COVID-19 Testing, Vaccines, and Treatments

LOB(s):	State(s):
☒ *Commercial* ☒ *Medicare*	☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:*
☒ *Medicaid*	☒ *Oregon* ☐ *Washington*

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 determinations 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

The Secretary of Health and Human Services (HHS) issued a declaration on February 4, 2020 pursuant to section 319F-3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures to reduce the threat of COVID-19.

The Federal Food, Drug and Cosmetic Act (FD&C Act), section 564 allows the Food and Drug Administration (FDA), once the Secretary of HHS declares a public health emergency, to authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions by Chemical, Biological, Radiological, or Nuclear (CBRN) threat agents when certain criteria are met, including there are no adequate, approved or available alternatives. The Emergency Use Authorization Declaration went into effect on March 27, 2020.

FDA Emergency Use Authorizations (EUA) Guidance and Information located at:

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Testing

The FDA has approved or granted emergency use authorization for two types of tests which are used to detect the presence of the SARS-CoV-2 virus: diagnostic (viral) tests and antibody (serology) tests:

- Diagnostic (viral) tests check samples from the respiratory system (e.g., 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. Diagnostic test can be performed in the following methods:

- Point-of-care or rapid result tests which are completed at an available testing site and may be available in less than an hour.
- Laboratory tests are sent to a laboratory to analyze and may take 1-2 days to obtain the results, depending on when the laboratory receives the tests. The FDA has granted emergency use authorization for COVID-19 diagnostic testing, which includes sequencing to identify variant strains or lineages. These tests must be performed in a certified Clinical Laboratory Improvement Amendments (CLIA) laboratory.
- Self-tests can be completed at home or elsewhere by following specific instructions and results are typically available within 15 to 20 minutes.

- 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.

Vaccines

The U.S. Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) for four COVID-19 vaccines, which include the Pfizer-BioNTech, Moderna, Janssen, and Novavax.

Prior to granting EUA, the FDA required vaccine manufactures to undergo a rigorous developmental process that included tens of thousands of study participants to generate needed non-clinical, clinical, and manufacturing data, which was comprehensively reviewed by the FDA. Prior to the issuance of a EUA, the manufacture had to show there was adequate manufacturing information to ensure quality and consistency and known potential benefits were shown to outweigh the known and potential risks of the vaccine. As part of the EUA approval, the manufactures must have an active safety plan to track deaths, hospitalizations, and other clinically significant adverse events, among persons who receive the vaccine under EUA, which informs the FDA of ongoing benefit-risk determinations to support continuation of the EUA.

The FDA informs the public about the Emergency Use Authorization by publishing “fact sheets” which can be located on the FDA website (links can also be found in the vaccine approval and emergency use authorization section of this policy).

The FDA has also granted approval of two vaccines. The Pfizer-BioNTech vaccine was granted FDA approval on 8/23/2021, under the name Comirnaty, as a two-dose series in individuals 16 years of age or older. The Moderna vaccine was granted FDA approval on 1/31/2022, under the name Spikevax, as a two-dose series in individuals 18 or older. See vaccine approval and emergency use authorization section for further details regarding Comirnaty and Spikevax.

Monoclonal Antibody Therapies

According to the Centers for Disease Control and Prevention (CDC) monoclonal antibody therapies help the immune system recognize and respond more effectively to the virus. The CDC has COVID-19 Guidelines for COVID-19 treatments (including monoclonal antibodies) available at: https://www.cdc.gov/coronavirus/2019-ncov/your-health/treatments-for-severe-illness.html

U.S. Department of Health and Human Services, also describes monoclonal antibodies as being created in a laboratory and administered through an intravenous (IV) infusion or injections to help a

patient whose natural antibodies may not be designed to recognize the novel (new) SARS-CoV-2, combat the SARS CoV-2 infection. The monoclonal antibody therapies do not replace the need for immunity from a vaccine but may reduce a patient's risk for developing a serious COVID-19 infection.

The FDA has issued EUAs (the issuance of a EUA does not constitute FDA approval) for the following monoclonal antibodies:

- Investigational monoclonal antibody therapies 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 including hospitalization or death. These products are:
    - Bebtelovimab: This monoclonal antibody works by binding to the spike protein of the virus that causes COVID-19. (See Monoclonal Antibodies EUA section of the policy, as of 2/11/22, this treatment is authorized to treat the omicron variants).
    - *Bamlanivimab plus etesevimab:* These are neutralizing monoclonal antibodies that bind to different but overlapping epitopes in the spike protein RBD of SARS-CoV-2 (see Monoclonal Antibodies EUA section of the policy, as of 1/24/22, this treatment is not authorized to treat the omicron variants).
    - *Casirivimab plus imdevimab (*REGEN-COV™*):* These are recombinant human monoclonal antibodies that bind to nonoverlapping epitopes of the spike protein RBD of SARS-CoV-2 (see Monoclonal Antibodies EUA section of the policy, as of 1/24/22, this treatment is not authorized to treat the omicron variants).
    - *Sotrovimab:* This monoclonal antibody was originally identified in 2003 from a SARS-CoV survivor. It targets an epitope in the RBD of the spike protein that is conserved between SARS-CoV and SARS-CoV-2 (see Monoclonal Antibodies EUA section for the policy, as of 4/5/22, this treatment is not authorized to treat the omicron variants.
- Investigational monoclonal antibody therapy for the treatment of COVID-19 in hospitalized adults and pediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO):
    - *ACTEMRA® or tocilizumab:* A recombinant humanized anti-human interleukin 6 (IL-6) receptor monoclonal antibody of the immunoglobulin $IgG1_K$ (gamma 1, kappa) subclass with a typical H_2L_2 polypeptide structure. Each light chain consists of 214 and 448 amino acids, respectively. The four polypeptide chains are linked inter- and inter-molecularly by disulfide bonds. Tocilizumab binds specifically to both soluble and membrane-bound IL-6 receptors (sIL-6R and mIL6R) and has been shown to inhibit IL-6-mediated signaling through these receptors.
- Investigational monoclonal antibody therapy for the pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and pediatric individuals (12 years of age and older weighing at least 40 kilograms [about 88 pounds]:
    - AstraZeneca's Evusheld (tixagevimab co-packaged with cilgavimab and administered together) Tixagevimab and cilgavimab are two recombinants human IgG1κ monoclonal antibodies with amino acid substitutions to extend antibody half-life (YTE), reduce antibody effector function, and minimize the potential risk of antibody-dependent enhancement of disease (TM). Tixagevimab and cilgavimab can simultaneously bind to non-overlapping regions of the receptor binding domain (RBD) of SARS-CoV-2 spike protein. Tixagevimab, cilgavimab, and their combination bind to spike protein with

equilibrium dissociation constants of KD = 2.76 pM, 13.0 pM and 13.7 pM, respectively, blocking its interaction with human ACE2, the SARS-CoV-2 receptor, which is required for virus attachment. Tixagevimab, cilgavimab, and their combination blocked RBD binding to human ACE2 with IC50 values of 0.32 nM (48 ng/mL), 0.53 nM (80 ng/mL), and 0.43 nM (65 ng/mL), respectively (see Monoclonal Antibodies EUA section for the policy, **as of 2/24/22**, the authorization directed increased dosage for this monoclonal antibody treatment).

Antiviral Therapies

According to the Centers for Disease Control and Prevention (CDC), antiviral therapies target specific parts of the SARS-CoV-2 virus to help reduce the virus' multiplication and spread through the patient's body. The CDC has COVID-19 Guidelines for COVID-19 treatments (including antiviral therapies) available at: https://www.cdc.gov/coronavirus/2019-ncov/your-health/treatments-for-severe-illness.html

The U.S. Food and Drug Administration approved Veklury® (remdesivir), an antiviral medication, which is a nucleotide analog ribonucleic acid (RNA) polymerase inhibitor. The authorized product includes commercially available Veklury for injections (100 mg/vial, NDC 61958-2901-2), which is supplied as a single dose vial containing a sterile, preservative-free white to off-white to yellow lyophilized powder. It requires reconstitution and further dilution prior to administration intravenous infusion. Veklury® (remdesivir) also has an emergency use authorization (EUA) indication; however, it was revoked on 4/25/2022.

