the diagnosis of the disease or condition of having current or past infection with SARS-CoV-2, the virus which causes COVID-19. The Food and Drug Administration (FDA) currently believes such tests should not be used as the sole basis for diagnosis. FDA has advised the Departments that serological tests for COVID-19 meet the definition of an in vitro diagnostic product for the detection of SARS-CoV-2 or the diagnosis of COVID-19. Therefore, plans and issuers must provide coverage for a serological test for COVID-19 that otherwise meets the requirements of section 6001(a)(1) of the FFCRA, as amended by section 3201 of the CARES Act.

Question Six from FAQ[5]:

May a plan or issuer impose any cost-sharing requirements, prior authorization requirements, or medical management requirements for benefits that must be provided under section 6001(a) of the FFCRA, as amended by section 3201 of the CARES Act?

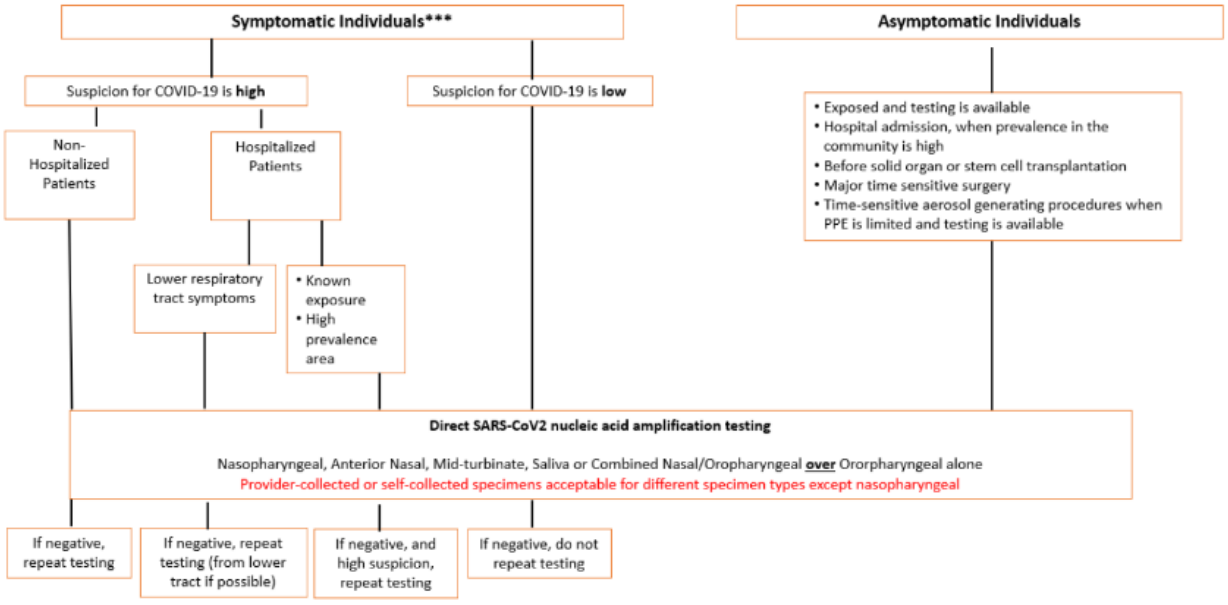
> No. Section 6001(a) of the FFCRA provides that plans and issuers shall not impose any cost-sharing requirements (including deductibles, copayments, and coinsurance), prior authorization requirements, or other medical management requirements for these items and services. These items and services must be covered without cost sharing when medically appropriate for the individual, as determined by the individual's attending healthcare provider in accordance with accepted standards of current medical practice.

Infectious Diseases Society of America (IDSA)[10]

In the Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19 (published May 6, 2020, and updated December 23, 2020) stated:

"…an expert panel consisting of clinicians, medical microbiologists and methodologists critically appraised the COVID-19 diagnostic literature using Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology to assess the certainty of evidence. Per GRADE, recommendations are categorized as "strong" or "conditional". The word "recommend" indicates strong recommendations and "suggest" implies conditional recommendations" See Figure 1: IDSA Algorithm for SARS-CoV-2 Nucleic Acid Testing (below).

Figure 1. IDSA Algorithm for SARS-CoV-2 Nucleic Acid Testing



*** Testing should be prioritized for symptomatic patients first.
When resources are adequate, testing for selected asymptomatic individuals can also be considered

Association of Public Health Laboratories (APHL)[11]

Public Health Considerations Serologic Testing for COVID-19, Version 1 May 7, 2019

In the document prepared by: Association of Public Health Laboratories **aphl.org** and **CSTE.org** with funding from CDC, the following information was provided:

Serologic assays have several important public health applications in the current coronavirus disease (COVID-19) response. Despite their importance, serologic assays do not replace molecular methods as the primary tool for the diagnosis of acute or active infection. One essential application is the use of high-quality serologic test methods to estimate the prevalence

of *past* viral infection or estimate the cumulative incidence of infection in the US population. Serologic testing can improve our understanding of disease transmission patterns and data from serologic surveys can be used to understand the proportion of persons previously infected, among various populations."

