Medicare Medical Policy

COVID-19 Testing

MEDICARE MEDICAL POLICY NUMBER: 401

Effective Date: 1/1/2024

Last Review Date: 11/2023

Next Annual Review: 9/2024

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

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

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Notes:

- This policy does not address **panel** testing for SARS-CoV-2 infection and COVID-19 diagnosis. These are addressed by the separate Medicare *Respiratory Viral Panels* medical policy (see Policy Cross References).
- Over-the-counter (OTC) at-home COVID-19 antibody tests (HCPCS K1034) are subject to individual member supplemental benefits and are not addressed by this Medicare medical policy.

Service	Medicare Guidelines

COVID-19 Testing	For CPT code **87635, U0001, U0002:**
	• Testing performed in **AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:**
	  ○ Local Coverage Determination (LCD): MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L39003)
	  ○ Local Coverage Article (LCA): Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (A58726)
	• Testing performed in **CA or NV**:
	  ○ LCD: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L39001)
	  ○ LCA: Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (A58720)
	• Testing performed in **VA, WV, NC, SC, GA, TN, or AL**:
	  ○ LCD: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L38988)
	  ○ LCA: Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (A58710)
	
	For CPT code **87913**:

- Testing performed in FL: LCD: Respiratory Pathogen Panel Testing (L38918) and companion LCA (A58577)
- Testing performed in the states of CO, NM, OK, TX, AR, LA, MI, DE, MD, NJ, and PA): LCD: Respiratory Pathogen Panel Testing (L38916) and companion LCA (A58575)

For CPT/HCPCS codes not listed above (**0224U, 0226U, 0408U, 86328, 86408, 86409, 86413, 86769, 87426, 87635, 87811) *OR*** for codes listed above but testing is performed in a state not addressed, then in the absence of a more specific Medicare policy (NCD, LCD, etc.), the following Medicare-based guidelines apply *(Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §80.1 - Clinical Laboratory Services)*:

I. Diagnostic COVID-19 testing may be **medically necessary** when the test meets **all** of the following:

A. The intended purpose of the test is to diagnose or treat a specific medical condition related to the test; **and**,
B. The test is ordered by a physician who is treating the member for a specific medical problem related to the test; **and**,
C. The test results will be used promptly in the management of that specific medical problem.

II. Tests not used for patient management or when test results are not expected to improve health outcomes for the member are considered **not medically necessary**. Examples of non-covered tests or testing scenarios include, but may not be limited to, the following:

A. Tests with the intended purpose of screening or other indication other than to diagnose or treat an illness or condition.
B. Tests performed for public health surveillance, epidemiologic, school, travel, recreational (e.g., for camp, sports, or social events), or for employment purposes.
C. Tests performed to determine eligibility for plasma donation.
D. Tests performed to determine the need for personal protective equipment (PPE).
E. Tests performed for screening purposes.
F. Tests used to determine how effective the immune system is at neutralizing or 'blocking' the virus.

NOTE: CPT codes 0226U, 86408 and 86409 represent non-covered tests; however, codes for other tests may also be considered non-

	covered (not medically necessary) if Medicare's coverage requirements for diagnostic testing are not met.

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Respiratory Viral Panels, MP255

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

COVID-19

Coronavirus Disease 2019, more commonly referred to as COVID-19, is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). 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 and Antibody Testing

According to the Centers for Disease Control (CDC), "antigen tests are immunoassays that detect the presence of a specific viral antigen, which indicates current viral infection… SARS-CoV-2 antigen tests are currently authorized for nasopharyngeal swab and nasal swab specimens. The currently authorized antigen tests include point-of-care (POC), laboratory-based, and self-tests available without a prescription."[1] These tests perform quickly, usually producing results in 15-30 minutes.

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.[2]

In other words, COVID-19 **antigen** tests look for an *active* infection, while **antibody** tests are intended to look for signs of a *past* infection.

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]

Neutralizing Antibody Tests

COVID-19 neutralizing antibody testing (NAT) is used to detect the presence of antibodies that may be able to neutralize the SARS-CoV-2 virus. Unlike the general antibody testing described above, NAT is **not** intended to be used to determining whether a person has been infected with SARS-CoV-2. This testing is performed to identify individuals who may be candidates for convalescent plasma donation, which is an experimental treatment for COVID-19.

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.[4,5]

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."

Thus, 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. Testing performed for the purposes of screening are also generally non-covered under the Medicare program.[6,7]

<u>At-Home Antigen Testing</u>

The Medicare over-the-counter (OTC) COVID-19 test demonstration ended on May 11, 2023. Starting on May 12, 2023, Original Medicare no longer covers or pays for OTC COVID-19 tests.[8]

However, coverage of OTC tests may continue for COVID-19 diagnostic (antigen) tests intended for at-home use (including tests where the individual performs self-collection of a specimen at home) for

Medicare Advantage members. Coverage is subject to member benefits and limitations and is not addressed by this Medicare medical policy.

