

COVID-19 Testing

MEDICAL POLICY NUMBER: 350

Effective Date: 10/1/2023
Last Review Date: 8/2023
Next Annual Review: 9/2023
COVERAGE CRITERIA 2
POLICY CROSS REFERENCES..... 3
POLICY GUIDELINES..... 3
REGULATORY STATUS..... 4
MEDICARE ADVANTAGE 6
BILLING GUIDELINES AND CODING 8
REFERENCES..... 13
POLICY REVISION HISTORY..... 14

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP*

Medicare**

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered “**not medically necessary**” for Medicare members.

COVERAGE CRITERIA

Note: This policy does not address panel testing for SARS-CoV-2 infection and COVID-19 diagnosis. See the Respiratory Viral Panels medical policies for criteria addressing panel testing.

- Company [Respiratory Viral Panels](#)
- Medicare [Respiratory Viral Panels](#)

Antigen Testing

- I. Molecular or antigen testing for SARS-CoV-2 is considered **medically necessary** when **all** of the following criteria are met:
 - A. Testing is primarily intended for individualized diagnosis of COVID-19 (see diagnosis codes in [Billing Guidelines](#) below); **and**
 - B. Testing is ordered by a licensed or authorized health care provider (see [Policy Guidelines](#)); **or**
 - C. The test is FDA approved or has an Emergency Use Authorization (EUA); **and**
 - D. Testing is performed by a CLIA-accredited lab or is CLIA-waived as indicated in the test instructions for use. *Note: The Plan may request the appropriate CLIA-certification or waiver as well as the manufacturer and name of the test being performed.*

Antibody Testing

- II. Antibody testing for SARS-CoV-2 is considered **medically necessary** when criterion I. above is met **and** results will be used to diagnose a condition related to COVID-19 infection (e.g., MISC) (see diagnosis codes in [Billing Guidelines](#) below). **The Food and Drug Administration (FDA) currently believes such tests should not be used as the sole basis for diagnosis.**

Recurrent Testing

- III. High frequency antigen, molecular, or antibody testing of SARS-CoV-2 (e.g., multiple tests per day for a single member) may be subject to medical necessity review. Medical records may be requested and must demonstrate that testing was performed in accordance with criteria I. and II. above.

Non-Covered, Non-Diagnostic Testing

- IV. Antigen and antibody in vitro testing for SARS-CoV-2 is considered **not medically necessary** when criteria I. or II. above is not met. Including, but not limited to, the following:
- A. For purposes not primarily intended to diagnose individuals with COVID-19
 - B. Public health surveillance testing, including epidemiologic research purposes (CPT 87913)
 - C. Testing done for employment or school purposes. This may include, but is not limited to:
 - 1. Return to work or school programs
 - 2. Testing to screen for general workplace or school safety
 - 3. Work-or-school related travel
 - 4. Participation in sports
 - 5. Pre-employment verification
 - 6. Routine physicals
 - 7. Insurance purposes
 - D. General screening. This may include, but is not limited to:
 - 1. Travel
 - 2. Social requirements
 - 3. Community tracking
 - 4. Determining need for personal protective equipment

POLICY CROSS REFERENCES

- Company [Respiratory Viral Panels](#), MP256
- Medicare [Respiratory Viral Panels](#), MP255

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

BACKGROUND

COVID-19

COVID-19 is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).¹ Symptoms generally include fever, coughing and shortness of breath. Symptoms appear 2 to 14 days after exposure to the virus, which is primarily spread between people during close contact, often

via droplets produced by coughing, sneezing and talking. While most cases result in mild symptoms, some lead to acute respiratory distress syndrome and death.

Antigen Testing

According to the CDC, “antigen tests are immunoassays that detect the presence of a specific viral antigen, which indicates current viral infection. Antigen tests are currently authorized to be performed on nasopharyngeal, nasal swab, or saliva specimens placed directly into the assay’s extraction buffer or reagent. The currently authorized antigen tests include point-of-care, laboratory-based, and self-tests.”² These tests perform quickly, usually producing results in 15-30 minutes.