The U.S. Food and Drug Administration issued an emergency use authorization (EUA) for two additional oral antiviral medications, the issuance of a EUA does not constitute FDA approval:

- Pfizer's Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use. Paxlovid consists of nirmatrelvir, which inhibits a SARS-CoV-2 protein to stop the virus from replicating, and ritonavir, which slows down nirmatrelvir's breakdown to help it remain in the body for a longer period at higher concentrations. Paxlovid is administered as three tablets (two tablets of nirmatrelvir and one tablet of ritonavir) taken together orally twice daily for five days, for a total of 30 tablets. Paxlovid is available by prescription, should be initiated as soon as possible after diagnosis of COVID-19, and should be given within five (5) days of symptom onset.
- Merk's Molnupiravir is a medication that works by introducing errors into the SARS-CoV-2 virus genetic code, which prevents the virus from further replicating. Molnupiravir is administered as four 200 milligram capsules taken orally every twelve (12) hours for five (5) days, for a total of 40 capsules. Molnupiravir is available by prescription only, should be initiated as soon as possible after diagnosis of COVID-19, and should be given within five (5) days of symptom onset.

The FDA informs the public about the Emergency Use Authorization by publishing "fact sheets" which can be located on the FDA website (links can also be found in the vaccine approval and emergency use authorization section of this policy).

The Centers for Medicare and Medicaid Services (CMS) issued guidance on 11/23/2021, to Part D sponsors regarding oral antiviral medications that become available under a EUA. CMS explained the EUA-approved oral antiviral medications would initially be procured by the federal government and dispensed free of charge to patients through contracts with certain pharmacies during the public health emergency. While pharmacies will obtain the drug at no cost, the procurement will not include payment of a dispensing fee. CMS did not expect all participating pharmacies in Part D networks to be included

in the contractual arrangements to dispense the USG-procured EUA oral antiviral medications. The guidance letter can be found at: https://www.cms.gov/files/document/hpms-memo-oral-antiviral-guidance.pdf

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 https://www.cdc.gov/coronavirus/2019-ncov/testing/

In addition to the CDC guidance, the FDA has announced EUAs for COVID-19 tests, as well as recalls and revisions of EUAs for COVID-19 tests. The EUA, revisions and recalls can be found on the following FDA websites:

- To search if a diagnostic test has received a EUA or a revision was made to the EUA visit: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2?utm_medium=email&utm_source=govdelivery#individual-molecular
- To search if a serology test has received a EUA or a revision was made to the EUA visit: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2
- To search if a test has been recalled visit: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

On September 23, 2021, the FDA established additional Conditions of Authorization in response to the continued emergence of COVID-19 variants. The conditions have been included in the COVID-19 test EUAs and requires test developers to update their authorized labeling and evaluate the impact of COVID-19 viral mutations on their test's performance.

For additional questions related to COVID-19 tests, the FDA has created an FAQ website

II. PacificSource covers COVID-19 viral 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.
- The CDC has self-testing guidance available at https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html

- An at-home COVID-19 viral 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. In addition, on 1/15/2022, at-home over-the-counter (OTC) COVID-19 tests may be available on 1/15/2022, to PacificSource members. Each PacificSource member's household can receive a one-time shipment of four (4) free OTC COVID-19 tests from the federal government, which are available to order at: https://www.covidtests.gov/. The free OTC COVID-19 test program from the federal government will end on 9/02/2022 due to funding depletion.
    - On 8/11/2022, The FDA advised members should perform repeat or serial testing (over a 2-to-4-day period) following a negative result on any at-home COVID antigen test, during early infection or exposure to reduce the risk an infection may be missed (false negative result) and to help prevent people from unknowingly spreading COVID-19. Guideline available at: https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-fda-safety-communication?utm_medium=email&utm_source=govdelivery
    - On 2/6/2023, The FDA in conjunction with the National Institute of Health (NIH) created the make my test count website to report OTC COVID-19 test results voluntarily and anonymously.

Commercial

PacificSource members may obtain at-home OTC COVID-19 home test kits through CVS Caremark® pharmacies. The following link can be accessed to locate or to determine if a pharmacy is a CVS Caremark®: https://pacificsource.com/members/prescription-drug-information/find-a-pharmacy

PacificSource members are eligible to receive up to eight (8) at-home test kits per eligible member, every 30 days without a prescription. Each at-home test kits includes four (4) tests, which will count towards the eight (8) tests per eligible member.

PacificSource members who choose to purchase at-home OTC COVID-19 from a non-participating pharmacy or an online retailer will not be eligible for the no cost share but may submit reimbursement requests through Caremark® by utilizing their online portal, app, or paper forms. The member may be reimbursed $12.00 per test or the actual cost of the test, whichever is lower.

The following at-home OTC COVID-19 tests are currently available for PacificSource Commercial members, but are subject to change, through CVS pharmacy for PacificSource members:

Label Name	Manufacturer	GPI	NCD-UPC	Tests per package
BINAXNOW COVID-19 AG CARD HOME TEST	ABBOTT DIAGNOSTICS SCARBO	94101024356400	11877-0011-40	2
FLOWFLEX COVID-19 AG HOMETEST	ACON	94101024356400	82607-0660-26	1
INTELISWAB COVID-19 RAPID TEST	ORASURE TECHNOLOGIES	94101024356400	08337-0001-58	2
ON/GO COVID-19 ANTIGEN SELF-TEST	ACCESS BIO	94101024356400	60006-0191-66	2

QUICKVUE AT-HOME COVID-19 TEST	QUIDEL	9410102435 6400	14613-0339-72	2
QUICKVUE AT-HOME COVID-19 TEST	QUIDEL	9410102435 6400	14613-0339-68	5

Medicaid

PacificSource Community Solutions (PCS) members may obtain at-home COVID-19 tests from a pharmacy enrolled with Oregon Medicaid. Members are eligible to receive four (4) at-home tests per month if purchased through the approved Oregon Medicaid Pharmacy. At-home tests purchased by the member are not eligible for reimbursement. If additional tests are needed, a prior authorization must be obtained.

Medicare

PacificSource Medicare members are eligible as of April 4, 2022, to access at-home OTC COVID-19 tests at no cost. Members are eligible to receive up to eight (8) tests per calendar month from participating pharmacies and health providers during the public health emergency declaration by using their red, white, and blue Medicare card to purchase the at-home tests. Medicare members may also continue to obtain diagnostic tests through a provider's office, clinic, urgent care, emergency room or retail pharmacy.

- Participating pharmacies, include Costco, CVS, Rite Aid Corp., Walgreens, and Walmart. However, a complete list of participating pharmacies can be located at: https://www.medicare.gov/medicare-coronavirus
- For additional questions related to COVID-19 tests OTC at-home tests for Medicare members, CMS has created an FAQ website.

For members and providers, who have questions related to at-home OTC tests (e.g., how to store the tests, when do the test expire, etc.), the FDA created an FAQ for guidance.

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. https://www.cdc.gov/nchs/data/icd/ICD-10cmguidelines-FY2021-COVID-update-January-2021-508.pdf

Exclusions for Viral Diagnostic Testing (not to include the at-home OTC COVID-19 tests):

COVID-19 viral 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 another 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 (see above for cost associated with at-home OTC COVID-19 tests) and diagnosis-related office visits, urgent-care visits, telemedicine visits, ER visits, testing, and radiology if billed with one of the COVID Diagnosis (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.

Coding Information for Diagnostic 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.

COVID-19 Diagnostic Testing HCPCS/CPT Code	Description
U0001	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel **Effective February 4, 2020
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types, or subtypes (includes all targets), non-CDC **Effective February 4, 2020
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 **Effective March 18, 2020
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 **Effective March 18, 2020
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 **Effective January 1, 2021
0098U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types, 14 targets (adenovirus, coronavirus, human metapneumovirus)

	Effective date: July 1, 2019. **Termed date: April 1, 2021
0099U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types, or subtypes, 20 targets (adenovirus, coronavirus 229E, coronavirus) **Effective date: July 1, 2019. **Termed date: April 1, 2021**
0100U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types, or subtypes, 21 targets (adenovirus, coronavirus 229E, coronavirus) **Effective date: July 1, 2019. **Termed date: April 1, 2021**
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 detected **Effective date: May 20, 2020
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 **Effective date: June 25, 2020
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 **Effective date: August 10, 2020
0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum. **Effective date: August 10, 2020
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. **Effective date: October 6, 2020
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 **Effective date: October 6, 2020
C9803	Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source) **Effective date: March 1, 2020
G2023	Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS CoV-2) (Coronavirus disease [COVID-19]), any specimen source. **Effective date: March 1, 2020