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.[9] According to CMS, FDA-authorized COVID-19 serology (antibody) tests are subject to the same order requirements.[9]

CMS has published a list of COVID-19, influenza, and other respiratory testing to which these rules apply and it can be viewed on this 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."[9] Therefore, other tests may continue to be subject to Medicare's physician order rules, as well as LCD and LCA coverage guidelines.[5]

As of the end of the PHE, these Medicare flexibilities regarding physician or non-physician orders for diagnostic testing, including COVID-19 tests, have ended and standard practitioner order requirements are reimplemented.[10]

Health Care Provider (HCP)

Medicare has been allowing pharmacists, as well as other health care professionals who are authorized to order lab tests under the state scope of practice and other relevant laws, to order COVID-19 tests for Medicare members during the PHE. This does not mean that pharmacists and other health care professionals have been able to enroll in the Medicare program to furnish and bill for services they furnish to beneficiaries; rather, it has allowed Medicare to pay for tests that they order.

As of the end of the PHE, these Medicare flexibilities regarding pharmacists to order COVID-19 tests will end and standard Medicare provider enrollment rules are reimplemented.[10]

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

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.[11]

BILLING GUIDELINES AND CODING

GENERAL

HCPCS codes G2023 and G2024, as well as CPT codes U0003-U0005, were used for some COVID-19 tests prior to being deleted effective May 11, 2023. More information regarding these codes can be found below.

At Home Testing

HCPCS code K1034 is used to bill for a single test and applies to all OTC FDA-approved, authorized, or cleared COVID-19 tests (that are self-administered with a specimen that's self-collected).[8] However, this policy does not address at home testing with over-the-counter (OTC) test kits, and therefore, HCPCS code K1034 does not fall under the scope of this medical policy.

- If the member **has** supplemental benefits which allow at-home OTC COVID-19 tests, then coverage is allowed up to the benefit limits noted in the member's EOC.
- If the member does **not** have a supplemental benefit to allow at-home COVID-19 tests, then code K1034 would be denied not a covered benefit and would be member liability as a direct plan exclusion.

Specimen Collection from Homebound or Non-Hospital (SNF) Part B Inpatient Members[12]

"Medicare established two codes, G2023 and G2024, for specimen collection for COVID-19 clinical diagnostic laboratory tests. Independent clinical diagnostic laboratories can bill for these services as well as a travel allowance (HCPCS codes P9603 and P9604) when they collect specimens from beneficiaries who are homebound or non-hospital (SNF) Part B inpatients, that is, individuals in a Part B SNF stay and individuals whose samples will be collected by a laboratory on behalf of a" home health agency (HHA). Note that these specimen collection fee codes may not be billed for a hospital or SNF inpatient in a Part A stay, as the costs for tests (including sample collection) for those patients are already included in the reimbursement of the stay. HCPCS codes G2023 and G2024 were deleted effective May 11, 2023.

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).[13] 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 termed on May 11, 2023.[14] 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).[13]

Non-Covered Testing

Research Related Testing (CPT 89713)

The AMA released CPT code 87913 to report research related testing. Therefore, claims reported with this CPT code will not be reimbursed.

COVID-19 Neutralizing Antibody Testing (Includes Surrogate Neutralizing Antibody Testing)

Claims reported with CPT code 0226U, 86408 or 86409 will be denied as not medically necessary.

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. Table 1 includes coding guidelines based on this reference:

Table 1: Diagnosis coding for common clinical scenarios that may involve COVID-19

COMMON CONDITIONS/SCENARIOS	DIAGNOSIS CODE ASSIGNMENT AND NOTES
Active 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. • **Confirmed** diagnosis: Code U07.1 *(COVID-19)*. ○ In this context, "confirmation" does not require documentation of a positive test result for COVID19; the provider's documentation that the individual has COVID-19 is sufficient. • **Unconfirmed** diagnosis: If the provider documents "suspected," "possible," "probable," or "inconclusive" COVID-19, do **not** assign code U07.1 *(COVID-19)*. Instead, code the signs and symptoms reported.
Respiratory manifestation of COVID-19	• Code U07.1 *(COVID-19)* as the principal/first-listed diagnosis • Code for the respiratory manifestation(s) as additional diagnoses
Pneumonia confirmed as due to COVID-19	• U07.1 *(COVID-19)* • J12.82 *(Pneumonia due to coronavirus disease 2019)*.
Acute bronchitis confirmed as due to COVID-19	• U07.1 *(COVID-19)* • J20.8 *(Acute bronchitis due to other specified organisms)*.
Bronchitis not otherwise specified (NOS) due to COVID-19	• U07.1 *(COVID-19)* • J40 *(Bronchitis, not specified as acute or chronic)*.

