MEDICAL POLICY	COVID-19 Testing
Effective Date: 12/1/2022  12/1/2022 Medical Officer Date	Medical Policy Number: 350 Medical Policy Committee Approved Date: 8/2022; 10/2022; 11/2022

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

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

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid 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.

POLICY 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.

- Respiratory Viral Panels (All Lines of Business Except Medicare)
- Respiratory Viral Panels (Medicare Only)

Antigen Testing

I. In accordance with the Families First Coronavirus Response Act (see Policy Guidelines section for complete detail), and through the end of the Federal Public Health Emergency (PHE), molecular or antigen testing for SARS-CoV-2 is considered **medically necessary** with **no member cost share**, when **all** of the following criteria are met:

   A. Testing is primarily intended for individualized diagnosis of COVID-19; **and**
   B. **At least one** of the following are met:

1. Testing is ordered by a licensed or authorized health care provider (see Policy Guidelines); **or**
2. Testing is performed with an over-the-counter (OTC) at-home rapid antigen test (limited to 8 tests per month). Not applicable to Medicare members*; **and**

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-waved as indicated in the test instructions for use**.

*Effective April 15, 2022, members with Original Medicare Part B coverage including those enrolled in a Medicare Advantage plan can get up to 8 free OTC at-home COVID-19 tests for each calendar month at authorized pharmacies or other participating entities through the end of the federal public health emergency. Members will be able to receive the OTC COVID-19 tests at no cost and will not need to be reimbursed, as Original Medicare will pay the pharmacy or other entity directly.

**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. In accordance with the Families First Coronavirus Response Act (see Policy Guidelines section for complete detail), and through the end of the Federal Public Health Emergency (PHE), an antibody test for SARS-CoV-2 is considered **medically necessary** with **no member cost share** when criterion I. above is met and results will be used to diagnose a condition related to COVID-19 infection (e.g., MISC). **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 the federal regulations outlined in 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 and not covered** 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 GUIDELINES

CARES Act and FFCRA

The above policy criteria are 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.[1-6]

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.

Physician Self-Referral Law[7]

The Physician Self-Referral Law, also known as the Stark law, "prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies." Financial relationships include both ownership/investment interests and compensation arrangements. For example, if you invest in an imaging center, the Stark law requires the resulting financial relationship to fit within an exception or you may not refer patients to the facility and the entity may not bill for the referred imaging services.

"Designated health services" are:

- **clinical laboratory services;**
- physical therapy, occupational therapy, and outpatient speech-language pathology services;
- radiology and certain other imaging services;
- radiation therapy services and supplies;
- DME and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services.

CMS Benefit Policy Manual, Chapter 16—General Exclusions from Coverage
Section 130—Charges Imposed by Immediate Relatives of the Patient or Members of the Patient's Household[8]

Subsection D. "Charges for Provider Services" states: *Payment is not made under Part A or Part B for items and services furnished by providers to immediate relatives* of the owner(s) of the providers. This exclusion applies whether the provider is a sole proprietor who has an excluded relationship to the patient, or a partnership in which even one of the partners is related to the patient.*

*CMS Defines "immediate relatives" as:

- Husband and wife;
- Natural or adoptive parent, child, and sibling;
- Stepparent, stepchild, stepbrother, and stepsister;
- Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, and sister-in-law;
- Grandparent and grandchild; and
- Spouse of grandparent and grandchild.

Subsection E. "Charges for Physicians and Physician-Related Services" states: *This exclusion applies to physician services, including services of a physician who belongs to a professional corporation, and services furnished incident to those services (for example, by the physician's nurse or technician) if the*

physician who furnished the services or who ordered or supervised services incident to their services has an excluded relationship to the beneficiary.

CODING GUIDELINES

COVID-19 Laboratory Testing Using High-Throughput Technologies

- HCPCS codes U0003, U0004, and U0005 should only be used by clinical diagnostic laboratories using high-throughput amplified probe technologies to detect and diagnose COVID-19 AND having the requisite CLIA license.
    - Claims submitted for these codes with any place of service other than clinical laboratory (POS 81), inpatient/outpatient hospital (POS 21/22), or emergency room (POS 23) will deny as not covered.
- HCPCS code U0005 is an add-on code for laboratories performing a COVID-19 diagnostic test run on high throughput technology if the laboratory completes the test in 2 calendar days or less.

COVID-19 Diagnosis Coding Guidelines

The following coding guidelines are based on the ICD-10-CM Official Guidelines for Coding and Reporting, updated in January of 2021 in response to the COVID-19 public health emergency. 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 COVID19; 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 Cough
    - 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.
- **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.

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.

BILLING & REIMBURSEMENT GUIDELINES

Disallowed Codes

Per criterion IV. above, and in accordance with the federal regulations, the following diagnosis codes will be considered not medically necessary and not covered because they are not primarily used for the *diagnosis* of COVID-19:

- Z01.84: Encounter for antibody response examination
- Z02.0: Encounter for examination for admission to educational institution
- Z02.1: Encounter for pre-employment examination
- Z02.3: Encounter for examination for recruitment to armed forces
- Z02.5: Encounter for examination for participation in sport
- Z02.6: Encounter for examination for insurance purposes
- Z02.71: Encounter for disability determination
- Z02.79: Encounter for issue of other medical certificate
- Z02.89: Encounter for other administrative examinations
- Z02.9: Encounter for administrative examinations, unspecified
- Z11.52: Encounter for screening for COVID-19
- Z11.59: Encounter for screening for other viral diseases

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

Pricing

According to Section 3202(a) of the CARES Act health plans must reimburse diagnostic testing as follows:

1. If the plan or issuer has a negotiated rate with such provider in effect before the public health emergency declared under section 319 of the PHS Act, such negotiated rate shall apply throughout the period of such declaration.
2. If the plan or issuer does not have a negotiated rate with such provider, the plan or issuer shall reimburse the provider in an amount that equals the cash price for such service as listed by the provider on a public internet website, or the plan or issuer may negotiate a rate with the provider for less than such cash price.

CPT/HCPCS CODES

All Lines of Business	
No Prior Authorization Required	
Molecular Tests	
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
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	Infectious agent detection by nucleic acid (DNA or RNA); Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease COVID-19), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R
U0005	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
Antigen Tests	
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)
87449	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; multiple-step method, not otherwise specified, 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)
Over-the-Counter (OTC)	
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

Antibody Tests	
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
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)
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
Specimen Collection	
C9803	Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease covid-19), any specimen source
G2023	Specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease covid-19), any specimen source
G2024	Specimen collection for severe acute respiratory syndrome coronavirus -2 (sars-cov-2) (coronavirus disease covid-19) from an individual in a SNF or by a laboratory on behalf of a hha, any specimen source
Not Covered	
87913	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease COVID-19) mutation identification in targeted region(s)

DESCRIPTION

COVID-19

COVID-19 is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[9] 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."[10] 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.[11]

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.[9]

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 Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

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.

REGULATORY STATUS

See Policy Guidelines section above for complete details of the federal regulations on which this policy is based.

U.S. Food and Drug Administration

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.[12]

Mental Health Parity Statement

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.

REFERENCES

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