Molecular Testing

Molecular tests detect viral RNA using a specialized test that creates millions of copies of small segments of the SARS-CoV-2 virus. If SARS-CoV-2 is present in the sample, then even low levels of virus genomic material can be amplified into millions of copies detected during a molecular diagnostic assay. Most molecular tests are performed in a laboratory setting because of the complexity and sensitivity of the testing process. Some laboratory-based tests can take 1 or more days to return results.³

Serological (Antibody) Testing

Serological tests refer to assays that detect antibodies (e.g., IgM, IgG) that a person generates in response to an infection. SARS-CoV-2 antibody tests are intended for use as a supplemental aid in identifying individuals with an adaptive immune response to SARS-CoV-2, and indicating recent or prior infection. Serology tests cannot be used to diagnose a current infection.¹

REGULATORY STATUS

CARES Act and FFCRA

Prior to 5/11/2023, the above policy criteria were written in accordance with the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, and the Families First Coronavirus Response Act (FFCRA). Section 6001(a) of the FFCRA requires plans and issuers to provide coverage for an in vitro diagnostic test, as defined below.⁴⁻⁹

In Vitro Diagnostic Test

An in vitro diagnostic test as defined in section 809.3 of title 21, Code of Federal Regulations,¹² (or its successor regulations) for the detection of SARS-CoV-2 or the diagnosis of COVID-19, and the administration of such a test, that—

- A. Is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 360(k), 360c, 360e, 360bbb-3);
- B. The developer has requested, or intends to request, emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3), unless and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable time frame;

- C. Is developed in and authorized by a State that has notified the Secretary of HHS of its intention to review tests intended to diagnose COVID-19; or
- D. Other tests that the Secretary of HHS determines appropriate in guidance.

Health Care Provider (HCP)

As defined in the FFCRA, a health care provider need not be “directly” responsible for providing care to the patient to be considered an attending provider, as long as the provider makes an individualized clinical assessment to determine whether the test is medically appropriate for the individual in accordance with current accepted standards of medical practice. Therefore, an attending provider for purposes of section 6001 of the FFCRA is an individual who is licensed (or otherwise authorized) under applicable law, who is acting within the scope of the provider’s license (or authorization), and who is responsible for providing care to the patient.

Effective 4/8/2020, a pharmacist licensed and enrolled in the state that the services are rendered in and practicing within the scope of their license and part of appropriate medical care as determined by the attending health care provider may order COVID-19 diagnostic testing.

At-Home Antigen Testing

COVID-19 tests intended for at-home testing (including tests where the individual performs self-collection of a specimen at home) must be covered, when the test is ordered by an attending health care provider who has determined that the test is medically appropriate for the individual based on current accepted standards of medical practice and the test otherwise meets the statutory criteria in section 6001(a)(1) of the FFCRA.

Beginning January 15, 2022, individuals with private health insurance coverage or covered by a group health plan who purchase an over-the-counter COVID-19 diagnostic test authorized, cleared, or approved by the U.S. Food and Drug Administration (FDA) will be able to have those test costs covered by their plan or insurance. Insurance companies and health plans are required to cover 8 free over-the-counter at-home tests per covered individual per month.

Antibody Testing

Serological tests for COVID-19 are used to detect antibodies against the SARS-CoV-2 virus, and are intended for use in the diagnosis of the disease or condition of having current or past infection with SARS-CoV-2, the virus which causes COVID-19. **The Food and Drug Administration (FDA) currently believes such tests should not be used as the sole basis for diagnosis.** FDA has advised the Departments that serological tests for COVID-19 meet the definition of an in vitro diagnostic product for the detection of SARS-CoV-2 or the diagnosis of COVID-19. Therefore, plans and issuers must provide coverage for a serological test for COVID-19 that otherwise meets the requirements of section 6001(a)(1) of the FFCRA, as amended by section 3201 of the CARES Act.

Surveillance Testing

Testing conducted to screen for general workplace health and safety (such as employee “return to work” programs), for public health surveillance for SARS-CoV-2, or for any other purpose not primarily

intended for individualized diagnosis or treatment of COVID-19 or another health condition is beyond the scope of section 6001 of the FFCRA.

Recurrent Testing

The FFCRA is not limited with respect to the number of diagnostic tests for an individual, provided that the tests are diagnostic and medically appropriate for the individual, as determined by an attending health care provider in accordance with current accepted standards of medical practice... providers are urged to consult guidance issued by the CDC, as well as state, tribal, territorial, and local health departments or professional societies, when determining whether diagnostic testing is appropriate for a particular individual.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

In response to the COVID-19 pandemic, the FDA employed its Emergency Use Authorization (EUA) authority to allow the use of COVID-19 tests that have not received traditional FDA approval. The FDA maintains a listing of all such serological tests authorized for use for COVID-19 on its website.¹⁰