Lower respiratory infection, not otherwise specified (NOS)	• U07.1 *(COVID-19)* • J22 *(Unspecified acute lower respiratory infection)*
Acute respiratory infection, not otherwise specified (NOS)	• U07.1 *(COVID-19)* • J22 *(Unspecified acute lower respiratory infection)*
COVID-19 documented as associated with a respiratory infection, not otherwise specified (NOS)	• U07.1 *(COVID-19)* • J98.8 *(Other specified respiratory disorders)*
Acute respiratory distress syndrome (ARDS) due to COVID-19	• U07.1 *(COVID-19)* • J80 *(Acute respiratory distress syndrome)*.
Acute respiratory failure due to COVID-19	• U07.1 *(COVID-19)* • J96.0- *(Acute respiratory failure)*.
Non-respiratory manifestations (e.g., viral enteritis) of COVID-19	• U07.1 *(COVID-19)* as the principal/first-listed diagnosis • Code(s) for the manifestation(s) as additional diagnoses.
Exposure to COVID-19	• **Asymptomatic** individuals with actual or suspected exposure to COVID-19: Z20.822 *(Contact with and (suspected) exposure to COVID-19)*. • **Symptomatic** individuals with actual or suspected exposure to COVID-19 and the infection has been ruled out, or test results are inconclusive or unknown: Z20.822 *(Contact with and (suspected) exposure to COVID-19)*.
Screening for COVID-19	• Diagnosis code Z11.52 *(Encounter for screening for COVID-19)* is not appropriate during the COVID-19 pandemic. **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	• Z86.16 *(Personal history of COVID-19)*.
Follow-up visits after COVID-19 infection has resolved (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)	• Z09 *(Encounter for follow-up examination after completed treatment for conditions other than malignant neoplasm)* • Z86.16 *(Personal history of COVID-19)*.
Encounter for antibody testing when not being performed to confirm a	• Z01.84 *(Encounter for antibody response examination)*.

current COVID-19 infection, nor is a follow-up test after resolution of COVID-19	
Multisystem Inflammatory Syndrome (MIS)	• For individuals **with 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 COVID19, 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	• When COVID-19 is the reason for admission/encounter:
	  ○ Code O98.5- *(Other viral diseases complicating pregnancy, childbirth and the puerperium)* as the principal/first-listed diagnosis,
	  ○ Code U07.1 *(COVID-19)*
	  ○ Assign as additional diagnoses appropriate codes for associated manifestation(s).
	• When the reason for admission/encounter is unrelated to COVID-19 but the patient tests positive for COVID-19 during the admission/encounter:
	  ○ The reason for admission/encounter should be coded as the principal/first-listed diagnosis, followed by:

	○ O98.5- *(Other viral diseases complicating pregnancy, childbirth and the puerperium)* ○ U07.1 *(COVID-19)* ○ Assign as additional diagnoses appropriate codes for associated manifestation(s).

Allowable Diagnoses Codes

In accordance with the ICD-10-CM Official Guidelines for Coding and Reporting, COVID-19 laboratory testing for the *diagnosis* of COVID-19 will be considered **medically necessary** and having met Medicare's coverage requirements for diagnostic laboratory testing if reported one of the below diagnosis codes:

Table 2: Diagnosis codes for the diagnosis of COVID-19

CODE	DESCRIPTION
U07.1	COVID-19
J12.82	Pneumonia due to coronavirus disease 2019
J20.8	Acute bronchitis due to other specified organisms
J22	Unspecified acute lower respiratory infection
J40	Bronchitis, not specified as acute or chronic
J80	Acute respiratory distress syndrome
J96.00	Acute respiratory failure, unspecified w hypoxia or hypercapnia
J96.01	Acute respiratory failure with hypoxia
J96.02	Acute respiratory failure with hypercapnia
J98.8	Other specified respiratory disorders
M35.81	Multisystem inflammatory syndrome
O98.51	Other viral diseases complicating pregnancy
O98.52	Other viral diseases complicating childbirth
O98.53	Other viral diseases complicating the puerperium
P35.8	Other congenital viral diseases
R05.1	Acute cough
R05.9	Cough, unspecified
R06.02	Shortness of breath
R50.9	Fever, unspecified
U09.9	Post COVID-19 condition, unspecified
Z01.84	Encounter for antibody response examination
Z09	Encounter for follow-up examination after completed treatment for conditions other than malignant neoplasm
Z20.822	Contact with and (suspected) exposure to COVID-19
Z86.16	Personal history of COVID-19

PRICING

Medically reasonable and necessary COVID-19 diagnostic testing for Medicare Advantage members continues to pay at rates 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 *(COVID-19 Antibody Test, by 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 *(Tru–Immune™, Ethos Laboratories)*
	0408U	Infectious agent antigen detection by bulk acoustic wave biosensor immunoassay, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) *(Omnia™ SARSCoV-2 Antigen Test, by Qorvo Biotechnologies)*
	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 (SARS-CoV-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
	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)
HCPCS	~~C9803~~	**TERMED 12/31/2023** ~~Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source~~
	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

***Coding Notes:**

- The code list above 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. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*

- 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 (CDC). Considerations for SARS-CoV-2 Antigen Testing for Healthcare Providers Testing Individuals in the Community. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html. Updated 5/11/2023. Accessed 8/9/2023.
2. 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/hcp/testing/antibody-tests-guidelines.html. Published 2020. Updated 12/16/2022. Accessed 8/9/2023.
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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
12/2023 1/2024	New Medicare Advantage medical policy Q1 2024 Code Updates