In order for these methods to be used effectively for both population level studies and individual use, scientists need more data on the performance characteristics of these tests and the human immune response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. This includes the persistence and protection offered by antibodies. Without this information, results from these methods cannot be properly interpreted.

With those caveats, potential public health applications include:

- Determining how widespread COVID-19 infection has been in a community or population to both understand the scale of the current pandemic and in preparation for future vaccine development and deployment.
- Identification of persons with an antibody response to serve as convalescent plasma donors.
- Determining if a person had an immune response to SARS-CoV-2, irrespective of whether they had symptoms or not. At this time there is not enough data to determine whether or not an immune response confers immunity or for how long.
- Until more evidence about protective immunity is available, serologic test results should not be used to make staffing decisions (return to work), decisions regarding the need for personal protective equipment, or need to discontinue social distancing measures.
- If used in conjunction with other diagnostic tests and clinical history etc., serologic tests may be used as part of the testing algorithm to establish a diagnosis of COVID-19 and identify probable cases.

The US Food and Drug Administration (FDA)

On April 17, 2020, and updated June 19, 2020, the FDA provided recommendations in a letter to health care providers on the Use of Serological (Antibody) Tests for COVID-19. The FDA recommended:

- "Do not use serological (antibody) tests as the sole basis to diagnose COVID-19 but instead as information about whether a person may have been exposed. "[12]

Regulatory Status

The US Food and Drug Administration (FDA) has issued emergency use authorizations (EUAs), an authorization that is available to certain products in a declared public health emergency, for certain antibody tests. The FDA also has a policy of enforcement discretion for certain laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) provided by CMS for performing high-complexity testing to develop and validate their own serological tests, called laboratory-developed tests (LTDs).[13] The FDA does not generally regulate antibody tests that are used for surveillance purposes only, where test results are not returned to patients or healthcare providers.

While there is a small number of commercial serological tests that have been granted EUAs, there are over a hundred serological tests currently on the market, some of which have not been validated or authorized by the FDA.[14]

References

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History

Date	Comments
05/27/20	New policy, approved May 26, 2020, effective for dates of service on or after May 27, 2020. Add to Pathology / Laboratory section. Serology testing may be considered medically necessary in the inpatient setting when previous diagnostic testing was performed and the individual exhibits acute illness. Use of serology testing alone is not medically necessary to determine a COVID-19 diagnosis.
06/10/20	Interim Review, approved June 9, 2020, effective June 10, 2020. Coverage criteria modified in accordance with CDC interim guidelines issued May 23, 2020, to include when used to support diagnosis of acute COVID-19 illness for persons presenting 9-14 days after illness onset, and 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.
07/01/20	Interim Review, approved June 18, 2020, effective July 1, 2020. Coverage criteria modified in accordance with CDC Interim Guidelines issued May 23, 2020 and the FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation, Q4 & Q6, published April 11, 2020. The Plan relies on the Centers of Disease Control (CDC) as the source of accepted standard of

Date	Comments
	medical practice for COVID-19 diagnostic testing and will cover serology testing for support in diagnosing persons presenting late or patients with late complications of COVID-19. Serology tests to determine immune status of an individual are not covered. References, reorganized, updated, and added.
07/01/20	Coding update. Added CPT code 0224U.
09/11/20	Coding update. Added CPT code 86413.
11/01/20	Interim Review, approved October 22, 2020. Added CDC definitions of diagnostic, screening, and surveillance testing to policy related information.
04/01/21	Annual Review, approved March 2, 2021. Benefit coverage guideline reviewed. References updated. Guideline statements unchanged.
02/01/22	Annual Review, approved January 24, 2022. Benefit coverage guideline reviewed. References updated. Guideline statements unchanged.
02/01/23	Annual Review, approved January 9, 2023. Benefit coverage guideline reviewed. References updated. Guideline statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
03/01/24	Annual Review, approved February 26, 2024. Benefit coverage guideline reviewed. Reference added. Guideline statements unchanged. Noted in the document that the public health emergency end date was May 11, 2023.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs, or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

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PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-607-0546 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-607-0546 (телетайп: 711).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 800-607-0546 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ ኣማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-607-0546 (መስማት ለተሳናቸው: 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-607-0546 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-607-0546 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-607-0546 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-607-0546 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-607-0546 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-607-0546 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-607-0546 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-607-0546 (ATS : 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-607-0546 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-607-0546 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-607-0546 (TTY: 711) تماس بگیرید.