

Clinical Policy: COVID-19 Test Quantity Limit

Reference Number: MDN.CP.PMN.357

Effective Date: 9.1.26

Last Review Date: 7.10.26

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Coronavirus-2019 (COVID-19) testing kits are used to detect current infection with SARS-CoV-2 virus.

FDA Approved Indication(s): COVID-19 test kits are FDA-authorized over-the-counter diagnostic tests intended for self-testing at home or other locations to detect current infection with SARS-CoV-2, the virus that causes COVID-19.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that COVID-19 test kits in excess of 8 kits per 365 days are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. COVID-19 Test in excess of 8 tests/365 days (must meet one of the following):

1. Immunocompromised status (e.g., transplant recipient, active cancer treatment, advanced immunodeficiency).
2. Documentation of need for frequent testing ordered as recommended by a provider due to a chronic condition or high-risk medical status.
3. Recent exposure or recurring symptoms requiring serial testing.
4. Residence or employment in a high-risk setting where frequent testing is medically necessary.

Approval Duration: Duration of request or 3 months (whichever is less)

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. COVID 19 Test in excess of 8 tests/365 days:

1. Previously authorized to receive > 8 COVID-19 test kits in a 365-day period via Centene benefit or member has previously met the initial approval criteria;
2. Provider submits a letter of medical necessity detailing why the member must continue to perform testing

Approval duration: Duration of request or 3 months (whichever is less)

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents;

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

COVID-19: Coronavirus-2019

Appendix B: General Information

COVID-19 test kits are diagnostic tests used to detect a current infection with SARS-CoV-2, the virus that causes COVID-19. Most over-the-counter at-home test kits are antigen tests, which detect viral proteins and typically provide results in 15–30 minutes.

At-home COVID-19 antigen tests are authorized for self-testing and can be used without a prescription. A positive result generally indicates a current COVID-19 infection. A negative antigen test does not fully rule out infection, especially early in illness or when symptoms are

present; repeat testing 48 hours apart may be recommended according to FDA instructions. Users should follow the test manufacturer's instructions, including proper sample collection, timing, storage, and expiration date guidance.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): None
- Boxed warning(s): None

V. Product Availability

Varies by manufacturer

VI. References

1. Food and Drug Administration. At-Home OTC COVID-19 Diagnostic Tests. Available at: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests>. Accessed July 13, 2026.
2. Food and Drug Administration. Understanding At-Home OTC COVID-19 Antigen Diagnostic Test Results. Available at: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/understanding-home-otc-covid-19-antigen-diagnostic-test-results>. Accessed July 13, 2026.
3. Centers for Disease Control and Prevention. Testing for COVID-19. Available at: <https://www.cdc.gov/covid/testing/index.html>. Accessed July 13, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created per HFS PDL	07.10.26	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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