Clinical Policy: Diagnostic Testing Guidelines for 2019-Novel Coronavirus

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 tests 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.

Priorities for Testing:
A. Priority 1: Ensure optimal care options for all hospitalized patients, lessen the risk of nosocomial infections, and maintain the integrity of the healthcare system:
   1. Hospitalized patients;
   2. Symptomatic* healthcare workers;
B. Priority 2: Ensure that those who are at highest risk of complication of infection are rapidly identified and appropriately triaged:
   1. Patients in long-term care facilities with symptoms*;
   2. Patients 65 years of age and older with symptoms*;
   3. Patients with underlying conditions with symptoms*;
   4. First responders with symptoms*;
C. Priority 3: As resources allow, test individuals in the surrounding community of rapidly increasing hospital cases to decrease community spread, and ensure health of essential workers:
   1. Critical infrastructure workers with symptoms*;
   2. Individuals who do not meet any of the above categories with symptoms*;
   3. Health care workers and first responders;
   4. Individuals with mild symptoms* in communities experiencing high COVID-19 hospitalizations;
D. Non-priority:
   1. Individuals without symptoms*.
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*Note: Symptoms include fever, cough, and difficulty breathing.

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%.

COVID-19) is a betacoronavirus in the same subgenus as the severe acute respiratory syndrome (SARS) virus, and is also called (SARS-CoV-2). 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. 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.

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 2019, 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.

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<th>CPT® Codes</th>
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<tr>
<td>86328</td>
<td>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])</td>
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<tr>
<td>86769</td>
<td>Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])</td>
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<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>
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### HCPCS Codes

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<tr>
<td>U0001</td>
<td>(Effective 4/1/2020) 2019 Novel Coronavirus Real Time RT-PCR Diagnostic Test Panel</td>
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<tr>
<td>U0002</td>
<td>(Effective 4/1/2020) Non-CDC laboratory tests for SARS-CoV-2/2019-nCoV (COVID-19)</td>
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### ICD-10-CM Diagnosis Codes that Support Coverage Criteria

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<tr>
<td>U07.1</td>
<td>COVID-19, confirmed by laboratory testing</td>
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<tr>
<td>U07.2</td>
<td>Clinical or epidemiological diagnosis of COVID-19, laboratory confirmation inconclusive or not available</td>
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<tr>
<td>Z03.818</td>
<td>Encounter for observation for suspected exposure to other biological agents ruled out</td>
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<tr>
<td>Z20.828</td>
<td>Contact with and (suspected) exposure to other viral communicable diseases</td>
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### Reviews, Revisions, and Approvals

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- 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.
- Added new CPT-87635.
- 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.
- Added CPT codes 86328 and 86769.

### References

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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.
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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](http://www.cms.gov) for additional information.

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