Molina Clinical Policy
COVID-19 Co-Pays and Cost Share – Medicaid: Policy No. 364b

Last Approval: 2/9/2022
Next Review Due By: February 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

COVID-19 is a disease caused by a virus called SARS-CoV-2. Two main variants of the virus have included Delta and Omicron. The Delta virus was predominant throughout 2021 however, in December 2021 the Omicron variant was detected in the United States ([1] CDC, 2021). While most have mild symptoms and improve within a few weeks, others can become severely ill and experience post-COVID conditions. Post-COVID conditions include a range of new, returning, or ongoing health problems that people experience four weeks or more after first being infected. It is spread when an infected individual transmits droplets and very small particles that contain the virus. Other people can breathe in these droplets and particles and acquire the virus through their eyes, noses, or mouth. The virus can also be transmitted through the air by coughing and sneezing as well as through close personal contact (touching or shaking hands) and via contaminated surfaces. People are recommended to stay at least six (6) feet apart from an infected individual to reduce transmission. ([2] CDC, 2021).

People with heart and lung disease or weakened immune systems, as well as infants and older adults, are at higher risk for more severe symptoms from this illness ([3] CDC, 2021). Symptoms range from mild symptoms to severe illness that appear 2-14 days after exposure to the virus. Common symptoms include fever, cough, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea. Respiratory symptoms such as shortness of breath may also be present; severe cases can lead to pneumonia, acute respiratory distress syndrome, kidney failure, and even death.

Emergency Use Authorization (EUA)

Under Section 564 of the Federal Food, Drug & Cosmetic Act (FD&C Act), the FDA may authorize an unapproved product or unapproved uses of an approved product for emergency use. The FDA must determine that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition caused by a chemical, biological, radiological, or nuclear agent; that the known and potential benefits outweigh the known and potential risks for the product; and that there are no approved, available alternatives. Emergency use authorization is NOT the same as FDA approval or licensure. EUAs are evaluated to determine continuation. ([1] FDA, 2021).

New drug applications (NDAs) are approved by the FDA as pursuant under Section 505(c) of the FD&C Act and biologics license applications (BLAs) under Section 351 of the Public Health Service Act (PHS Act). To approve an NDA/BLA, FDA reviewers must determine that the drug is safe and effective for its labeled use(s), and that the benefits of the drug outweigh the risks; that the drug's labeling (package insert) is appropriate; and that the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity. ([1] FDA, 2021). For additional information regarding EUA and COVID-19, including vaccines, drugs and non-vaccine biological products and medical devices, visit the FDA. ([2] FDA, 2022).

FDA Approved Vaccines

Three vaccines have been authorized for use in the United States to prevent COVID-19. Pfizer-BioNTech or Moderna (COVID-19 mRNA vaccines) are preferred however, Johnson & Johnson's Janssen vaccine is available. A person is considered fully vaccinated two weeks after their second dose in a two-shot series (Pfizer-BioNTech or Moderna vaccines) or two weeks after a single-dose vaccine (Johnson & Johnson/Janssen vaccine). ([4] CDC, 2021). Those who

receive the Janssen Johnson & Johnson vaccine ages 18 years and older should receive a booster of Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) at least 2 months after their initial vaccine in most situations ([5] CDC, 2021). For additional information about COVID-19 vaccines, visit the FDA ([3] FDA, 2022). For the most current information on boosters, visit the FDA website here. ([4] FDA, 2022). Please see the *Supplemental Information* section below for additional information on the vaccines noted above.

Laboratory Testing

Tests detect either SARS-CoV-2 (the virus that causes COVID-19) or antibodies that the body makes after getting COVID-19 or after getting vaccinated. Two common types of tests are rapid antigen tests and molecular polymerase chain reaction (PCR) laboratory tests. They use samples from the nose or mouth and rapid tests can be performed in minutes. Laboratory tests can take days to receive results. Some test results may need confirmatory testing. Self-tests are a type of rapid test that can be administered anywhere, are easy to use, and produce quick results. COVID-19 self-tests aid in risk-reduction and the spread of COVID-19 along with vaccination, masking, and physical distancing ([6] CDC, 2021). Tests have varying sensitivity and specificity depending on the variant of COVID-19.