MEDICARE ADVANTAGE

Note: The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

MEDICARE AND MEDICAL NECESSITY

General Coverage Rules

In order to be eligible for Medicare coverage, Medicare requires diagnostic laboratory tests be ordered by the physician who is treating the beneficiary for a specific medical problem and who will use the test results in the management of that specific medical problem. Testing that will not be used for patient management or for which the test results are not expected to improve health outcomes for that individual would not meet Medicare's medical necessity requirements. ([42 CFR 410.32\(a\)](#) and *Medicare Benefit Policy Manual, Pub. No. 100.02, Chapter 15 – Covered Medical and Other Health Services, §80.1 - Clinical Laboratory Services*)

Therefore, COVID-19 testing, including viral (molecular [PCR-based] and antigen) and antibody (serology) tests may be medically necessary when used to diagnose or manage a specific medical condition.

§1862(a)(1)(A) of the Social Security Act states Medicare payment may not be made for services that are not reasonable and necessary to treat or diagnose an illness or condition. 42 CFR §410.32(a) states, “All... diagnostic laboratory tests... must be ordered by... the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary’s specific medical problem.” Therefore, COVID-19 testing (viral and antibody) is considered not medically necessary when performed for public health surveillance, epidemiologic, school, travel, recreational (e.g., for camp, sports, or social events), employer purposes, or to determine eligibility for plasma donation or the need for personal protective equipment (PPE), as these do not meet Medicare’s medical necessity requirements for diagnostic laboratory services. Some of these testing scenarios may also be considered “screening” in nature, which are also generally non-covered under the Medicare program.

CMS Flexibilities Regarding Physician Orders

During the public health emergency (PHE), for select COVID-19 and related influenza or respiratory syncytial virus (RSV) clinical diagnostic laboratory tests, Medicare removed the requirement that these specific diagnostic laboratory tests must be ordered by a treating physician or non-physician practitioner (NPP). Specifically, effective September 2, 2020, “the order of a physician or other practitioner is not required for one otherwise covered diagnostic laboratory test for COVID-19 and for one otherwise covered diagnostic laboratory test each for influenza virus or similar respiratory condition needed to obtain a final COVID-19 diagnosis, when performed in conjunction with a COVID-19 diagnostic laboratory test in order to discount influenza virus or related diagnosis. This includes FDA-authorized COVID-19 serology tests, as they are reasonable and necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected prior COVID-19 infection.” While one COVID-19 or related test is covered without a physician order, repeat COVID-19, influenza or RSV testing will require a physician order after September 2, 2020. ([CMS-3401-IFC](#)) According to CMS, FDA-authorized COVID-19 serology (antibody) tests are subject to the same order requirements. ([CMS-3401-IFC](#))

CMS has published a list of COVID-19, influenza, and other respiratory testing to which these rules apply and it can be viewed on the CMS web site. ([Commonly Ordered COVID-19, Influenza, and RSV Clinical Diagnostic Laboratory Tests for which Medicare Does Not Require a Practitioner Order During the PHE*](#)) The CMS-3401-IFC Rule also states, “Medicare continues to cover other medically necessary clinical diagnostic laboratory tests when a treating physician or other practitioner orders them, and that other Medicare conditions of coverage and payment continue to apply, including any applicable local coverage determinations.” ([CMS-3401-IFC](#)) Therefore, other tests may continue to be subject to Medicare’s physician order rules, as well as LCD and LCA coverage guidelines. (*Medicare Benefit Policy Manual, Pub. No. 100.02, Chapter 15 – Covered Medical and Other Health Services, §80.1 - Clinical Laboratory Services*)

COVID-19 Laboratory Testing Using High-Throughput Technologies

During the COVID-19 PHE, CMS adjusted their payment rates for “high throughput technologies” tests in order to reimburse them at a higher rate. To accommodate this different payment structure, separate procedure codes were developed for use (codes U0003-U0005).¹¹ However, CMS has determined when the PHE ends, this extra payment for these technologies will also end. Therefore, these separate “high throughput technology” codes are no longer needed and are being terminated on May 11, 2023.¹² While CMS has not specifically provided instruction regarding what CPT or HCPCS codes will be used for these technologies after the PHE ends, to re-standardize payments for these tests, it is anticipated laboratories will use one of the existing, generic CPT codes (e.g., treat high throughput technology tests in the same manner as tests otherwise identified using CPT codes 87635 or U0002).¹¹

COVID-19 Diagnosis Coding Guidelines

The following coding guidelines are based on the [ICD-10-CM Official Guidelines for Coding and Reporting](#), updated in April of 2023. According to these guidelines, encounters for COVID-19 testing, including preoperative testing, should be coded as exposure to COVID-19 with diagnosis Z20.822. In addition, per CDC guidelines, diagnosis code Z11.52 (encounter for screening for COVID-19) is not appropriate during the COVID-19 pandemic. Additional coding details are provided in the subsections below.