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. **Effective date: March 1, 2020
K1034	Provision of COVID-19-test, nonprescription self-administered and self-collected use, FDA approved, authorized, or cleared, one test count. **Effective date: April 4, 2022
86413	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative **Effective date: September 8, 2020
87426	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19]) **Effective date: June 25, 2020, Update date: 10/6/2020
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. **Effective date: November 10, 2020
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. **Effective date: January 1, 2015
87635	Infection agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique **Effective date: March 13, 2020
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 **Effective date: October 6, 2020
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. **Effective date: October 6, 2020
87811	Infectious agent antigen detection by immunoassay with direct optical (i.e., visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) **Effective date: October 6, 2020

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) **Effective date: February 21, 2022
99072	Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease **Effective date: November 10, 2020

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

Coding Information 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). **Effective date: June 25, 2020

86318 Immunoassay for infections agent antibody(ies), qualitative or semiquantitative, single-step method (e.g., reagent strip) **Effective date: April 10, 2020

86328 Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (e.g., reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease (COVID-19) **Effective date: April 10, 2020

86408 Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); screen **Effective date: August 10, 2020

86409 Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); titer **Effective date: August 10, 2020

86769 Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease (COVID-19) **Effective date: April 10, 2020

87999 Unlisted Microbiology procedure

Vaccine Approval and Emergency Use Authorization

FDA Approved Vaccines

- COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. **As of 8/23/2021**, it is approved as a 2-dose series for the prevention of COVID-19 in individuals 16 years of age and older. **Updated 7/8/2022**, the FDA approved Comirnaty for use in additional age group of individuals aged 12 through 15 years of age. The Pfizer-BioNTech vaccine also remains authorized for emergency use in individuals 12 through 15 years, provision of a third dose and booster dose. The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series. **Updated 12/17/2021**, the FDA approved a manufacturing change for Comirnaty (COVID-19 Vaccine, mRNA) to include a formulation that uses a different buffer. Buffers help maintain a vaccine's pH and stability. This new formulation is more stable at refrigerated temperatures for longer periods of time, permitting greater flexibility for vaccination providers. This formulation does not need to be diluted before use. **Updated 3/29/2022**, the FDA approved a second booster dose of the Pfizer-BioNTech COVID-19 vaccine for individuals 50 years of age and older and individuals 12 years of age and older with immunocompromised conditions or solid organ transplantation, at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine. **Updated 4/13/2022**, the FDA updated the expiration dates for the two presentations of the Tris/Surcose formulation (supplied in multiple dose vials with orange caps and labels with orange border and in multiple dose vials with gray caps and labels with a

gray border). The frozen vials may be stored in an ultra-low temperature freezer at -90ºC to -60ºC (-130ºF to -76ºF) for up to 12 months from the date of manufacture. **Updated 6/01/2022**, the FDA updated the expiration dates for the PBS/Sucrose formulation (supplied in multiple dose vials with the purple caps) from 9 months to 12 months when stored between -90ºC to -60ºC. Further information is available at: https://www.fda.gov/media/150386/download

- Spikevax (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Moderna. **As of 1/31/2022**, it is approved as a 2-dose series given one month apart for individuals 18 years of age and older. Spikevax can be used interchangeably with the EUA Moderna COVID-19 vaccine to provide the COVID-19 vaccination series. The Moderna COVID-19 vaccine remains under EUA for the primary series, third primary series dose for individuals 18 years of age and older who have determined to have certain kinds of immunocompromised, and a single booster dose for in individuals 18 years of age and older than at least five months after completing a primary series vaccine. **Updated 3/29/2022**, the FDA approved a manufacturing change for the Moderna COVID-19 vaccine to include an additional presentation of the vaccine for booster vaccination doses only. The Moderna COVID-19 vaccine is now authorized for individuals 18 and older in two presentations: 1) multiple dose vials with red caps and labels with a light blue border, formulated to provide doses for the primary vaccination (each 0.25 mL dose containing 100 microgram mRNA) or doses for booster vaccination (each 0.25 mL dose containing 50 microgram mRNA), 2) multiple dose vials with dark blue caps and labels with a purple border, formulated to provide doses for booster vaccination only (each 0.5 mL dose containing 50 microgram mRNA). Further information is available at: https://www.fda.gov/media/155815/download

FDA Fact Sheets for Emergency Use Authorization of Vaccines

- Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA) of Pfizer-BioNTech (12 years or older); **Updated 8/12/2021**, for third dose authorization for immunocompromised/solid organ recipients to be administered at least 28 days following the two-dose primary series.; **Updated 9/22/2021**, for use of a single booster dose at least six months after completion of primary series for individuals 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19). **Updated 10/20/2021**, the FDA authorized the use of a heterologous (or “mix and match”) booster dose in eligible individuals following completion of primary vaccination with a different available COVID-19 vaccine. **Updated 11/19/21**, for a single booster dose for all individuals 18 years of age or older at least six months after completion of primary vaccination series of the Moderna COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine or at least two months after completion of primary vaccination with the Janssen COVID-19 Vaccine. **Updated 12/09/2021,** for single booster dose to individuals 16 and 17 years of age at least six months after completion of primary vaccination with the Pfizer-BioNTech COVID-19 Vaccine. **Updated 1/03/2022**, a single Pfizer-BioNTech COVID-19 vaccine booster dose (0.3 mL) may be administered at least five months after completing a primary series of the Pfizer-BioNTech COVID-19 Vaccine or COMRNATY to individuals 12 years of age and older. **Updated 3/29/2022**, the FDA approved a second booster dose of the Pfizer-BioNTech COVID-19 vaccine for individuals 50 years of age and older and individuals 12 years of age and older with immunocompromised conditions or solid organ transplantation, at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine. Available at: https://www.fda.gov/media/153713/download

Updated 8/31/2022, the FDA authorized a bivalent formulation for use as a single booster dose at least two months following primary and booster vaccination for individuals 12 years of age and older. The bivalent vaccine, referred to as "updated booster", contains two messenger RNA (mRNA) components of SARS-CoV-2 virus, one of the original strain of SARS-CoV-2 and the other one in common between the BA.4 and BA.5 lineages of the omicron variant of SARS-CoV-2. Available at: https://www.fda.gov/media/161327/download

- Fact Sheet for Healthcare Providers Emergency Use (EUA) of Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 5 years through 11 years of age. **On October 29, 2021**, the FDA authorized the Pfizer-BioNTech COVID-19 vaccine which is administered as a two-dose primary series, 3 weeks apart, but is a lower dose (10 micrograms) than that used for individuals 12 years of age and older (30 micrograms). **Updated 1/03/2022**, a third primary series dose at least 28 days following the second dose is authorized to children 5 through 11 years of age who have undergone solid organ transplantation, or who have been diagnosed with conditions that are considered to have an equivalent level of immunocompromised. **Updated 5/17/2022,** the FDA amended the EUA for the Pfizer-BioNTech COVID-19 Vaccine, authorizing the use of a single booster dose for administration to individuals 5 to 11 years of age at least five months after completion of a primary series with the Pfizer-BioNTech COVID-19 vaccine. **Updated 10/12/2022**, the FDA authorized a bivalent formulation for use as a single booster dose at least two months following primary and booster vaccination for individuals 5 years of age and older. The bivalent vaccine, referred to as "updated booster", contains two messenger RNA (mRNA) components of SARS-CoV-2 virus, one of the original strain of SARS-CoV-2 and the other one in common between the BA.4 and BA.5 lineages of the omicron variant of SARS-CoV-2. Available at: https://www.fda.gov/media/153714/download and https://www.fda.gov/media/162250/download
- Fact Sheet for Healthcare Providers Emergency Use (EUA) of Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 6 months through 4 years of age. On June 17, 2022, the FDA authorized the Pfizer-BioNTech COVID-19 vaccine, which is administered, after dilution, as a primary series of three 3 doses (0.2 mL each). The initial two doses are administered 3 weeks apart followed by a third dose administered at least 8 weeks after the second dose in individuals 6 months through 4 years of age. Individuals who will turn from 4 years to 5 years old between any doses in a primary series may receive: 1) a two-dose primary services with the Pfizer-BioNTech COVID-19 vaccine authorized for use in individuals 5 through 11 years of age, or 2) a three-dose primary series initiated with the Pfizer-BioNTech COVID-19 vaccine authorized for use in individuals 6 months to 4 years of age. **Updated 12/8/2022**, the FDA updated the authorization for individuals 6 months through 4 years of age who have not yet begun the three-dose primary series of the Pfizer-BioNTech COVID-19 vaccine or have not yet received the third does of their primary series will now receive the updated (bivalent) Pfizer-BioNTech COVID-19 vaccine as the third dose in the primary series following two doses of the original (monovalent) Pfizer-BioNTech COVID-19 Vaccine. Individuals 6 month to 4 years of age who have already completed the three-dose primary series with the original (monovalent) Pfizer-BioNTech COVID-19 vaccine will not be eligible for a booster dose of an updated bivalent vaccine at this time. Available at: https://www.fda.gov/media/159312/download
- Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA) of Moderna for individuals 18 years or older. **Updated 8/12/2021**, for third dose authorization for immunocompromised/solid organ recipients to be administered at least 28 days following the two-dose primary series. **Updated 10/20/2021**, for a single booster dose of the Moderna COVID

