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

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

## Enterprise Policy

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

## Background

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 located at:**

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

### Testing

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

- Diagnostic (viral) tests check samples from the respiratory system (such as swabs of the inside of the nose) to determine if an individual currently has an infection with SARS-CoV-2, the virus that causes COVID-19. Some tests are point-of-care tests, meaning results may be available at

the testing site in less than an hour. Other tests must be sent to a laboratory to analyze, a process that takes 1-2 days once received by the lab.

- Antibody (serology) tests check the blood by looking for antibodies, which can determine if an individual had a past infection with the virus that causes COVID-19. Antibodies are proteins that help fight off infections and usually provide protection against getting that disease again (immunity). Antibodies are disease specific. For example, measles antibody will protect a person who is exposed again to measles but will have no effect if the person is exposed to mumps.

## Vaccines

The U.S. Food and Drug Administration initially issued an emergency use authorization (EUA) for three COVID-19 vaccines, which include the Pfizer-BioNTech, Moderna, and Janssen. The Pfizer-BioNTech vaccine was granted FDA approval on 8/23/2021, as a two dose series in individuals 16 years of age or older (see vaccine approval and emergency use authorization section for further details).

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).

## Monoclonal Antibody Therapies

The U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the 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. The issuance of a EUA does not constitute FDA approval. These products are:

- *Bamlanivimab plus etesevimab:* These are neutralizing monoclonal antibodies that bind to different but overlapping epitopes in the spike protein RBD of SARS-CoV-2.
- *Casirivimab plus imdevimab:* These are recombinant human monoclonal antibodies that bind to nonoverlapping epitopes of the spike protein RBD of SARS-CoV-2.
- *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.

The U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the 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 tocilizumb:* 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.

The U.S. Food and Drug Administration issued an emergency use authorization (EUA) for AstraZeneca's Evusheld (tixagevimab co-packaged with cilgavimab and administered together) 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]. The product is only authorized for those individuals who are not currently infected with the SARS-CoV-2 virus and 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.
    - Tixagevimab and cilgavimab are two recombinant 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.

## 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/

**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.
- 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.
- The CDC has self-testing guidance available at https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html

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

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

**Exclusions for Diagnostic Testing:**

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 other employer-directed program;
- For public health surveillance testing;
- For any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition; **OR**
- For asymptomatic individuals who are being screened for COVID-19 and have no known exposure to the virus, and the test results are either unknown or negative.

## Member Cost Share for Diagnostic Testing

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

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

These benefits have been extended through the end of Emergency Declaration.

## 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.

**HCPCS and CPT codes for COVID-19 laboratory tests**

| Code | Description |
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| U0001 | CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel<br>**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<br>**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<br>**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<br>**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<br>**Effective January 1, 2021 |
| 0098U | Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types, 14 targets (adenovirus, coronavirus, human metapneumovirus)<br>**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)<br>**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)<br>**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<br>**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<br>**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<br>**Effective date: August 10, 2020 |

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| 0226U | Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum.<br>**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.<br>**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<br>**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)<br>**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.<br>**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.<br>**Effective date: March 1, 2020 |
| 86413 | Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative<br>**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])<br>**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.<br>**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.<br>**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<br>**Effective date: March 13, 2020 |

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| 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<br>**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.<br>**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)<br>**Effective date: October 6, 2020 |
| 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<br>**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 Vaccine

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. It also remains authorized for emergency use in individuals 12 through 15 years and to provide a third dose or booster. 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. Further information is available at: https://www.fda.gov/media/151710/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 8/12/21 for third dose authorization for immunocompromised/solid organ recipients; updated 9/22/21 for a single booster 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 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; update 12/9/21 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. Available at: https://www.fda.gov/media/153713/download

Fact Sheet for Healthcare Providers Emergency Use (EUA) of Pifzer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 5 years of age and older. On October 29, 2021, the FDA authorized the Pfizer-BioTech COVID-19 vaccine which is administered as a two-dose primary series, 3 weeks apart, but is a lower does (10 micrograms) than that used for individuals 12 years of age and older (30 micrograms). Available at: https://www.fda.gov/media/153714/download

Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA) of Moderna (18 years or older; updated 8/12/21 for third dose authorization for immunocompromised/solid organ recipients); updated 10/20/21 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 11/19/21 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. https://www.fda.gov/media/144637/download

Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA) of Janssen, also called Johnson & Johnson (18 years or older). On October 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. Also 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. Update 12/14/21, 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. https://www.fda.gov/media/146304/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

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

**HCPCS and CPT codes for COVID-19 Vaccines**

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| 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<br>**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<br>**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<br>**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<br>**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<br>** Effective date: September 3, 2021 |
| 91307 (Pfizer-BioNTech COVID-19 Pediatric Vaccine) | 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<br>Effective 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<br>Effective October 29, 2021 |

