

Clinical Policy: Diagnostic Testing Guidelines for 2019-Novel Coronavirus

Reference Number: CP.MP.183

Last Review Date: 07/20

[Coding Implications](#)

[Revision Log](#)

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

Description

Coronavirus disease 2019 (COVID-19) is caused by the virus SARS-CoV-2. Clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Most patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing).¹

Other considerations that may guide testing are epidemiologic factors such as the occurrence of local community transmission of COVID-19 infections in a jurisdiction. Clinicians are strongly encouraged to test for other causes of respiratory illness.¹

Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation[®] that nucleic acid and antigen tests that are FDA approved or authorized under the FDA Emergency Use Authorization (EUA) for diagnosing COVID-19 are **medically necessary** when following the CDC guidelines for evaluation and laboratory testing for COVID-19.

Note: *CDC guidance for COVID-19 testing may be adapted by state and local health departments to respond to rapidly changing local circumstances.*

Categories for nucleic acid and antigen testing:

- A. Individuals with signs or symptoms consistent with COVID-19 (e.g., fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, or diarrhea);
- B. Asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2 to control transmission;
- C. Asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings (e.g., vulnerable populations in close quarters for extended periods of time);
- D. Neonates meeting all of the following:
 - 1. Requested test is a reverse transcription polymerase chain reaction (RT-PCR);
 - 2. Born to a mother with confirmed or suspected COVID-19, regardless of mother's symptoms;
 - 3. Testing timeline meets one of the following:
 - a. Initial test at approximately 24 hours of age, or for asymptomatic neonates expected to be discharged <48 hours of age, between 24-48 hours of age;
 - b. At 48 hours of age if initial test results are negative, or not available;
- E. Individuals being tested to determine resolution of infection, one of the following:

CLINICAL POLICY
Diagnostic Testing Guidelines for 2019-Novel Coronavirus

1. Requested in order to discontinue transmission-based precautions or to enable healthcare provider return to work, and one of the following:
 - a. Symptomatic of, and has, COVID-19, and all of the following:
 - i. One of the following indications:
 - a) A test-based strategy could enable discontinuation of transmission-based precautions earlier than a symptom-based strategy;
 - b) Concern exists for the patient being infectious for more than 20 days (i.e. severely immunocompromised), and local infectious disease experts are consulted;
 - ii. Fever has resolved without fever-reducing medications;
 - iii. Respiratory symptoms such as cough and shortness of breath have improved;
 - iv. Up to two tests of respiratory specimens are requested;
 - v. If initial test is negative, second test is performed ≥ 24 hours from first test. The second test is not necessary if the first is positive;
 - b. Asymptomatic, with laboratory-confirmed COVID-19, and both of the following:
 - i. One of the following indications:
 - a) A test-based strategy could enable discontinuation of transmission-based precautions earlier than a symptom-based strategy;
 - b) Concern exists for the patient being infectious for more than 20 days (i.e. severely immunocompromised), and local infectious disease experts are consulted;
 - ii. Up to two tests of respiratory specimens are requested;
 - iii. If initial test is negative, second test is performed ≥ 24 hours apart. The second test is not necessary if the first is positive;
 2. Empiric transmission-based precautions are being considered for discontinuation, and both of the following:
 - a. COVID-19 is suspected;
 - b. One test is requested, or an additional test is requested after a negative first molecular assay for detection of SARS-CoV-2 RNA and there is a high level of clinical suspicion for COVID-19;
 3. Requested to discontinue home isolation for persons with confirmed or suspected COVID-19, or for healthcare providers to return to work, and all of the following:
 - a. Severely immunocompromised patient;
 - b. Local infectious disease experts have been consulted;
 - c. Up to two tests of respiratory specimens are requested;
 - d. If initial test is negative, second test is performed ≥ 24 hours from first test. The second test is not necessary if the first is positive.
- II.** It is the policy of health plans affiliated with Centene Corporation that serology or antibody tests for diagnosing acute COVID-19 infection is **medically necessary** for the following indications:
- A.** To support clinical assessment of those presenting late in illness, when used in conjunction with viral detection tests;
 - B.** When post-infection syndrome (e.g., Multisystem Inflammatory Syndrome in Children), caused by SARS-CoV-2 infection, is suspected.

CLINICAL POLICY
Diagnostic Testing Guidelines for 2019-Novel Coronavirus

Background

In late 2019, 2019-Novel Coronavirus (COVID-19) caused severe pneumonia cases clustered in Wuhan, China, and spread rapidly. The Chinese Center for Disease Control and Prevention released a report stating that of 44,500 infections in the sample, 81% were estimated as mild (no or mild pneumonia), 14 % were estimated as severe (e.g., with dyspnea, hypoxia, or >50 % lung involvement on imaging within 24 to 48 hours), 5% were critical (e.g., with respiratory failure, shock, or multiorgan dysfunction), and the overall case-fatality rate was 2.3%⁵.

COVID-19) is a betacoronavirus in the same subgenus as the severe acute respiratory syndrome (SARS) virus, and is also called (SARS-CoV-2).⁴ Infected people present with respiratory symptoms such as cough, dyspnea, pneumonia, and fever.

