COVID-19 Diagnostic (Viral) and Antibody (Serology) Testing and Monoclonal Antibody Infusion and Vaccines for COVID-19

State(s):	LOB(s):
☒ Idaho ☒ Montana ☒ Oregon ☒ Washington ☐ Other:	☒ 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.

The American Medical Association's (AMA's) Current Procedural Terminology (CPT®) Editorial Panel released the following SARS-CoV-2 vaccine and immunization administration CPT codes and guidelines.

- Six Category I codes (0001A, 0002A, 0011A, 0012A, 91300, 91301), new and revised guidelines and parenthetical notes, and a new Appendix Q.
- The new CPT codes are unique for each of two coronavirus vaccines: Pfizer (91300), and Moderna (91301). The administration codes are also unique to each such vaccine and dose: Pfizer (0001A and 0002A), and Moderna (0011A and 0012A).

The U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the investigational monoclonal antibody therapies bamlanivimab and casirivimab and imdevimab, administered together, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or hospitalization.

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/symptoms-testing/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.

CPT and HCPCS Code Information

The following list of codes are for informational purposes only and may not be all-inclusive.
Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

HCPCS and CPT codes for COVID-19 laboratory tests.

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
0225U	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARSCoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum.
0241U	Infectious disease (viral respiratory tract infection), pathogen specific RNA, 4 targets severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected
0240U	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected.
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 an HHA, any specimen source.
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiqualitative, single step method; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

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	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 **(**SARSCoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
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])
87428	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; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B.
87631	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets.
87635	Infection agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique
87636	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 **(**SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus type
87637	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique.
87811	Infectious agent antigen detection by immunoassay with direct optical(i.e. visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV2))

HCPCS and CPT codes for COVID-19 Vaccines are effective upon receiving Emergency Use Authorization or approval from the Food and Drug Administration

HCPCS and CPT codes for COVID-19 Vaccines

91300 (Pfizer-BioNTech COVID-19 Vaccine	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, for intramuscular use
0001A admin for 91300	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 ((SARS-CoV-2) coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; first dose

0002A admin for 91300	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 ((SARS-CoV-2) coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; second dose
91301 (Moderna COVID-19 Vaccine	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19}) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use.
0011A admin for 91301	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 ((SARS-CoV-2) coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; first dose
0012A admin for 91301	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 ((SARS-CoV-2) coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; second dose
91302 (AstraZeneca COVID-19 Vaccine)	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19}) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5X10 viral particle/0.5L dosage, for intramuscular use
0021A admin for 91302	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x10 viral particles/0.5mL dosage; first dose
0022A admin for 91302	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x10 viral particles/0.5mL dosage; second dose
91303 (Janssen Covid-19 Vaccine)	(Janssen) Severe acute resp syndrome coronavirus 2 ([COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 vector, preservative free, 0.5ml dosage, intramuscular use
0031A admin for 91303	Immun admin by intramus inj of coronavirus 2 ((SARS-CoV-2) [COVID-19]) vaccine, DNA, spike protein, adenovirus typep 26 vector, preservative free, 0.5mL dosage; single dose

AMA Appendix Q resource for COVID-19 vaccine administration

The new Appendix Q on the AMA site can be used as a stand-alone “quick reference” guide that is available to aid health care professionals responsible for administering the new vaccines to accurately report the appropriate code(s). **Appendix Q** will be accessible on the AMA’s website dedicated to COVID-19 resources at https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-vaccine-and-immunization-codes

COVID-19 Monoclonal Antibodies and their Administration during Public Health Emergency

CODE	Vaccine/Procedure
Q0239	Injection bamlanivimab. 700 mg
M0239	Intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring

Q0243	Injection, casirivimab and imdevimab, 2400 mg
M0243	Intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring
Q0245	Injection, bamlanivimab and etesevimab, 2100 mg
M0245	Intravenous infusion bamlanivimab and etesevimab includes infusion and post administration monitoring

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FDA Fact Sheets for Emergency Use Authorization of Monoclonal Antibody Infusions

Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA) of Bamlanivimab
http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf

Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA) of Casirivimab and Imdevimab
https://www.fda.gov/media/143892/download

Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA) of Bamlanivimab And Etesevimab
https://www.fda.gov/media/145802/download

Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA)

ICD-10 codes for COVID-19 billing

Condition	**ICD-10 Diagnosis Codes**
Acute bronchitis, confirmed as due to COVID-19	J20.8, B97.29, U07.1
Acute respiratory distress syndrome, confirmed as due to COVID-19	J80, B97.29, U07.1
Acute/lower respiratory infection NOS, confirmed as due to COVID-19	J22, B97.29, U07.1
Bronchitis NOS, confirmed as due to COVID-19	J40, B97.29, U07.1
Contact with and (suspected) exposure to COVID-19	Z20.822
Coronavirus infection, unspecified	B34.2
Encounter for screening for COVID-19	Z11.52
Encounter of screening for other viral diseases.	Z11.59
Exposure to confirmed COVID-19	Z20.828

nCoV acute respiratory disease	U07.1
Personal History of COVID-19	Z86.16
Pneumonia, confirmed as due to COVID-19	J12.89, B97.29, U07.1
Pneumonia due to SARS-associated coronavirus	J12.81
Pneumonia due to coronavirus disease 2019	J12.82
Possible exposure to COVID-19, condition ruled-out	Z03.818
Respiratory infection NOS, confirmed as due to COVID-19	J98.8, B97.29, U07.1
SARS-associated coronavirus as the cause of diseases classified elsewhere	B97.21

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
- for public health surveillance testing
- 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, and the test results are either unknown or negative,

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.

Exclusions for SARS-COV-2 Antibody (Serology) Testing

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

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

CPT Codes for Serology Testing

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

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 (e.g., 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)

87999 Unlisted Microbiology procedure

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Appendix

Policy Number:

Effective: 8/11/2020 **Next review:** 6/30/2021

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s):

Commercial Ops: 5/2021

Government Ops: 4/2021