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| 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<br>Effective October 29, 2021 |
| 91305 (Pfizer-BioNTech COVID-19 Vaccine) | Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use<br>***TBD |
| 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<br>***TBD |
| 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<br>***TBD |
| 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<br>***TBD |
| 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<br>***TBD |
| 91301 (Moderna COVID-19 Vaccine) | Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19}) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use.<br>**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<br>**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<br>**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<br>**Effective date: August 12, 2021 |
| 91306 (Moderna COVID-19 Vaccine) | 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<br>**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<br>**Effective date: October 20, 2021 |
| 91302 (AstraZeneca COVID-19 Vaccine) | Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5X10 viral particle/0.5L dosage, for intramuscular use<br>***TBD |
| 0021A admin for 91302 | Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x10 viral particles/0.5mL dosage; first dose<br>***TBD |
| 0022A admin for 91302 | Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x10 viral particles/0.5mL dosage; second dose<br>***TBD |
| 91303 (Janssen Covid-19 Vaccine) | (Janssen) Severe acute resp syndrome coronavirus 2 ([COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 vector, preservative free, 0.5ml dosage, intramuscular use<br>**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<br>**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<br>Effective date: October 20, 2021 |
| 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<br>**Effective date: June 8, 2021 |



## Monoclonal Antibodies Emergency Use Authorization

**FDA Fact Sheets for Emergency Use Authorization of Monoclonal Antibody Infusions**

Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA) of REGEN-COV™ (casirivimab and imdevimab) https://www.fda.gov/media/145611/download

Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Bamlanivimab And Etesevimab
https://www.fda.gov/media/145801/download

Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) for ACTEMRA® (tocilizumab) https://www.fda.gov/media/150321/download

Fact Sheet for Health Care Providers Emergency Use Authorizations (EUA) of Sotrovimab https://www.fda.gov/media/149534/download

Fact Sheet for Health Care Providers Emergency Use Authorization for EVUSHELD™ (tixagevimab co-packaged with cilgavimab) https://www.fda.gov/media/154701/download

## Coding Information for Monoclonal Antibodies

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

| CODE | Vaccine/Procedure |
|---|---|
| M0239 | Intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring<br>**Termed date: April 17, 2021<br>** Effective dates: November 10, 2020 through April 16, 2021 |
| M0240 | Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring, subsequent repeat doses<br>**Effective date: July 30, 2021 |
| M0241 | 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<br>**Effective date: July 30, 2021 |
| M0243 | Intravenous infusion or subcutaneous injection, casirivimab and imdevimab, includes infusion or injection, and post administration monitoring<br>**Effective date: November 21, 2020 |
| M0244 | 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<br>**Effective date: May 6, 2021 |
| M0245 | Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring<br>**Effective date: February 9, 2021 |
| M0246 | 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<br>**Effective date: May 6, 2021 |
| M0247 | Intravenous infusion, sotrovimab, includes infusion and post administration monitoring<br>**Effective May 26, 2021 |

| | |
|---|---|
| M0248 | 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<br>**Effective May 26, 2021 |
| M0249 | 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<br>**Effective date: June 24, 2021 |
| M0250 | 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<br>**Effective date: June 24, 2021 |
| Q0239 | Injection bamlanivimab. 700 mg<br>**Termed date: April 17, 2021<br>**Effective date: November 10, 2020 through April 16, 2021 |
| Q0240 | Injection, casirivimab and imdevimab, 600 mg<br>**Effective date: July 30, 2021 |
| Q0243 | Injection, casirivimab and imdevimab, 2400 mg<br>**Effective date: November 21, 2020 |
| Q0244 | Injection, casirivimab and imdevimab, 1200 mg<br>**Effective date: June 3, 2021 |
| Q0245 | Injection, bamlanivimab and etesevimab, 2100 mg<br>**Effective date: February 9, 2021 |
| Q0247 | Injection, sotrovimab, 500 mg<br>**Effective date: May 26, 2021 |
| Q0249 | 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<br>**Effective date: June 24, 2021 |



## 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/lower respiratory infection NOS, confirmed as due to COVID-19 | J22, B97.29, U07.1 |
| Bronchitis NOS, confirmed as due to COVID-19 | J40, B97.29, U07.1 |
| Contact with and (suspected) exposure to COVID-19 | Z20.822 |
| Coronavirus infection, unspecified | B34.2 |
| Encounter for screening for COVID-19 | Z11.52 |
| Encounter of screening for other viral diseases. | Z11.59 |
| Exposure to confirmed COVID-19 | Z20.828 |
| Multisystem inflammatory syndrome (MIS) | M35.81 |
| nCoV acute respiratory disease | U07.1 |
| Other specified systemic involvement of connective tissue | M35.89 |
| Personal History of COVID-19 | Z86.16 |
| Pneumonia, confirmed as due to COVID-19 | J12.89, B97.29, U07.1 |
| Pneumonia due to SARS-associated coronavirus | J12.81 |
| Pneumonia due to coronavirus disease 2019 | J12.82 |
| Possible exposure to COVID-19, condition ruled-out | Z03.818 |
| Respiratory infection NOS, confirmed as due to COVID-19 | J98.8, B97.29, U07.1 |
| SARS-associated coronavirus as the cause of diseases classified elsewhere | B97.21 |

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## Appendix

**Policy Number:**

**Effective:** 8/11/2020 **Next review:** 2/28/2022

**Policy type:** Enterprise

**Author(s):**

**Depts.:** Health Services

**Applicable regulation(s):**

**Commercial Ops:** 12/2021

**Government Ops:** 12/2021