09-J4000-73

Original Effective Date: 03/15/24

Reviewed: 02/12/25

Revised: 03/15/25

Subject: SARS-CoV-2 (COVID-19) Testing

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

To help prevent the spread of the SARS-CoV-2 virus (COVID-19 infection), antigen tests and molecular nucleic acid amplification tests are used to diagnose infections. Testing strategies for COVID-19 infection are provided by the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Infectious Diseases Society of America (IDSA). In general, emphasis is placed on identifying active infection with testing performed on anyone with current signs and symptoms consistent with COVID-19 or following a recent known or suspected exposure to the virus. However, if a person is exposed to COVID-19 but does not have symptoms, it is recommended to wait 2 to 5 days after the exposure before testing to prevent an inaccurate result. Additionally, if a negative test result occurs with an antigen test, it may be appropriate to consider using a laboratory-based molecular COVID-19 test. Tests for COVID-19 infection must be approved or cleared by the FDA or have received an Emergency Use Authorization (EUA).

POSITION STATEMENT:

SARS-CoV-2 (COVID-19) testing **meets the definition of medical necessity** when **ALL** of the following are met:

1. **ONE** of the following (a, b, or c):
    a. Member has symptoms of COVID-19 (e.g., cough, difficulty breathing, fatigue, fever, headache, nasal congestion, new loss of sense of taste or smell, sore throat)
    b. Member is asymptomatic with a known exposure to another individual with suspected or confirmed COVID-19
    c. Member is asymptomatic and undergoing pre-admission or pre-procedural testing
2. Ordered by a physician or other licensed healthcare professional who treats COVID-19

3. Test is either an antigen or molecular diagnostic test that is approved or cleared by the FDA or has received EUA
4. Testing does not exceed two tests total per month (e.g., PCR molecular test after a negative antigen test)

Approval duration: 6 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA approved or cleared/Emergency Use Authorization Tests

- The most current list of FDA approved or cleared COVID-19 tests can be found here: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-tests-granted-traditional-marketing-authorization-fda
- The most current list of COVID-19 antigen diagnostic tests with EUAs can be found here: https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2
- The most current list of COVID-19 molecular diagnostic tests with EUAs can be found here: https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- None

Precautions/Warnings

- None

BILLING/CODING INFORMATION:

HCPCS Coding

86328	Rapid Response COVID-19 Test Kit
87811	QuickVue at-home COVID-19 Test Kit
87635	ID Now COVID-19 Test Kit
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC

ICD-10 Diagnosis Codes That Support Medical Necessity

B34.2	*Coronavirus infection, unspecified*
U07.1	COVID-19
Z11.52	Encounter for screening for COVID-19
Z20.822	Contact with and (suspected) exposure to COVID-19

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

None

RELATED GUIDELINES:

None

OTHER:

None

REFERENCES:

1. Centers for Disease Control and Prevention. Considerations for testing in different scenarios. Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html#ConsiderationsScenarios Accessed 1/30/24.
2. Centers for Disease Control and Prevention. Testing for COVID-19. Available at: https://www.cdc.gov/covid/testing/index.html Accessed 1/28/25.

3. Infectious Diseases Society of America. Guideline on the Diagnosis of COVID-19: Molecular Diagnostic Testing. Available at: https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics/#null Accessed 1/28/25.
4. US Food and Drug Administration. COVID-19 Tests Granted Traditional Marketing Authorization by the FDA. Available at: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-tests-granted-traditional-marketing-authorization-fda . Accessed 1/28/25.
5. US Food and Drug Administration. In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2. Available at: https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2 . Accessed 1/28/25.
6. US Food and Drug Administration. In Vitro Diagnostics EUAs - Molecular Diagnostic Tests for SARS-CoV-2. Available at: https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2 . Accessed 1/28/25.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 02/12/25.

GUIDELINE UPDATE INFORMATION:

03/15/24	New Medical Coverage Guideline – SARS-CoV-2 (COVID-19) antigen and molecular diagnostic testing.
03/15/25	Review and revision to guideline; consisting of updating references.