COVID-19 Infection

- Code only a confirmed diagnosis of the 2019 novel coronavirus disease (COVID-19) as documented by the provider or documentation of a positive COVID-19 test result. For a confirmed diagnosis, assign code U07.1, COVID-19. In this context, “confirmation” does not require documentation of a positive test result for COVID-19; the provider’s documentation that the individual has COVID-19 is sufficient.
- If the provider documents “suspected,” “possible,” “probable,” or “inconclusive” COVID-19, do not assign code U07.1. Instead, code the signs and symptoms reported.

Acute Respiratory Manifestations of COVID-19

- When the reason for the encounter/admission is a respiratory manifestation of COVID-19, assign code U07.1, COVID-19, as the principal/first-listed diagnosis and assign code(s) for the respiratory manifestation(s) as additional diagnoses.
- The following conditions are examples of common respiratory manifestation of COVID-19
 - *Pneumonia*
 - For a patient with pneumonia confirmed as due to COVID-19, assign codes U07.1, COVID-19, and J12.82, Pneumonia due to coronavirus disease 2019.
 - *Acute bronchitis*
 - For a patient with acute bronchitis confirmed as due to COVID-19, assign codes U07.1, and J20.8, Acute bronchitis due to other specified organisms.
 - Bronchitis not otherwise specified (NOS) due to COVID-19 should be coded using code U07.1 and J40, Bronchitis, not specified as acute or chronic.

- *Lower respiratory infection*
 - If the COVID-19 is documented as being associated with a lower respiratory infection, not otherwise specified (NOS), or an acute respiratory infection, NOS, codes U07.1 and J22, Unspecified acute lower respiratory infection, should be assigned.
 - If the COVID-19 is documented as being associated with a respiratory infection, NOS, codes U07.1 and J98.8, Other specified respiratory disorders, should be assigned.
- *Acute respiratory distress syndrome*
 - For acute respiratory distress syndrome (ARDS) due to COVID-19, assign codes U07.1, and J80, Acute respiratory distress syndrome.
- *Acute respiratory failure*
 - For acute respiratory failure due to COVID-19, assign code U07.1, and code J96.0-, Acute respiratory failure.
- *Non-respiratory manifestations of COVID-19*
 - When the reason for the encounter/admission is a non-respiratory manifestation (e.g., viral enteritis) of COVID-19, assign code U07.1, COVID-19, as the principal/first-listed diagnosis and assign code(s) for the manifestation(s) as additional diagnoses.
- *Exposure to COVID-19*
 - For asymptomatic individuals with actual or suspected exposure to COVID-19, assign code Z20.822, Contact with and (suspected) exposure to COVID-19.
 - For symptomatic individuals with actual or suspected exposure to COVID-19 and the infection has been ruled out, or test results are inconclusive or unknown, assign code Z20.822, Contact with and (suspected) exposure to COVID-19.
- *Screening for COVID-19*
 - During the COVID-19 pandemic, a screening code is generally not appropriate. **Do not assign code Z11.52, Encounter for screening for COVID-19.** For encounters for COVID-19 testing, including preoperative testing, code as exposure to COVID-19.
- *Signs and symptoms without definitive diagnosis of COVID-19*
 - For patients presenting with any signs/symptoms associated with COVID-19 (such as fever, etc.) but a definitive diagnosis has not been established, assign the appropriate code(s) for each of the presenting signs and symptoms such as:
 - R05.1, acute cough, or R05.9, cough, unspecified
 - R06.02 Shortness of breath
 - R50.9 Fever, unspecified
 - If a patient with signs/symptoms associated with COVID-19 also has an actual or suspected contact with or exposure to COVID-19, assign Z20.822, Contact with and (suspected) exposure to COVID19, as an additional code.
- *Personal history of COVID-19*
 - For patients with a history of COVID-19, assign code Z86.16, Personal history of COVID-19.
- *Follow-up visits after COVID-19 infection has resolved*
 - For individuals who previously had COVID-19, without residual symptom(s) or condition(s), and are being seen for follow-up evaluation, and COVID-19 test results are negative, assign codes Z09, Encounter for follow-up examination