The U.S. Centers for Disease Control and Prevention (CDC) have released interim guidance on evaluating persons under investigation (PUI) for infection with COVID-19. The CDC developed a panel to test for COVID, called the 2019 Novel Coronavirus Real Time RT-PCR Diagnostic Test Panel. The panel received emergency use authorization by the FDA and is being distributed to public health and clinical laboratories.

Clinicians should immediately implement recommended infection prevention and control practices if a patient is suspected of having COVID-19.¹ They should also notify infection control personnel at their healthcare facility and their state or local health department if a patient is classified as a PUI for COVID-19.¹

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT Codes That Support Coverage Criteria

CPT® Codes	Description
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported
0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected

CLINICAL POLICY
Diagnostic Testing Guidelines for 2019-Novel Coronavirus

CPT® Codes	Description
0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed (Do not report 0224U in conjunction with 86769)
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])
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
87426	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19]).
87635	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

HCPCS Codes That Support Coverage Criteria

HCPCS Codes	Description
C9803	Hospital outpatient clinic visit specimen collection for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source
G2023	Specimen collection for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source
G2024	Specimen collection for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source
U0001	2019 Novel Coronavirus Real Time RT-PCR Diagnostic Test Panel
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC
U0003	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, making use of high throughput technologies as described by CMS-2020-01-R
U0004	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

ICD-10-CM Diagnosis Codes That Support Coverage Criteria

+ Indicates a code requiring an additional character

CLINICAL POLICY
Diagnostic Testing Guidelines for 2019-Novel Coronavirus

ICD-10-CM Code	Description
U07.1	COVID-19, confirmed by laboratory testing
Z03.818	Encounter for observation for suspected exposure to other biological agents ruled out
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed	02/20	03/20
Modified medical necessity statement to state that testing following CDC guidelines is medically necessary. Changed criteria to reflect CDC guidelines as of 3/4/20.	03/20	03/20
Added new CPT-87635.	03/20	
Updated description. Changed medical necessity statement to replace persons under investigation language with evaluation and laboratory testing for COVID-19. Modified criteria to reflect priorities for testing per 3/24/20 CDC update. Added that state and local health departments may adapt testing recommendations to respond to rapidly changing local circumstances. Added codes U07.1 and U07.2, and removed B97.27, J12.89, J20.8, J22, J40, and J80. Updated background.	03/20	03/20
Added CPT codes 86328 and 86769.	04/20	
Specified that the first medical necessity statement applies to nucleic acid/antigen testing. Updated priority groups per CDC update on 5/3/20. Added statement that antibody testing is not medically necessary for diagnosing acute infection, with background support. Categorized codes as supporting coverage criteria or not supporting coverage criteria. Added HCPCS codes C9803, G2023, G2024, U003, and U004. Removed ICD-10 code U07.2.	05/20	05/20
Modified criteria to reflect CDC testing guidelines as of 7/20/20. Added criteria for neonatal testing. Added criteria for discontinuation of transmission-based precautions, home isolation, and for return to work for healthcare providers. Changed antibody/serology testing medical necessity statement to medically necessary for those presenting late in illness, in conjunction with viral testing, and when post-acute infection syndrome is suspected. Removed background statement about antibody testing not being appropriate for diagnosis of acute infection. Added antibody testing code 86328 to the table supporting medical necessity, as well as codes 0202U, 0223U, 0224U. References updated.	07/20	07/20

References

- Centers for Disease Control and Prevention (CDC). Coronavirus Disease 2019 (COVID-19): Evaluating and Reporting Persons Under Investigation (PUI). Centers for Disease Control and Prevention. Updated May 4, 2020. Accessed July 28, 2020. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html>.

CLINICAL POLICY**Diagnostic Testing Guidelines for 2019-Novel Coronavirus**

2. Centers for Medicare and Medicaid Services (CMS). Public Health News Alert: CMS Develops New Code for Coronavirus Lab Test. CMS.gov. Feb. 13, 2020. <https://www.cms.gov/newsroom/press-releases/public-health-news-alert-cms-develops-new-code-coronavirus-lab-test>.
3. CDC. ICD-10-CM Official Coding Guidelines - Supplement Coding encounters related to COVID-19 Coronavirus Outbreak. Centers for Disease Control and Prevention. Effective Feb. 20, 2020. Accessed Feb. 27, 2020. <https://www.cdc.gov/nchs/data/icd/ICD-10-CM-Official-Coding-Guidance-Interim-Advice-coronavirus-feb-20-2020.pdf>
4. McIntosh, K. Coronavirus disease 2019 (COVID-19). UpToDate. Hirsch MS, Bloom A (Eds.). Accessed Mar. 5, 2020.
5. Wu Z, McGoogan JM. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention. JAMA 2020.
6. CDC. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19). Centers for Disease Control and Prevention. Updated July 8, 2020. Accessed July 10, 2020. <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>.
7. CDC. Coronavirus Disease 2019 (COVID-19): Returning from International Travel. Updated May 27, 2020. Accessed July 10, 2020. <https://www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html>.
8. CDC. Coronavirus Disease 2019 (COVID-19): Evaluation and Management Considerations for Neonates At Risk for COVID-19. Updated May 20, 2020. Accessed July 10, 2020. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/caring-for-newborns.html>.

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.

CLINICAL POLICY

Diagnostic Testing Guidelines for 2019-Novel Coronavirus

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.

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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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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