COVID-19: In Vitro Diagnostic Testing

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Related Coverage Resources

COVID-19 Drug/Biologic Therapeutics

PURPOSE

Administrative Policies are intended to provide further information about the administration of standard Cigna benefit plans. In the event of a conflict, a customer’s benefit plan document always supersedes the information in an Administrative Policy. Coverage determinations require consideration of 1) the terms of the applicable benefit plan document; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Administrative Policies and; 4) the specific facts of the particular situation. Administrative Policies relate exclusively to the administration of health benefit plans. Administrative Policies are not recommendations for treatment and should never be used as treatment guidelines.

Administrative Policy

In vitro diagnostic testing using molecular, antigen or serologic tests is covered when the test is approved and performed in compliance with FDA Emergency Use Authorization (EUA) and/or guidance outlined in the Families First Coronavirus Response Act (FFCRA) or Coronavirus Aid, Response and Economic Security Act (CARES) for EITHER of the following:

- Molecular nucleic acid amplification testing and antigen testing
  - when a determination of active infection and or infectivity is needed based on clinical symptoms OR
  - there is concern for exposure to COVID-19

- Serologic (antibody) testing
  - when there is concern for the presence of an active infection or infectivity and the test will be used to aid in the diagnosis of COVID-19

Diagnostic or serologic tests using self-contained home based kits; or materials or methods, including specimen collection, not approved under the FDA EUA or alternative FDA non-review registration process are not covered.

General Background

Effective March 18, 2020 and March 21, 2020, respectively, the Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security Act (CARES) require a group health plan or health insurance issuer offering group or individual health insurance coverage (including a grandfathered health
plan as defined by the Patient Protection and Affordable Care Act) to provide coverage of in vitro diagnostic testing (i.e., molecular, serology/antibody) products:

- without cost sharing (including deductibles, copayments, and coinsurance)
- without prior authorization or other medical management requirements

According to the Acts:

- the test product should be approved, cleared or authorized under the Federal Food, Drug and Cosmetic Act for the detection or diagnosis of SARS-CoV-2 (COVID-19)
- the test is a clinical laboratory service performed in a laboratory (including a public health laboratory) certified to conduct high-complexity testing for which the developer has requested, or intends to request, emergency use authorization
- test is developed in a State that has notified the Secretary of Health and Human Services of its intention to review tests to diagnosis COVID-19
- other test that the Secretary determines appropriate in guidance

In Vitro Diagnostic Testing

There are currently three in vitro diagnostic methods to detect the presence of SARS-CoV-2. They are molecular (nucleic acid amplification [NAAT]) tests, antigen tests and serology (antibody) tests.

Molecular NAAT testing for COVID-19 is considered the gold standard to determine the presence or absence of COVID-19 virus and to make a diagnosis of active infection. Molecular testing involves the in vitro qualitative detection of ribonucleic acid (RNA) from the SARS-CoV-2. The test is highly accurate with near 100% analytic sensitivity and specificity. Performance is unknown in asymptomatic patients (FDA, 2020).

The antigen test detects the nucleocapsid protein antigen from SARS-CoV-2. The antigen is generally detectable during the acute phase of infection. Positive results indicate the presence of viral antigens, may not be the definite cause of disease. Clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management (FDA, 2020).

At this time, no antibody test has been validated to establish a diagnosis of SARS-CoV-2 infection; the primary role for such testing is to inform on exposure to a specific pathogen. Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized (FDA, 2020). Individuals may have detectable virus present for several weeks following seroconversion. Antibody testing may be used as an aid in diagnosis but is of limited value when COVID-19 infection is suspected because such testing cannot be used to rule in or out an active infection. Likewise a positive test does not necessarily assure immunity. Accuracy of an antibody test depends in part on the prevalence of the infection in the population. Sensitivity and specificity are typically reported between 80-95%. Clinical utility is uncertain, as current evidence calls in to question the relationship between the presence of antibodies and re-infection and or re-activation of the virus.

Multiple methods are used in formation and processing of both molecular and serologic tests, including the use of different probes, reagents and interpretation and reporting standards. It should be noted that lab developed tests tend to developed with a limited number of samples, and the statistical confidence intervals of the results may vary broadly as a result, decreasing with sample size.

