of Tennessee

Policy

Reimbursement Policy

Coronavirus Testing in the Outpatient Setting

I. Policy Description

Human coronaviruses, first characterized in the 1960s, are named based on the spiked proteins located on their surface. As of 2020, seven coronaviruses are known to infect humans. Four, of which—229E, NL63, OC43, and HKU1—are associated with the common cold. MERS-CoV is the coronavirus that causes Middle East Respiratory Syndrome, or MERS. SARS-CoV is the causative agent of Severe Acute Respiratory Syndrome (SARS), and SARS-CoV-2 is the virus that causes coronavirus disease 2019, or COVID-19.[1,2] As of June 1, 2024, the United States had reported that nearly 1.2 million people have died of COVID-19.[1] Testing for a possible coronavirus infection can include molecular tests, such as nucleic acid-based testing like reverse transcription polymerase chain reaction (RT-PCR); host antibody testing; and antigen testing.

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

This policy only addresses testing for the purpose of medical decision making in the outpatient setting. This policy does not address work, school, state, or federally mandated SARS-CoV-2 testing.

1) Targeted nucleic acid testing (e.g., RT-PCR, rapid molecular tests) for COVID-19 (SARS-CoV-2**) MEETS COVERAGE CRITERIA** in any of the following situations:
   a) For individuals displaying signs and symptoms of possible COVID-19 infection (See Note 1).
   b) For asymptomatic individuals with known exposure to COVID-19, **EXCEPT** when the individual has had a previous COVID-19 infection within the last 90 days.
2) For individuals with signs or symptoms of SARS and who have traveled to endemic areas or who have been exposed to persons with SARS, targeted nucleic acid testing (e.g., RT-PCR)

for the detection of severe acute respiratory syndrome (SARS) coronavirus RNA **MEETS COVERAGE CRITERIA**.

3) For individuals with signs or symptoms of Middle East respiratory syndrome (MERS) and who have traveled to endemic areas or who have been exposed to persons with MERS, targeted nucleic acid testing (e.g., RT-PCR) for the detection of MERS coronavirus RNA **MEETS COVERAGE CRITERIA**.

4) To support a diagnosis of multisystem inflammatory syndrome in children (MIS-C) (see Note 2), multisystem inflammatory syndrome in adults (MIS-A) (see Note 3), or post-acute sequelae of SARS-CoV-2 infection (PASC), nucleic acid amplification testing and host antibody serology testing **MEET COVERAGE CRITERIA**.

5) For symptomatic individuals, antigen-detecting diagnostic tests for SARS-CoV-2 (e.g., antigen rapid tests) once every 48 hours **MEET COVERAGE CRITERIA**.

6) For the diagnosis of SARS-CoV-2 reinfection, whole genome sequencing of paired specimens from distinct lineages (as defined in Nextstrain or GISAID) **DOES NOT MEET COVERAGE CRITERIA**.

7) For all other situations not described above, host antibody serology testing **DOES NOT MEET COVERAGE CRITERIA**.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

8) In the outpatient setting, SARS-CoV-2 genotyping **DOES NOT MEET COVERAGE CRITERIA**.

9) For all situations, neutralization antibody testing for SARS-CoV-**2 DOES NOT MEET COVERAGE CRITERIA**.

10) Testing for other endemic coronaviruses, such as 229E, NL63, OC43, and HKU1, **DOES NOT MEET COVERAGE CRITERIA**.

NOTES:

Note 1: Signs and symptoms associated with a possible COVID-19 infection can include fever, cough, fatigue, shortness of breath or difficulty breathing, congestion or runny nose, chills, muscle or body aches, headache, sore throat, new loss of taste or smell, nausea, vomiting, and diarrhea.[3]

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Note 2: According the CDC,[4] MIS-C is defined as an illness that is found in a person less than 21 years of age when **all** of the following conditions are met:

- Subjective or documented fever of at least 38°C;
- Clinical severity requiring hospitalization;
- Evidence of systemic inflammation indicated by elevated C-reactive protein (CRP);
- New onset of manifestations in at least **two** of the following categories:
  - Cardiac involvement indicated by **one** of the following:
    - Left ventricular ejection fraction <55%.
    - Coronary artery dilatation, aneurysm, or ectasia.
    - Elevated troponin.
  - Mucocutaneous involvement indicated by **one** of the following:
    - Rash.
    - Inflammation of the oral mucosa.
    - Conjunctivitis or conjunctival injection.
    - Extremity findings (e.g., erythema or edema of the hands or feet).
  - Shock.
  - Gastrointestinal involvement indicated by **one** of the following:
    - Abdominal pain.
    - Vomiting.
    - Diarrhea.
  - Hematologic involvement indicated by **one** of the following:
    - Platelet count <150,000 cells/μL.
    - Absolute lymphocyte count.

Note 3: According to the CDC,[4] MIS-A is defined as an illness that is found in a person 21 years of age or older when all of the following conditions are met:

- Hospitalization for 24 hours or more;
- Subjective or documented fever of at least 38°C for one of the following:
  - 24 or more hours prior to hospitalization.
  - Within the first 3 days of hospitalization.
- No alternative diagnosis (e.g., bacterial sepsis).
- At least **three** of the following (occurring prior to hospitalization or within the first three days of hospitalization), with at least one being a primary clinical criterion:
  - Primary clinical criteria:
    - Severe cardiac illness (e.g., myocarditis, pericarditis, coronary artery dilation/aneurysm, new-onset right or left ventricular dysfunction, $2^{nd}/3^{rd}$ degree A-V block, ventricular tachycardia).
    - Rash **and** non-purulent conjunctivitis.
  - Secondary clinical criteria:

- New-onset neurologic signs and symptoms (e.g., encephalopathy in an individuals without prior cognitive impairment, seizures, meningeal signs, peripheral neuropathy including Guillain-Barré syndrome).
- Shock or hypotension not attributable to medical therapy.
- Abdominal pain, vomiting, or diarrhea.
- Thrombocytopenia.

- Evidence of SARS-CoV-2 infection;
- Evidence of systemic inflammation (elevated CRP, ferritin, interleukin-6, erythrocyte sedimentation rate, or procalcitonin).

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, please visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

The FDA issued an "Immediately in Effect Guidance on policy for diagnostics testing in laboratories certified to perform high complexity testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the public health emergency" in February 2020.[59] This policy was updated on May 11, 2020 to state that the "policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act)".[42]

In March 2023, the FDA released a "transition plan for medical devices that fall within enforcement policies issued during the coronavirus disease 2019 (COVID-19) public health emergency" and a "transition plan for medical devices issued emergency use authorizations (EUAs) related to coronavirus disease 2019."[89] These guidelines are meant to outline the FDA's recommendations during the transition from the COVID-19 pandemic to normal operations.[123,124]

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
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])
86408	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID19]); screen
86409	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID19]); titer
86413	Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
87426	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, 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
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism
87811	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
87913	Infectious agent genotype analysis by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), mutation identification in targeted region(s)
0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed Proprietary test: COVID-19 Antibody Test Lab/Manufacturer: Mount Sinai Laboratory/Mt Sinai
0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum Proprietary test: Tru-Immune™ Lab/Manufacturer: Ethos Laboratories/GenScript® USA Inc

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0408U	Infectious agent antigen detection by bulk acoustic wave biosensor immunoassay, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) Proprietary test: Omnia™ SARS-CoV-2 Antigen Test Lab/Manufacturer: Qorvo Biotechnologies
U0001	CDC Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
U0002	Non-CDC laboratory test for 2019-nCoV (COVID-19), any method

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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Reimbursement Policy

VI. Revision History

Revision Date	Summary of Changes
06/04/2025	Reviewed and Updated: Updated the background, guidelines and recommendations, and evidence-based scientific references. Literature review did not necessitate any modifications to coverage criteria. The following changes were made for clarity and consistency: Removed CC6 and CC8, antigen panel testing for respiratory pathogens moved to the more appropriate policy of G2149-Pathogen Panel Testing. Results in removal of Note 4 describing broad signs/symptoms of a respiratory infection Removed CPT code 86318, 87428