Vaccine that may be administered at least 6 months after completion of the primary series to individuals who are 65 years of age and older, 18 through 64 years of age at high risk of severe COVID-19, and 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2. **Additionally, on 10/20/2021**, the FDA authorized the use of a heterologous (or "mix and match") booster dose in eligible individuals following completion of primary vaccination with a different available COVID-19 vaccine. **Updated 11/19/2021**, for a single booster dose for all individuals 18 years of age or older at least six months after completion of primary vaccination series of the Moderna COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine or at least two months after completion of primary vaccination with the Janssen COVID-19 Vaccine. **Updated 01/07/2022** for a single booster dose for all individuals 18 years of age or older at least five months after completion of primary vaccination series of the Moderna COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine or at least two months after completion of primary vaccination with the Janssen COVID-19 Vaccine. **Updated 3/29/2022**, the FDA approved a second booster dose of the Moderna COVID-19 vaccine for individuals 50 years of age and older and individuals 18 years of age and older with immunocompromised conditions or solid organ transplantation, at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine. **Additionally, on 3/29/2022**, the FDA approved a manufacturing change for the Moderna COVID-19 vaccine to include an additional presentation of the vaccine for booster vaccination doses only. The Moderna COVID-19 vaccine is now authorized for individuals 18 and older in two presentations: 1) multiple dose vials with red caps and labels with a light blue border, formulated to provide doses for the primary vaccination (each 0.25 mL dose containing 100 microgram mRNA) or doses for booster vaccination (each 0.25 mL dose containing 50 microgram mRNA), 2) multiple dose vials with dark blue caps and labels with a purple border, formulated to provide doses for booster vaccination only (each 0.5 mL dose containing 50 microgram mRNA). Available at: https://www.fda.gov/media/157232/download (labels with purple border) and https://www.fda.gov/media/157233/download (labels with light blue border). **Updated 8/31/2022**, the FDA authorized a bivalent formulation for use as a single booster dose at least two months following primary and booster vaccination for individuals 18 years of age and older. The bivalent vaccine, referred to as "updated booster", contains two messenger RNA (mRNA) components of SARS-CoV-2 virus, one of the original strain of SARS-CoV-2 and the other one in common between the BA.4 and BA.5 lineages of the omicron variant of SARS-CoV-2. Available at: https://www.fda.gov/media/161318/download

- Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA) of Moderna for individuals 12 years old through 17 years old (primary series) and incorporates the booster doses for 18 years and older. **On June 17, 2022**, the FDA authorized the Moderna COVID-19 vaccine which is administered as a two-dose primary series to individuals 12 years of age and older. The FDA also authorized a third primary dose to individuals 12 years of age and older with immunocompromised conditions. **Updated 10/12/2022**, the FDA authorized a bivalent formulation for use as a single booster dose at least two months following primary and booster vaccination for individuals 6 years of age and older. The bivalent vaccine, referred to as "updated booster", contains two messenger RNA (mRNA) components of SARS-CoV-2 virus, one of the original strain of SARS-CoV-2 and the other one in common between the BA.4 and BA.5 lineages of the omicron variant of SARS-CoV-2. Available at: https://www.fda.gov/media/157233/download and https://www.fda.gov/media/161318/download
- Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA) of Moderna for individuals 6 years old through 11 years of age. **On June 17, 2022**, the FDA authorized the Moderna COVID-19 vaccine, supplied in a multiple-dose vial with a dark blue cap and a label

with a purple boarder or supplies in a multiple-dose vial with a dark blue cap and a label with a teal border is administered as a primary series of two-doses (0.5 mL) 1 month apart to individuals 6 years through 11 years of age. The FDA also authorized a third primary series dose (0.5 mL) of Moderna COVID-19 vaccine, with the dark blue cap/label with purple border or dark blue cap/label with teal border, to be administered 1 months following the second dose to individuals 6 years through 11 years of age with immunocompromised conditions. **Updated 10/12/2022**, the FDA authorized a bivalent formulation for use as a single booster dose at least two months following primary and booster vaccination for individuals 6 years of age and older. The bivalent vaccine, referred to as "updated booster", contains two messenger RNA (mRNA) components of SARS-CoV-2 virus, one of the original strain of SARS-CoV-2 and the other one in common between the BA.4 and BA.5 lineages of the omicron variant of SARS-CoV-2. Available at: https://www.fda.gov/media/159308/download and https://www.fda.gov/media/161318/download

- Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA) of Moderna for individuals 6 months old through 5 years of age. **On June 17, 2022**, the FDA authorized the Moderna COVID-19 vaccine, supplied in a multiple-dose vial with a dark blue cap and label with magenta border, administered as a two-dose primary series to individuals 6 months through 5 years of age. The FDA also authorized a primary third dose to individuals 6 months through 5 years of age with immunocompromised conditions. **Updated 12/8/2022**, the FDA authorized a bivalent formulation for use as a single booster dose two months following primary series (monovalent) Moderna COVID-19 vaccine for individuals 6 months of age through 5 years of age. Available at: https://www.fda.gov/media/159307/download
- Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA) of Janssen, also called Johnson & Johnson (18 years or older). **Updated 10/20/2021**, the FDA authorized a single booster dose of the Janssen (Johnson and Johnson) COVID-19 Vaccine administered at least 2 months after completion of the single-dose primary regimen to individuals 18 years of age and older. **Additionally, on October 20, 2021**, the FDA authorized the use of a heterologous (or "mix and match") booster dose for currently available (i.e., FDA-authorized or approved) COVID-19 vaccines. Therefore, Janssen COVID-19 Vaccine recipients 18 years of age and older may receive a single booster dose of Janssen COVID-19 Vaccine, Moderna COVID-19 Vaccine (half dose) or Pfizer-BioNTech COVID-19 Vaccine at least two months after receiving their Janssen COVID-19 Vaccine primary vaccination. **Updated 12/14/2021**, a contraindication for the administration of the Janssen COVID-19 vaccine to individuals with a history of thrombosis with thrombocytopenia following the Janssen COVID-19 vaccine or any other adenovirus-vectored COVID-19 vaccine, and to update the information about the risk of thrombosis with thrombocytopenia syndrome or TTS following vaccination. **Updated 1/11/2022**, reports of adverse events following the use of the J&J vaccine, which suggests an increased risk of Immune Thrombocytopenia (ITP) during the 42 days following vaccination and that individuals with a history of ITP should discuss the risk and potential need for platelet monitoring following vaccination with their healthcare provider. **Updated 4/07/2022**, the FDA authorized an extension of the shelf life of refrigerated Janssen COVID-19 vaccine, allowing the product to be stored at 2-8 degrees Celsius for 11 months. This extension applies to all refrigerated vials of Janssen vaccine which have been held in accordance with manufacturer storage conditions. **Updated 5/05/2022**, the FDA limited the use of the Janssen COVID-19 Vaccine to individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the

Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine. https://www.fda.gov/media/146305/download

- Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA) of Novavax COVID-19 Vaccine, **dated 7/13/2022**, adjuvanted for the prevention of COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The Novavax vaccine is a two-dose primary series, administered three weeks apart. **Updated 8/19/2022**, the FDA extended the EUA for Novavax COVID-19 vaccine to individuals 12 through 17 years of age. **Updated 9/12/2022**, the FDA revised the authorization of Novavax COVID-19 vaccine related to the Vaccine Event Reporting System (VAERS) reporting requirements for vaccination providers and Novavax, Inc. to include myocarditis and pericarditis after administration, as some cases of myocarditis and pericarditis may not meet the definition of serious adverse event, and this will allow reporting to VAERS. **Updated 10/19/2022**, the FDA updated the EUA for a first booster dose for individuals 18 years and older when they have completed the primary vaccination series at least 6 months before the booster, if an FDA-authorized mRNA bivalent COVID-19 booster is not accessible or clinically appropriate, and if the individual elected to receive the Novavax vaccine and would not otherwise receive a COVID-19 booster. Available at: https://www.fda.gov/media/159897/download

American Medical Association (AMA) COVID-19 vaccine administration guidelines and Appendix Q resource: AMA updated 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/system/files/2021-01/covid-19-immunizations-appendix-q-table.pdf

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

- Category I codes (0001A, 0002A, 0003A, 0011A, 0012A, 0013A, 91300, 91301), new and revised guidelines and parenthetical notes.
- The new CPT codes are unique for each coronavirus vaccines (e.g., Pfizer (91300), and Moderna (91301). The administration codes are also unique to each such vaccine and dose: Pfizer (0001A, 0002A, 0003A), and Moderna (0011A, 0012A, 0013A).