- after completed treatment for conditions other than malignant neoplasm, and Z86.16, Personal history of COVID-19.
- *Encounter for antibody testing*
 - For an encounter for antibody testing that is not being performed to confirm a current COVID-19 infection, nor is a follow-up test after resolution of COVID-19, assign Z01.84, Encounter for antibody response examination.
- *Multisystem Inflammatory Syndrome*
 - For individuals with multisystem inflammatory syndrome (MIS) and COVID-19, assign code U07.1, COVID-19, as the principal/first-listed diagnosis and assign code M35.81, Multisystem inflammatory syndrome, as an additional diagnosis.
 - If an individual with a history of COVID-19 develops MIS, assign codes M35.81, Multisystem inflammatory syndrome, and U09.9, Post COVID-19 condition, unspecified.
 - If an individual with a known or suspected exposure to COVID-19, and no current COVID-19 infection or history of COVID-19, develops MIS, assign codes M35.81, Multisystem inflammatory syndrome, and Z20.822, Contact with and (suspected) exposure to COVID-19. Additional codes should be assigned for any associated complications of MIS.
- *Post COVID-19 Condition*
 - For sequela of COVID-19, or associated symptoms or conditions that develop following a previous COVID-19 infection, assign a code(s) for the specific symptom(s) or condition(s) related to the previous COVID-19 infection, if known, and code U09.9, Post COVID-19 condition, unspecified.
 - Code U09.9 should not be assigned for manifestations of an active (current) COVID-19 infection.
 - If a patient has a condition(s) associated with a previous COVID-19 infection and develops a new active (current) COVID-19 infection, code U09.9 may be assigned in conjunction with code U07.1, COVID-19, to identify that the patient also has a condition(s) associated with a previous COVID-19 infection. Code(s) for the specific condition(s) associated with the previous COVID-19 infection and code(s) for manifestation(s) of the new active (current) COVID-19 infection should also be assigned

COVID-19 Infection in Pregnancy, Childbirth, and the Puerperium

During pregnancy, childbirth, or the puerperium, when COVID-19 is the reason for admission/encounter, code O98.5-, Other viral diseases complicating pregnancy, childbirth and the puerperium, should be sequenced as the principal/first-listed diagnosis, and code U07.1, COVID-19, and the appropriate codes for associated manifestation(s) should be assigned as additional diagnoses.

If the reason for admission/encounter is unrelated to COVID-19 but the patient tests positive for COVID-19 during the admission/encounter, the appropriate code for the reason for admission/encounter should be sequenced as the principal/first listed diagnosis, and codes O98.5- and U07.1, as well as the appropriate codes for associated COVID-19 manifestations, should be assigned as additional diagnoses.

COVID-19 Infection in Newborn

For a newborn that tests positive for COVID-19, assign code U07.1, COVID-19, and the appropriate codes for associated manifestation(s) in neonates/newborns in the absence of documentation indicating a specific type of transmission. For a newborn that tests positive for COVID-19 and the provider documents the condition was contracted in utero or during the birth process, assign codes P35.8, Other congenital viral diseases, and U07.1, COVID-19.

Allowable Diagnosis Codes

Per criterion I. above, and in accordance with the [ICD-10-CM Official Guidelines for Coding and Reporting](#), COVID-19 laboratory testing will be considered medically necessary for the *diagnosis* of COVID-19 as supported by any of the below diagnosis codes:

DIAGNOSES	DESCRIPTION
U071	COVID-19
Z20822	Contact with and (suspected) exposure to COVID-19
J1282	Pneumonia due to coronavirus disease 2019
J208	Acute bronchitis due to other specified organisms
J40	Bronchitis, not specified as acute or chronic
J22	Unspecified acute lower respiratory infection
J988	Other specified respiratory disorders
J80	Acute respiratory distress syndrome
J9600	Acute respiratory failure, unspecified w hypoxia or hypercapnia
J9601	Acute respiratory failure with hypoxia
J9602	Acute respiratory failure with hypercapnia
R051	Acute cough
R059	Cough, unspecified
R0602	Shortness of breath
R509	Fever, unspecified
Z8616	Personal history of COVID-19
Z09	Encounter for follow-up examination after completed treatment for conditions other than malignant neoplasm
Z0184	Encounter for antibody response examination
M3581	Multisystem inflammatory syndrome
U099	Post COVID-19 condition, unspecified
O9851	Other viral diseases complicating pregnancy
O9852	Other viral diseases complicating childbirth
O9853	Other viral diseases complicating the puerperium
P358	Other congenital viral diseases

The AMA released CPT code 87913 to report research related testing. Any claims billed with this code will not be reimbursed.