U.S. Food and Drug Administration (FDA)

The FDA issued an emergency declaration (i.e., FDA Emergency Use Authorization [EUA]) to authorize emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV). This guidance gives direction for laboratories and commercial manufacturers to help accelerate the use of tests they develop in order to achieve more rapid and widespread testing capacity in the United States. Because of a concern for lack of adequate volume of tests, the FDA subsequently offered an alternative registration/attestation review process document indicating “we do not intend to object to commercial manufacturers developing and
distributing, and laboratories developing and using serological tests in laboratories or by health care workers at
the point of care that have not been reviewed by the FDA where the test developers notify the FDA that they
conducted their own validation and include disclaimers about the limitations of the results generated by their tests,
as outlined in the guidance document.” The FDA requires that the labs attest to the accuracy of the tests, register
them with the FDA, and ensure that there is no misrepresentation or suggestion made by the commercial
manufacturer that they are FDA approved.

The majority of tests authorized under the FDA EUA process are molecular nucleic acid-based pathogen tests; to
date one antigen test has received an EUA designation. Several serology/antibody tests have also been reviewed
by the FDA under the EUA process. For further information regarding in vitro diagnostic tests that have been
authorized by the FDA please review the FDA guidance at URL address: https://www.fda.gov/medical-
devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.

The settings in which an emergency use authorization (EUA)-authorized test may be used are described in the
Letter of Authorization. The majority of tests require that the sample be collected by a trained professional.
However, a recent EUA authorizes a self-collection product which may decrease exposure of potentially infectious
specimens to healthcare providers.

Processing of the test typically occurs in a laboratory with a moderate- or high-complexity Clinical Laboratory
Improvement Amendments (CLIA) accreditation certification. When the FDA authorizes a test under EUA for use
at the point of care, including settings such as physician offices, urgent care, outreach clinics, and temporary
patient care settings, a waiver of CLIA certification is required.

At present there are no FDA EUAs or other approval or registration pathways for self-contained combination
collection and testing kits that can be performed at home or office. The FDA has specifically noted that EUA
authorization does not apply to such tests. These kits may be produced by a variety of manufacturers and
distributed through a variety of channels, but there is no regulatory oversight to such test kits and no pathway for
FDA oversight at this time. The clinical usefulness of these tests is not proven as there is a lack of evidence to
support accuracy, specimen stability, and test methodology reliability. At this time these kind of kits tend to be
antibody based.

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.

Molecular/Nucleic Acid Testing

Considered Covered when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>87635</td>
<td>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</td>
</tr>
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<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>U0001</td>
<td>CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel</td>
</tr>
<tr>
<td>U0002</td>
<td>2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC</td>
</tr>
<tr>
<td>U0003†</td>
<td>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</td>
</tr>
<tr>
<td>U0004†</td>
<td>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</td>
</tr>
</tbody>
</table>
†Note: Should not be used for tests that detect COVID-19 antibodies.

Serologic (antibody) Testing

Considered Covered when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>86328</td>
<td>Immunoassay for infectious agent antibody(ies), qualitative or semi quantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])</td>
</tr>
<tr>
<td>86769</td>
<td>Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])</td>
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ICD-10 diagnosis codes for exposure to COVID-19

<table>
<thead>
<tr>
<th>ICD-10 CM Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>Z03.818</td>
<td>Encounter for observation for suspected exposure to other biological agents ruled out</td>
</tr>
<tr>
<td>Z20.828</td>
<td>Contact with and (suspected) exposure to other viral communicable diseases</td>
</tr>
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ICD-10 diagnosis codes for confirmed COVID-19 diagnosis

<table>
<thead>
<tr>
<th>ICD-10 CM Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>B97.29</td>
<td>Other coronavirus as the cause of diseases classified elsewhere</td>
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<tr>
<td>U07.1</td>
<td>COVID-19</td>
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ICD-10 diagnosis code for Preadmission or Pre-Surgical Testing

<table>
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<th>Description</th>
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<tbody>
<tr>
<td>Z01.812</td>
<td>Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), any specimen source</td>
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ICD-10 diagnosis code for Return to Work Testing

<table>
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<th>ICD-10 CM Codes</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Z02.79</td>
<td>Encounter for issue of other medical certificate</td>
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</table>


References