Coding Information for Vaccines

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 Vaccines are effective upon receiving Emergency Use Authorization or approval from the Food and Drug Administration

COVID-19 Vaccine CPT/HCPCS Code	Description
91300 (Pfizer-BioNTech COVID-19 Vaccine/Comirnaty	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, for intramuscular use

*** For patients who are 12 years old and older**	**Effective date: December 11, 2020
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 **Effective date: December 11, 2020
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 **Effective date: December 11, 2020
0003A 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, third dose **Effective date: August 12, 2021
0004A 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/0.3 mL dosage, diluent reconstituted, booster dose ** Effective date: September 3, 2021
91305 (Pfizer-BioNTech COVID-19 Vaccine) *** For patients who are 12 years old and older**	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use ***Effective date: January 3, 2022
0051A admin for 91305	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/0.3 mL dosage, tris-sucrose formulation, first dose ***Effective date: January 3, 2022
0052A admin for 91305	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/0.3 mL dosage, tris-sucrose formulation, second dose ***Effective date: January 3, 2022
0053A admin for 91305	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/0.3 mL dosage, tris-sucrose formulation, third dose ***Effective date: January 3, 2022
0054A admin for 91305	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/0.3 mL dosage, tris-sucrose formulation, booster dose ***Effective date: January 3, 2022

91307 (Pfizer-BioNTech COVID-19 Pediatric Vaccine) *** For patients who are 5 through 11 years old**	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use **Effective date: October 29, 2021
0071A admin for 91307	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, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, first dose **Effective date: October 29, 2021
0072A admin for 91307	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, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, second dose **Effective date: October 29, 2021
0073A admin for 91307	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, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, third dose **Effective date: January 3, 2022
0074A admin for 91307	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, booster **Effective date: May 17, 2022
91308 (Pfizer-BioNTech COVID-19 Vaccine). *** For patients who are 6 months through 4 years old**	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use ** **Effective date: June 17, 2022
0081A admin for 91308	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, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, first dose **Effective date: June 17, 2022
0082A admin for 91308	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, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, second dose **Effective date: June 17, 2022
0083A admin for 91308	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, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, third dose **Effective date: June 17, 2022
91312 (Pfizer-BioNTech COVID-19 Bivalent) *** For patients who are 12 years old and older**	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use **Effective date: August 31, 2022
0124A admin for 91312	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, booster dose **Effective date: August 31, 2022
91315 (Pfizer-BioNTech COVID-19 Bivalent) *** For patients who are 5 through 11 years old**	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use **Effective October 12, 2022
0154A admin for 91315	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, booster dose **Effective October 12, 2022
91317 (Pfizer-BioNTech COVID-19 Vaccine). *** For patients who are 6 months through 4 years old**	Severe acute respiratory syndrome coronavirus 2 (SARS -CoV -2) (coronavirus disease [COVID -19]) vaccine, mRNA -LNP, bivalent spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris -sucrose formulation, for intramuscular use **Effective December 8, 2022
0173A admin for 91317	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, third dose **Effective December 8, 2022
91301 (Moderna COVID-19 Vaccine) *** For patients who are 12 years old and older**	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. **Effective date: December 18, 2020
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 **Effective date: December 18, 2020
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 **Effective date: December 18, 2020
0013A 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, third dose **Effective date: August 12, 2021
91306 (Moderna COVID-19 Vaccine) *** For patients who are 18 years old and older**	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, for intramuscular use **Effective date: October 20, 2021
0064A admin for 91306	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, 50 mcg/0.25 mL dosage, booster dose **Effective date: October 20, 2021
91309 (Moderna COVID-19 Vaccine) *** For patients who are 6 through 11 years old and older & booster dose for patients who are 18 years old and older (0094A)**	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, for intramuscular use **Effective date: March 29, 2022
0091A admin for 91309	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, 50 mcg/0.5 mL dosage; first dose, when administered to individuals 6 through 11 years **Effective date: June 17, 2022
0092A admin for 91309	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, 50 mcg/0.5 mL dosage; second dose, when administered to individuals 6 through 11 years **Effective date: June 17, 2022
0093A admin for 91309	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, 50 mcg/0.5 mL dosage; third dose, when administered to individuals 6 through 11 years **Effective date: June 17, 2022
0094A admin for 91309	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, 50 mcg/0.5mL dosage, booster dose **Effective date: March 29, 2022

91311 (Moderna COVID-19 Vaccine) *** For patients who are 6 months through 5 years old**	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 25 mcg/0.25 mL dosage, for intramuscular use **Effective June 17, 2022
0111A admin for 91311	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, 25 mcg/0.25 mL dosage, first dose **Effective June 17, 2022
0112A admin for 91311	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, 25 mcg/0.25 mL dosage, second dose **Effective June 17, 2022
0113A admin for 91311	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, 25 mcg/0.25 mL dosage; third dose **Effective June 17, 2022
91313 (Moderna COVID-19 Vaccine, Bivalent) *** For patients who are 18 years old and older and 12 through 17 years old**	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 50 mcg/0.5 mL dosage, for intramuscular use **Effective August 31, 2022
0134A admin for 91313	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 50 mcg/0.5 mL dosage, booster dose **Effective August 31, 2022
91314 (Moderna COVID-19 Vaccine, Bivalent) *** For patients who are 6 through 11 years old**	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 25 mcg/0.25 mL dosage, for intramuscular use **Effective October 12, 2022
0144A admin for 91314	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 25 mcg/0.25 mL dosage, booster dose **Effective October 12, 2022
91316 (Moderna COVID-19 Vaccine) *** For patients who are 6 months through 5 years old**	Severe acute respiratory syndrome coronavirus 2 (SARS -CoV -2) (coronavirus disease [COVID -19]) vaccine, mRNA -LNP, spike protein, bivalent, preservative free, 10 mcg/0.2 mL dosage, for intramuscular use **Effective December 8, 2022
0164A admin for 91316	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus

	disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 10 mcg/0.2 mL dosage, booster dose **Effective December 8, 2022
91303 (Janssen Covid-19 Vaccine) *** For patients who are 18 years old and older**	(Janssen) Severe acute resp syndrome coronavirus 2 ([COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 vector, preservative free, 0.5ml dosage, intramuscular use **Effective date: February 27, 2021
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 **Effective date: February 27, 2021
0034A admin for 91303	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral particles/0.5 mL dosage; booster dose Effective date: October 20, 2021
91304 (Novavax COVID-19 Vaccine) *** For patients who are 12 years old and older (0041A and 0042A) & booster dose for patients who are 18 years old and older (0044A)**	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage, for intramuscular use **Effective date: July 13, 2022
0041A admin for 91304	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage; first dose **Effective date: July 13, 2022
0042A admin for 91304	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage; second dose **Effective date: July 13, 2022
0044A admin for 91304	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5mcg/0.5mL dosage; booster **Effective date: July 13, 2022
M0201 admin for Covid-19 vaccine in the home	Covid-19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only covid-19 vaccine administration is performed at the patient's home **Effective date: June 8, 2021