Pricing

All Lines of Business except Medicare and Medicaid

As of 5/11/2023, if The Plan does not have a contracted rate with a provider, The Plan will price medically necessary COVID-19 diagnostic testing at 110% of the Medicare rate. Prior to 5/11/2023, The Plan priced COVID-19 diagnostic testing in accordance with Section 3202(a) of the CARES Act.

Medicare and Medicaid

Medically necessary COVID-19 diagnostic testing continues to pay at the rate established by the Centers for Medicare & Medicaid Services (CMS).

CODES*		
CPT	0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease COVID-19), includes titer(s), when performed; Mt Sinai, Mount Sinai Laboratory
	0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum
	0408U	Infectious agent antigen detection by bulk acoustic wave biosensor immunoassay, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])
	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 [COVID-19]); screen
	86409	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); 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) Multi-step method
	87426	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay - EIA, enzyme-linked immunosorbent assay - ELISA, fluorescence immunoassay (FIA), 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
	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	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease COVID-19) mutation identification in targeted region(s)

HCPCS	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	TERMED 5/11/2023 Specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease covid-19), any specimen source
	G2024	TERMED 5/11/2023 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
	K1034	Provision of COVID-19 test, nonprescription self-administered and self-collected use, FDA approved, authorized or cleared, one test count; Effective 1/15/2022; Published 4/5/2022
	U0001	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
	U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC
	U0003	TERMED 5/11/2023 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	TERMED 5/11/2023 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
	U0005	TERMED 5/11/2023 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, CDC or non-CDC, making use of high throughput technologies, completed within 2 calendar days from date of specimen collection (list separately in addition to either HCPCS code U0003 or U0004) as described by CMS-2020-01-R2

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Centers for Disease Control and Prevention. Interim Guidelines for COVID-19 Antibody Testing in Clinical and Public Health Settings. <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html>. Published 2020. Accessed 6/25/2020.
2. Centers for Disease Control and Prevention (CDC). Guidance for Antigen Testing for SARS-CoV-2 for Healthcare Providers Testing Individuals in the Community. <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>. Accessed 7/22/2022.
3. Johns Hopkins Center for Health Security. COVID-19 Testing Toolkit: Molecular Tests. <https://www.centerforhealthsecurity.org/covid-19TestingToolkit/testing-basics/types-of-COVID-19-tests/diagnostic-tests/molecular-tests.html>. Accessed 7/22/2022.
4. Families First Coronavirus Response Act (FFCRA). <https://www.congress.gov/116/bills/hr6201/BILLS-116hr6201eh.pdf>. Published 2020. Accessed 7/22/2022.
5. Coronavirus Aid, Relief, and Economic Security Act (CARES Act). <https://www.congress.gov/bill/116th-congress/senate-bill/3548/text>. Published 2020. Accessed 7/22/22.
6. FAQs ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION: PART 42. <https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf>. Published 2020. Accessed 7/22/2022.
7. FAQs ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION: PART 43. <https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf>. Published 2020. Accessed 7/22/2022.
8. Centers for Medicare & Medicaid Services. COVID-19 Over-the-Counter (OTC) Tests & Medicare Frequently Asked Questions. <https://www.cms.gov/files/document/covid-19-over-counter-otc-tests-medicare-frequently-asked-questions.pdf>. Accessed 7/22/2022.
9. FAQs ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION: PART 44. <https://www.cms.gov/files/document/faqs-part-44.pdf>. Published 2021. Accessed 7/22/2022.
10. U.S. Food and Drug Administration. In Vitro Diagnostics EUAs. <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>. Published 2020. Accessed 6/25/2020.
11. CMS Ruling. CMS-2020-01-R. <https://www.cms.gov/files/document/cms-2020-01-r.pdf>. Published 2020. Accessed 4/6/2023.
12. Laboratories: CMS Flexibilities to Fight COVID-19. <https://www.cms.gov/files/document/laboratories-cms-flexibilities-fight-covid-19.pdf>. Accessed 4/6/2023.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
4/2023	Updates made for termination of PHE on 5/11/2023.
10/2023	Code set update October 2023.