

# COVID-19 Testing for Diagnostic (Viral) and Antibody (Serology) Testing

 State(s):
 LOB(s):

 Idaho
 Montana
 Oregon
 Washington
 Other:
 Image: Commercial

Commercial Medicare Medicaid

# **Enterprise Policy**

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determination are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage

# Background

There are two types of tests commonly used to detect presence of the SARS-CoV-2 virus: diagnostic (viral) tests and antibody (serology) tests.

- Diagnostic (viral) tests check samples from the respiratory system (such as swabs of the inside of the nose) to determine if an individual currently has an infection with SARS-CoV-2, the virus that causes COVID-19. Some tests are point-of-care tests, meaning results may be available at the testing site in less than an hour. Other tests must be sent to a laboratory to analyze, a process that takes 1-2 days once received by the lab.
- Antibody (serology) tests check the blood by looking for antibodies, which can determine if an
  individual had a past infection with the virus that causes COVID-19. Antibodies are proteins that
  help fight off infections and usually provide protection against getting that disease again
  (immunity). Antibodies are disease specific. For example, measles antibody will protect a
  person who is exposed again to measles but will have no effect if the person is exposed to
  mumps.

#### Criteria for Diagnostic Tests (COVID-19 and SARS-CoV-2)

PacificSource considers COVID-19 and SARS-CoV-2 testing medically necessary when the following criteria are met:

- I. PacificSource Covers diagnostic testing based upon provider compliance with current CDC Guidelines
  - The CDC has testing guidance available at CDC.gov/coronavirus/2019-ncov/symptomstesting/testing.html.

II. PacificSource covers COVID-19 virus tests when medically appropriate for the individual, as determined by the individual's attending health care provider (as defined below)

- 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.
- SARS-CoV-2 (severe acute respiratory syndrome coronavirus) testing coverage is not to be limited with respect to the number of tests for an individual, provided that the tests are diagnostic and medically appropriate for the individual, as determined by an attending health care provider meeting the above criteria.
- An at-home COVID-19 virus test should be covered when ordered by an attending health care provider meeting these criteria using the paired ICD-10 and CPT-4 codes listed below

# III. PacificSource covers diagnostic testing when the appropriate ICD-10 and CPT-4 codes are entered on a HCFA – 1500.

PacificSource is recognizing claims with a combination of any of the following diagnosis and procedure codes for full coverage with no member cost share. CDC.gov/nchs/data/icd/ICD-10-CM-Official-Coding-Gudance-Interim-Advicecoronavirus-feb-20-2020.pdf.

Code	Description
U0001	Test for SARS-CoV-2 (CDC laboratory test)
U0002	Test for SARS-CoV-2 (non-CDC laboratory test)
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
0098U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types, 14 targets (adenovirus, coronavirus, human metapneumovirus)
0099U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 20 targets (adenovirus, coronavirus 229E, coronavirus)
0100U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 21 targets (adenovirus, coronavirus 229E, coronavirus)
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen- specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not
0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen- specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
G2023	Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS CoV-2) (Coronavirus disease [COVID-19]), any specimen source.

#### HCPCS for COVID-19 laboratory tests.

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 an HHA, any specimen source.
87635	Infection agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique.
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiqualitative, single step method; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (Coronavirus disease COVID-19)
87426	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19])

Condition	ICD-10
	Diagnosis Codes
Pneumonia, confirmed as due to COVID-19	J12.89, B97.29, U07.1
Acute bronchitis, confirmed as due to COVID-19	J20.8, B97.29, U07.1
Bronchitis NOS, confirmed as due to COVID-19	J40, B97.29, U07.1
Acute/lower respiratory infection NOS, confirmed as due to COVID-19	J22, B97.29, U07.1
Respiratory infection NOS, confirmed as due to COVID- 19	J98.8, B97.29, U07.1
Acute respiratory distress syndrome, confirmed as due to COVID-19	J80, B97.29, U07.1
Possible exposure to COVID-19, condition ruled- out	Z03.818
Exposure to confirmed COVID-19	Z20.828
Coronavirus infection, unspecified	B342
nCoV acute respiratory disease	U07.1
SARS-associated coronavirus as the cause of diseases classified elsewhere	B97.21
Pneumonia due to SARS- associated coronavirus	J12.81
Asymptomatic individuals screened for COVID-19, no known exposure to the	Z1159.1

# ICD-10 codes for COVID-19 billing

virus, test results are	
unknown or negative	

#### **Exclusions for Diagnostic Testing**

COVID-19 virus testing, regardless of the type, lacks the requisite medical need and is not covered if the test is solely directed or requested for **any** of the following:

- by an employer as part of "return-to-work" or other employer-directed program or
- for public health surveillance testing, or
- for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition
- for asymptomatic individuals who are being screened for COVID-19 and have no known exposure to the virus.