FDA Fact Sheets for Emergency Use Authorization of Monoclonal Antibody Infusions

- Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) for ACTEMRA® (tocilizumab). **Updated 12/23/2022**. The FDA approved a new indication for Actemra (tocilizumab) injection for the treatment of hospitalized adult patients with COVID-19, who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). https://www.fda.gov/media/150321/download
- Fact Sheet for Health Care Providers Emergency Use Authorization for Bebtelovimab. **Updated 5/20/2022**, the FDA authorized an extension to the shelf-life from 12 months to 18 months for specific lots of the refrigerated bebtelovimab. The extension applies to all unopened vials of bebtelovimab that have been held in accordance with storage conditions detailed in the EUA fact sheet (refrigerated at temperatures at 2ºC to 8ºC (36ºF to 46ºF) in the original carton to protect from light. **Updated 11/04/2022**, the FDA released information that bebtelovimab has an expected reduced activity against certain emerging Omicron subvariants BQ.1 and BQ1.1. At this time bebtelovimab remains authorized in all US regions, until further notice by the FDA. https://www.fda.gov/media/156152/download
- Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Bamlanivimab and Etesevimab. **Updated 1/24/2022,** the FDA revised the EUA to limit use to only when the patient is likely to have been infected with or exposed to a variant that is susceptible to these treatments. Bamlanivimab and Etesevimab have not been shown to be active against the omicron variant, which is circulating with high frequency in the US, therefore this treatment is not authorized for use in any US state, territory, or jurisdiction at this time. In the future, if patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to these treatments, then use of the treatments may be authorized in those regions. **Updated 5/04/2022**, the FDA authorized an extension of Bamlanivimab and Etesevimab shelf-life from 18 months to 24 months for specific lots of refrigerated Bamlanivimab and Etesevimab. Retained Bamlanivimab and Etesevimab must be appropriately held in accordance with storage conditions (refrigerated temperature at 2º C to 8º (36ºF to 46ºF) detailed in the EUA fact sheet. https://www.fda.gov/media/145802/download
- Fact Sheet for Health Care Providers Emergency Use Authorization for EVUSHELD™ (tixagevimab co-packaged with cilgavimab). The EUA granted on **12/08/2021**, for EVUSHELD is for pre-exposure prophylaxis (prevention of COVID-19) and is only authorized for those individuals who are not currently infected with the SARS-CoV-2 virus and for those who have not recently been exposed to an individual infected with SARS-CoV-2. The authorization also requires that individuals either have:
    - Moderate to severely compromised immune systems due to a medical condition or due to taking immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination;
    - A history of severe adverse reactions to a COVID-19 vaccine and/or component(s) of those vaccines, therefore vaccination with an available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended.

  Updated 2/24/2022, the FDA increased the initial authorized dosage to 300 mg tixagevimab and 300 mg of cilgavimab. Patients who have already received the previously authorized dose

(150 mg of tixagevimab and 150 mg of cilgavimab) should receive an additional dose of 150 mg of tixagevimab and 150 mg of cilgavimab as soon as possible to raise their monoclonal antibody levels to those expected for patients receiving the higher dose. **Updated 5/17/2022**, the FDA revised the scope of authorization to include new information on hypersensitivity reactions and the risk of cross-hypersensitivity with COVID-19 vaccines and related clinical recommendations. Clinicians should consider consulting an allergist-immunologist prior to administering Evusheld to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to COVID-19 vaccine. For all individuals, Evusheld should be administered under the supervision of a health care provider with appropriate medical support to manage severe allergic reactions. In addition, everyone who received Evusheld should be observed after injection for at least one (1) hour to monitor for hypersensitivity reactions. **Updated 6/28/2022**, the FDA authorized an extension of tixagevimab and cilgavimab shelf-life from 18 months to 24 months for specific lots of refrigerated tixagevimab and cilgavimab. Retained tixagevimab and cilgavimab must be appropriately held in accordance with storage conditions (refrigerated temperature at 2º C to 8º (36ºF to 46ºF) detailed in the EUA fact sheet. **Updated 7/01/2022**, the FDA recommend repeat dosing every six months with a dose of 300 mg of tixagevimab and 300 mg cilgavimab if patients need ongoing protection. **Updated 10/3/2022**, the FDA added a notification to individuals and health care providers that those who receive Evusheld may be at increased risk for developing COVID-19 when exposed to variants of SARs-CoV-2 that are not neutralized by Evusheld. Detailed neutralization data is available in the health care provider fact sheet. Health care providers should inform individuals of this risk and advise to promptly seek medical attention and treatment if they develop signs or symptoms or test positive for COVID-19. **Updated 1/26/2023,** the FDA revised the EUA as Evusheld it is not currently authorized for use the U.S. Available at: https://www.fda.gov/media/154701/download

- Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of REGEN-COV™ (casirivimab and imdevimab). **Updated 1/24/2022,** the FDA revised the EUA to limit use to only when the patient is likely to have been infected with or exposed to a variant that is susceptible to these treatments. REGEN-COV™ has not been shown to be active against the omicron variant, which is circulating with high frequency in the US, therefore this treatment is not authorized for use in any US state, territory, or jurisdiction at this time. In the future, if patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to these treatments, then use of the treatments may be authorized in those regions. **Updated 6/27/22**, the FDA authorized an extension of casirivimab and imdevimab shelf-life from 24 months to 30 months for specific lots of refrigerated casirivimab and imdevimab. Retained casirivimab and imdevimab must be appropriately held in accordance with storage conditions (refrigerated temperature at 2º C to 8º (36ºF to 46ºF) detailed in the EUA fact sheet. Available at: https://www.fda.gov/media/145611/download
- Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Sotrovimab. **Updated 2/25/2022,** Sotrovimab continues to be authorized to treat COVID-19 in all US Regions. **Updated 3/25/2022**, Sotrovimab is no longer authorized as the current authorized does is unlikely to be effective against the BA.2 sub-variant, which is estimated to account for more than 50% of cases in the following states and territories: HHS Region 1: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, and HHS Region 2: New Jersey, New York, Puerto Rico, and the Virgin Islands. **Updated 4/5/2022**, Sotrovimab is no longer authorized to treat COVID-19 in any US region due to increases in the proportion of COVID-19 cases caused by the Omicron BA.2 sub-variant. **Updated 5/12/2022**, the FDA authorized an extension for the shelf-life from 12 months to 18 months for all lots of Sotrovimab.

Retained product must be appropriately held in accordance with storage conditions (refrigerated temperature at 2º C to 8º (36ºF to 46ºF) detailed in the EUA fact sheet. The FDA continues to evaluate further extensions of Sotrovimab shelf-life. All Sotrovimab vials may continue to be retained regardless of the current labeled expiry date or the previously provided extension dates, until otherwise notified by the FDA. **Updated 7/29/2022**, the FDA authorized an extension for the shelf-life for refrigerated lots of Sotrovimab from 18 months to 24 months. https://www.fda.gov/media/149534/download

Coding Information for Monoclonal Antibodies

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 Monoclonal Antibodies are effective upon receiving Emergency Use Authorization or approval from the Food and Drug Administration.

COVID-19 Monoclonal Antibodies HCPCS/CPT Code	Description
Q0220 (tixagevimab and cilgavimab)	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), 300 mg **Effective date December 8, 2021
Q0221 (tixagevimab and cilgavimab)	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), 600 mg **Effective date February 24, 2022
M0220 (admin code for Q0220 and Q0221)	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), includes injection and post administration monitoring **Effective date December 8, 2021

M0221 (admin code for Q0220 and Q0221)	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), includes injection and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency **Effective date December 8, 2021
Q0222 (bebtelovimab)	Injection, bebtelovimab, 175 mg **Effective February 11, 2022
M0222 (admin code for Q0222)	Intravenous injection, bebtelovimab, includes injection and post administration monitoring **Effective February 11, 2022
M0223 (admin code for Q0222)	Intravenous injection, bebtelovimab, includes injection and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency **Effective February 11, 2022
Q0239 (bamlanivimab)	Injection bamlanivimab. 700 mg **Termed date: April 17, 2021 **Effective date: November 10, 2020, through April 16, 2021
M0239 (admin code for Q0239)	Intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring **Termed date: April 17, 2021 ** Effective dates: November 10, 2020, through April 16, 2021
Q0240 (casirivimab and imdevimab)	Injection, casirivimab and imdevimab, 600 mg **Effective date: July 30, 2021 ***Effective 1/24/2022 - Not authorized for Omicron variants*
M0240 (admin code for Q0240)	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring, subsequent repeat doses **Effective date: July 30, 2021 ***Effective 1/24/2022 - Not authorized for Omicron variants*
M0241 (admin code for Q0240)	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring in the home or residence, this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency, subsequent repeat doses **Effective date: July 30, 2021 ***Effective 1/24/2022 - Not authorized for Omicron variants*

Q0243 (casirivimab and imdevimab)	Injection, casirivimab and imdevimab, 2400 mg **Effective date: November 21, 2020 ***Effective 1/24/2022 - Not authorized for Omicron variants*
Q0244 (casirivimab and imdevimab)	Injection, casirivimab and imdevimab, 1200 mg **Effective date: June 3, 2021 ***Effective 1/24/2022 - Not authorized for Omicron variants*
M0243 (admin code for Q0243 and Q0244)	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab, includes infusion or injection, and post administration monitoring **Effective date: November 21, 2020 ***Effective 1/24/2022 - Not authorized for Omicron variants*
M0244 (admin code for Q0243 and Q0244)	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab, includes infusion or injection and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the COVID-19 public health emergency **Effective date: May 6, 2021 ***Effective 1/24/2022 - Not authorized for Omicron variants*
Q0245 (bamlanivimab and etesevimab)	Injection, bamlanivimab and etesevimab, 2100 mg **Effective date: February 9, 2021 ***Effective 1/24/2022 - Not authorized for Omicron variants*
M0245 (admin code for Q0245)	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring **Effective date: February 9, 2021 ***Effective 1/24/2022 - Not authorized for Omicron variants*
M0246 (admin code for Q0245)	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the COVID-19 public health emergency **Effective date: May 6, 2021 ***Effective 1/24/2022 - Not authorized for Omicron variants*
Q0247 (sotrovimab)	Injection, sotrovimab, 500 mg **Effective date: May 26, 2021 ***Effective 4/05/2022 - Not authorized for Omicron variants*
M0247 (admin code for Q0247)	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring **Effective May 26, 2021 ***Effective 4/05/2022 - Not authorized for Omicron variants*

M0248 (admin code for Q0247)	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency **Effective May 26, 2021 ***Effective 4/05/2022 - Not authorized for Omicron variants*
Q0249 (tocilizumab)	Injection, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) only, 1 mg **Effective date: June 24, 2021
M0249 (admin code for Q0249)	Intravenous infusion, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) only, includes infusion and post administration monitoring, first dose **Effective date: June 24, 2021
M0250 (admin code for Q0249)	Intravenous infusion, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) only, includes infusion and post administration monitoring, second dose **Effective date: June 24, 2021

Administration Codes - CMS Pricing

GPCI Adjustment by State: We can only apply the GPCI adjusted rates by state (not by actual area)	
Oregon	Portland rate of 41.71 for all of Oregon
Washington	Seattle rate of 45.41 for all of Washington
Idaho	Idaho = 36.59
Montana	Montana = 40.11

*Commercial – For dates of service 3-15-21, we use these GPCI adjusted rates for Commercial reimbursement of the COVID vaccine admin codes. *

This CMS GPCI adjusted rate per state will apply to ALL agreements.

* *Participating providers that dispute reimbursement with agreement language different from what is outlined in this policy must consult Provider Contracting.* *

2021 LOCALITY-ADJUSTED PAYMENT AMOUNTS FOR ADMINISTRATION OF MONOCLONAL ANTIBODIES USED TO TREAT COVID-19 *Updated 7/06/2021 to reflect addition of Tocilizumab* *Effective for claims with dates of service 5/6/2021 - 12/31/2021*			M0243 National RVUs: 12.89 National PW: 0.85	M0244 National RVUs: 21.50 National PW: 1.42 /	M0245 National RVUs: 12.89 National PW: 0.85	M0246 National RVUs: 21.50 National PW: 1.42 / PE: 19.62 /	M0247 National RVUs: 12.89 National PW: 0.85	M0248 National RVUs: 21.50 National PW: 1.42 /	M0249 National RVUs: 12.89 National PW: 0.85	M0250 National RVUs: 12.89 National PW: 0.85
Medicare Administrative Contractor (MAC)	Locality Number	Locality Name	Total Pay	Total Pay	Total Pay	Total Pay	Total Pay	Total Pay	Total Pay	Total Pay
02202	00	IDAHO	$ 393.76	$ 656.62	$393.76	$ 656.62	$393.76	$ 656.62	$393.76	$393.76
06102	99	REST OF ILLINOIS	$ 415.35	$ 692.88	$415.35	$ 692.88	$415.35	$ 692.88	$415.35	$415.35
03202	01	MONTANA	$ 449.56	$ 749.83	$449.56	$ 749.83	$449.56	$ 749.83	$449.56	$449.56
02302	01	PORTLAND	$ 471.92	$ 786.96	$471.92	$ 786.96	$471.92	$ 786.96	$471.92	$471.92
02302	99	REST OF OREGON	$ 423.62	$ 706.45	$423.62	$ 706.45	$423.62	$ 706.45	$423.62	$423.62
03502	09	UTAH	$ 414.61	$ 691.52	$414.61	$ 691.52	$414.61	$ 691.52	$414.61	$414.61
02402	02	SEATTLE (KING CNTY)	$ 528.40	$ 881.20	$528.40	$ 881.20	$528.40	$ 881.20	$528.40	$528.40
02402	99	REST OF WASHINGTON	$ 453.11	$ 755.68	$453.11	$ 755.68	$453.11	$ 755.68	$453.11	$453.11
03602	21	WYOMING	$ 448.27	$ 747.65	$448.27	$ 747.65	$448.27	$ 747.65	$448.27	$448.27

https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies

COVID-19 Vaccines and Monoclonal Antibodies – CMS Pricing

We adhere to CDC and CMS approved published rates. The effective date will follow CMS guidance. For Oregon Medicaid we follow OHA reimbursement rates.

COVID-19 Vaccines and Monoclonal Antibodies | CMS

Oregon Medicaid COVID-19 Provider Guide

Antiviral Medications Approval and Emergency Use Authorization

FDA Approved Antiviral Medications

- Fact Sheet for Health Care Providers Approval and Emergency Use Authorization (EUA) of Veklury® (remdesivir). On 10/22/20, Veklury® (remdesivir) was approved for use in adults and pediatric patients 12 years of age and older weighing at least 40 kilograms (about 88 pounds) for treatment of COVID-19 requiring hospitalization. Veklury should be only administered in a hospital or healthcare setting capable of providing acute care comparable to inpatient hospital care. **Updated 1/21/22**, the FDA expanded the approved indication for Veklury to include use in adults and pediatric patients 12 years of age and older weighing at least 40 kilograms (about 88 pounds) with positive results of direct SARS-CoV-2 viral testing, and who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death. **Updated 4/25/2022**, the FDA expanded the approval of Veklury® (remdesivir) to include pediatric patients 28 days of age and older weighing at least 3 kilograms (about 7 pounds) with positive results of direct SARS-CoV-2 viral testing, who are: hospitalized or not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.

  https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/214787Orig1s011ltr.pdf

FDA Fact Sheets for Emergency Use Authorization of Antiviral Medications

- The U.S. Food and Drug Administration issued an emergency use authorization (EUA) for Veklury® (remdesivir) for the treatment of suspected or laboratory confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg. Updated 1/21/22, the FDA expanded authorization for treatment of pediatric patients weighing 3.5 kilograms to less than 40 kilograms or pediatric patients less than 12 years of age weighing at least 3.5 kilograms, with positive results of direct SARS-CoV-2 viral testing, and who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including

hospitalization or death. **Updated 4/25/2022, the EUA was revoked due to expansion of FDA approval of Veklury® (remdesivir).**

- Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Paxlovid (nirmatrelvir co-packaged with ritonavir). Pfizer's Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) for the treatment of mild-to-moderate COVID-19 in adults and pediatric (12 years of age and older weighing at least 40 kilograms or about 88 pounds) patients with a positive COVID-19 test result who are at high risk for progressing to severe COVID-19 including hospitalization or death. The following limitation were listed as part of the EUA:
    - Not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19;
    - Not authorized for use as pre-exposure or as post-exposure prophylaxis for prevention of COVID-19;
    - Not authorized for use longer than five (5) consecutive days. https://www.fda.gov/media/155050/download

  The FDA has additional guidance, as of **6/7/2022**, for prescribers to evaluate potential drug interactions when using Paxlovid for treatment of COVID-19. Prescribers should review each patient's full list of medications and use other resources included on a checklist, which is available at: https://www.fda.gov/media/158165/download