# Member Cost Share for Diagnostic Testing

PacificSource covers other COVID-19 related services with no member cost share for a limited time:

PacificSource is waiving member out-of-pocket costs for COVID-19 testing and diagnosis-related office visits, urgent-care visits, telemedicine visits, ER visits, testing, and radiology if billed with one of the COVID DX codes. PacificSource providers are instructed not to collect copay/coinsurance or deductibles for visiting and testing services. Other services not specified above will adhere to the member's cost share under their standard benefit. Services provided by out-of-network providers will be paid at the same benefit as our in-network benefit.

These benefits have been extended through the end of Emergency Declaration

#### Criteria for SARS-COV-2 Antibody (Serology) Testing

PacificSource considers SARS-CoV 2 antibody (serology) testing medically necessary when **all** of the following criteria are met:

- Serology test has FDA Emergency Use Authorization (EUA) or FDA approval; **AND** one of the following:
  - Used to evaluate a hospitalized person under age 21 for possible multisystem inflammatory syndrome in children (MIS-C).
  - Used to support clinical assessment of persons who present late in their illnesses when used in conjunction with viral detection tests.

Use of a serologic test alone to diagnose coronavirus disease 2019 (COVID-19) infection is not reliable. In cases where individuals have been infected with the SARS-CoV-2 virus, depending upon when infected and the timing of the test, the test may not find antibodies, even when there is currently an illness with COVID-19.

Supporting documentation is expected to be available upon request.

PacificSource considers the following SARS-COV-2 serology (antibody testing) not medically necessary:

- testing that is not considered for diagnosis and treatment; or
- when performed as the sole test for COVID-19 diagnosis; or
- to determine immune status in individuals until the presence, durability, and duration of immunity is established; **or**
- testing for public health surveillance/ tracking purposes (i.e. workplace or facility surveillance);or
- to make decisions about grouping persons residing in or being admitted to congregate settings, such as schools, dormitories, or correctional facilities; **or**
- used to monitor disease burden by location and over time; or
- for the purpose of obtaining convalescent serum; or
- for any other testing purposes not noted above.

# **CPT Codes for Serology Testing**

- 0224U Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus Disease [COVID-19]), includes titer(s), when performed (Do not report 0224U in conjunction with 86769)
- 86328 Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS--CoV-2) (Coronavirus disease (COVID-19)
- 86769 Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease (COVID-19)

#### References

American Medical Association. Serological testing for SARS-CoV-2 antibodies. Updated May 14, 2020. Chicago, IL. https://www.ama-assn.org/delivering-care/public-health/serological-testing-sars-cov-2-antibodies Accessed June 19, 2020.

Centers for Disease Control and Prevention. Serology Testing for COVID-19. Last reviewed May 5, 2020. Atlanta, GA. https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html Accessed June 19, 2020.

Centers for Disease Control and Prevention. Interim guidelines for COVID-19 antibody testing. Last reviewed 5/23/2020. Atlanta, GA.

https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html. Accessed June 19, 2020.

Infectious Diseases Society of America. IDSA Covid-19 Antibody Testing Primer. Updated May 4, 020. Arlington, VA.

https://www.idsociety.org/globalassets/idsa/public-health/covid-19/idsa-covid-19-antibody-testing-primer.pdf Accessed June 19, 2020.

Infectious Diseases Society of America. Infectious Diseases Society of America Guidelines on the diagnosis of COVID-19. Published 5/6/2020. https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics/ Accessed May 2020.

U.S. Food and Drug Administration (FDA). Important information on the use of serological (antibody) tests for COVID-19-letter

to health care providers. 4/17/2020. Silver Spring, MD. https://www.fda.gov/medicaldevices/lettershealth-care-providers/important-information-use-serological-antibody-tests-covid-19letter-health-care-providers. Accessed June 19, 2020.

U.S. Food and Drug Administration (FDA). FDA Fact Sheet. Antibody test oversight and use for COVID-19. May 4, 2020. Silver Spring, MD. https://www.fda.gov/media/137599/download. Accessed May 2020.

U.S. Food and Drug Administration (FDA). Insight into FDA's revised policy on antibody tests: prioritizing access and accuracy. Silver Spring, MD. https://www.fda.gov/news-events/fdavoices/insight-fdas-revised-policyantibody-tests-prioritizing-access-and-accuracy Accessed May 2020.

U.S. Food and Drug Administration (FDA). Guidance document. Policy for coronavirus disease-2019 tests during the public health emergency (Revised). 5/11/2020. Silver Spring, MD. https://www.fda.gov/regulatoryinformation/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergencyrevised. Accessed May 2020.

# Appendix

Policy Number: [Policy Number]				
Effective: 6/22/2020	Next review: 6/22/2021			
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Depts: Health Services				
Applicable regulation(s): [Applicable Regulations(s)]				
External entities affected: [External Entities Affected]				
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