  The FDA revised the EUA for Paxlovid on **7/6/2022**, to allow state-licensed pharmacists to prescribe Paxlovid to eligible patients, with certain limitations to ensure appropriate patient assessment and prescribing of Paxlovid. The state-licensed pharmacists should refer patients for clinical evaluation by a physician, advanced practice registered nurse, or physician assistant licensed or authorized under state laws when: a) sufficient information is not available to assess renal and hepatic function, b) sufficient information is not available to assess for potential drug interaction, c) modification of other medications is needed due to a potential drug interaction, and d) Paxlovid is not appropriate therapeutic option based on the current fact sheet for health care providers or due to potential drug interactions for which recommended monitoring would not be feasible. **Updated 7/26/2022**, The FDA established a 12-month product shelf-life. Four lots of Paxlovid manufactured prior to the EUA issuance were labeled with a 9-month expiry. The FDA has extended expiration dates for these lots to reflect the 12-month shelf-life, when stored according to the storage conditions detailed in the EUA. **Updated 9/6/2022**, the FDA authorized an extension for the shelf-life from 12 to 18 months, for certain lots of Paxlovid (those with an expiration date from July 2022 to May 2023 may be stored an additional six months from the labeled date of expiry). **Updated 2/1/2023,** the FDA revised the EUA to remove positive COVID-19 test result prior to prescribing Paxlovid. Available at: https://www.fda.gov/media/155050/download

- Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Lagevrio (molnupiravir). Merk's Lagevrio (molnupiravir) for treatment of mild-to-moderate COVID-19 in adults with a positive COVID-19 test result, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate. The following limitations were listed as part of the EUA:
    - Not authorized for use longer than five (5) consecutive days;
    - Not authorized for use in patients younger than 18 years of age because Lagevrio (molnupiravir) may affect bone and cartilage growth;

- Not authorized for pre-exposure or post-exposure prevention of COVID-19;
- Not authorized for initiation of treatment in patients hospitalized due to COVID-19.

The FDA revised the EUA on **2/1/2023** to remove positive COVID-19 test result prior to prescribing for Lagevrio (molnupiravir). Available at: https://www.fda.gov/media/155054/download

Coding Information for Antiviral Medications

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

COVID-19 Antiviral Medication HCPCS/CPT Code	Description
J0248 Veklury™(remdesivir)	Injection, remdesivir, 1 mg

Claims and Billing ICD-10 Codes

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 respiratory failure, confirmed as due to COVID-19	J96.0, 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
Coronavirus infection, current infection	U07.1
Encounter for screening for COVID-19	Z11.52
Encounter for immunization	Z23
Encounter of screening for other viral diseases.	Z11.59
Exposure to confirmed COVID-19	Z20.828
Multisystem inflammatory syndrome (MIS) and COVID-19	M35.81, U07.1
CoV acute respiratory disease	U07.1
Other specified systemic involvement of connective tissue	M35.89
Partially vaccinated for COVID-19 (received at least one dose of multi-dose COVID-19 vaccine regiment)	Z28.311

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	U07.1, J12.82
Possible exposure to COVID-19, condition ruled-out	Z03.818
Post COVID-19 condition, unspecified	U09.9
Previous COVID-19 infection with current (active) infection	U09.9, U07.1
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
Unvaccinated for COVID-19 (not received at least one dose of COVID-19 vaccine)	Z18.310

Experimental/Investigational/Unproven

PacificSource considers Hyperbaric Oxygen Therapy (HBOT) for the treatment of post-COVID conditions to be experimental, investigational or unproven.

Related Policies

Hyperbaric Oxygen Therapy (HBOT)

References

American Medical Association. Serological testing for SARS-CoV-2 antibodies. Updated May 14, 2020. Chicago, IL. Accessed June 19, 2020, October 7, 2021, and August 31, 2022. https://www.ama-assn.org/delivering-care/public-health/serological-testing-sars-cov-2-antibodies

American Medical Association. (2020, November 10) COVID-19 CPT vaccine and immunization codes. Accessed October 7, 2021, and August 31, 2022. https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-vaccine-and-immunization-codes

Centers for Disease Control and Prevention. (Aug. 2, 2021). *COVID-19 Testing Overview.* Accessed October 5, 2021, and August 31, 2022. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html

Centers for Disease Control and Prevention. Serology Testing for COVID-19. Last reviewed May 5, 2020. Atlanta, GA. Accessed June 19, 2020, October 13, 2020, November 9, 2020, October 7, 2021, and August 31, 2022. https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html

Centers for Disease Control and Prevention. Global Information About Pfizer-BioNTech COVID-19 Vaccine. Atlanta, GA. Updated August 23, 2021. Accessed August 23, 2021, and August 31, 2022. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html

Centers for Disease Control and Prevention. Interim guidelines for COVID-19 antibody testing. Last reviewed 5/23/2020. Atlanta, GA. Accessed June 19, 2020, October 13, 2020, November 9, 2020,

October 7, 2021, and August 31, 2022. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

Centers for Medicare and Medicaid Services. (2020) COVID-19 Vaccines and Monoclonal Antibodies. Accessed on October 7, 2021, and August 31, 2022. https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies

Centers for Medicare and Medicaid Services (2020) Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction. Accessed on October 7, 2021, and August 31, 2022. https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf

Hayes Knowledge Center. (July 18, 2022). Evidence Analysis Research Brief. Hyperbaric Oxygen Therapy for Treatment of Post-Covid Conditions.

Health and Human Services Department. (March 17, 2020). Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. Accessed on December 7, 2021, and August 31, 2022. https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures

Infectious Diseases Society of America. IDSA Covid-19 Antibody Testing Primer. Updated May 4, 020. Arlington, VA. Accessed June 19, 2020, October 7, 2021, and August 31, 2022. https://www.idsociety.org/globalassets/idsa/public-health/covid-19/idsa-covid-19-antibody-testing-primer.pdf

Infectious Diseases Society of America. Infectious Diseases Society of America Guidelines on the diagnosis of COVID-19. Published 5/6/2020. Accessed May 2020, October 7, 2021, and August 31, 2022. https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics

National Institute of Health. (1/19/2022). The COVID-19 Treatment Guidelines Panel's Statement on Therapies for High-Risk, Nonhospitalized Patients with Mild to Moderate COVID-19. Accessed 1/20/2022, and August 31, 2022. https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/

U.S. Department of Health & Human Services (HHS). (January 10, 2022). Biden-Harris Administration Requires Insurance Companies and Group Health Plans to Cover the Cost of At-Home COVID-19 Tests, Increasing Access to Free Tests. https://www.hhs.gov/about/news/2022/01/10/biden-harris-administration-requires-insurance-companies-group-health-plans-to-cover-cost-at-home-covid-19-tests-increasing-access-free-tests.html

U.S. Food and Drug Administration (FDA). Comirnaty and Pfizer-BioNTech COVID-19 Vaccine. Sept 22, 2021. Silver Spring, MD. Accessed Sept 22, 2021, October 7, 2021, and August 31, 2022. https://www.fda.gov/media/144413/download

U.S. Food and Drug Administration (FDA). Emergency Use Authorization. Accessed December 7, 2021, and August 31, 2022. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

U.S. Food and Drug Administration (FDA). FDA Issues Emergency Use Authorization for Third Covid-19 Vaccine. 2/2021. Silver Spring, MD. Accessed March 5, 2021, October 7, 2021, and August 31, 2022. https://content.govdelivery.com/accounts/USFDA/bulletins/2c440b4

U.S. Food and Drug Administration (FDA). Important Information on the Use of Serological (Antibody) Tests for COVID-19-letter to Health Care Providers. 4/2020. Silver Spring, MD. Accessed Jun 19, 2020,

October 7, 2021, and August 31, 2022. https://www.fda.gov/medical-devices/letters-health-care-providers/important-information-use-serological-antibody-tests-covid-19-letter-health-care-providers#:~:text=The%20FDA%20recommends%20health%20care,person%20may%20have%20been%20exposed.

U.S. Food and Drug Administration (FDA). Insight into FDA's revised policy on antibody tests: prioritizing access and accuracy. Silver Spring, MD. Accessed May 2020, October 7, 2021, and August 31, 2022. https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy

U.S. Food and Drug Administration (FDA). Policy for coronavirus disease-2019 tests during the public health emergency (Revised). 5/11/2020. Silver Spring, MD. Accessed May 2020, October 7, 2021, and August 31, 2022. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised

U.S. Food and Drug Administration (FDA). FDA Authorizes Monoclonal Antibodies for Treatment of COVID-19. Feb 12, 2021. Silver Spring, MD. Accessed Feb 17, 2021, October 7, 2021, and August 31, 2022. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19-0?utm_medium=email&utm_source=govdelivery

Appendix

Policy Number:

Effective: 8/11/2020 **Next review:** 5/31/2023

Policy type: Enterprise

Author(s):

Depts.: Health Services

Applicable regulation(s): FD&C Act §564, RCW 48.02.060(5)

Commercial Ops: 3/2023

Government Ops: 3/2023