Molecular (or antigen in vitro) tests are not beneficial in determining between infective viruses and viruses that have been neutralized by the host – these tests are diagnostic in nature ([5] FDA, 2021). Samples are taken from a throat or nasal swab or by saliva collected in a tube. Serology (antibody) tests cannot diagnose a current infection and look to see if an individual has antibodies from a past or current COVID-19 infection ([6] FDA, 2021).

Serology (antibody) tests cannot diagnose a current infection and look to see if an individual has antibodies from a past or current COVID-19 infection ([6] FDA, 2021). Serology (antibody) testing does not diagnose but indicates if an individual has had a past infection. Following infection or vaccination, the body creates antibodies. The immune system, by producing antibodies, helps fight infection and future severity of illness. In November 2020, the FDA authorized the first serology test to detect neutralizing antibodies from a recent or prior infection. The tests primarily have a role in public health initiatives as they are not immediately positive and do not designate an active infection. ([7] FDA, 2020).

For tables containing molecular diagnostic tests, click here. ([6] FDA, 2021). For test performance of serology tests, click here. ([7] FDA, 2021). The analytic sensitivity, specificity and positive and negative predictive values of individual tests that have received an FDA EUA designation can also be accessed here. ([2] FDA, 2022). Tests have varying sensitivities depending on the variance of COVID-19.

Pharmaceuticals

Please contact the Molina pharmacy manager or director for your State for the most up-to-date guidance.

Vaccines

Moderna

On December 19, 2020 the FDA issued EUA for the Moderna COVID-19 vaccine. It is a two-dose primary series for individuals 18 years of age and older, as a third primary series dose for individuals 18 years of age and older who have been determined to have certain kinds of immunocompromise, and as a single booster dose for individuals 18 years of age and older at least five months after completing a primary series of the vaccine. On January 31, 2022 the FDA granted formal approval and the vaccine will be marketed as Spikevax. The Moderna COVID-19 Vaccine is also authorized for use as a heterologous (mix and match) single booster dose for individuals 18 years of age and older following completion of primary vaccination with a different available COVID-19 vaccine. For example, Pfizer-BioNTech COVID-19 Vaccine and Janssen COVID-19 vaccine recipients 18 years of age and older may receive a single booster dose of the Moderna COVID-19 Vaccine. ([11] FDA, 2022).

Janssen

On February 27, 2021 the FDA issued an Emergency Use Authorization (EUA) for the vaccine as a single primary vaccination dose for individuals 18 years of age and older and as a single booster dose for individuals 18 years of age and older at least two months after completing primary vaccination with the vaccine. The Janssen COVID-19 Vaccine is also authorized for use as a heterologous (or mix and match) single booster dose for individuals 18 years of age and older following completion of primary vaccination with a different available COVID-19 vaccine. For example, Pfizer-

BioNTech COVID-19 Vaccine and Moderna COVID-19 vaccine recipients 18 years of age and older may receive a single booster dose of the Janssen COVID-19 vaccine. ([12] FDA, 2022).

Comirnaty / Pfizer-BioNTech

In August 2021 the Comirnaty / Pfizer-BioNTech COVID-19 vaccine was the first vaccine approved for the prevention of COVID-19 in individuals 16 years of age and older. It was authorized for emergency use and is available under the EUA as a two-dose primary series for individuals 5 years of age and older, as a third primary series dose for individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise, and as a single booster dose for individuals 12 years of age and older at least five months after completing a primary series of the vaccine. The vaccine is also approved for use as a heterologous (mix and match) single booster dose for individuals 18 years of age and older following completion of primary vaccination with a different available COVID-19 vaccine. For example, Moderna and Janssen COVID-19 vaccine recipients 18 years of age and older may receive a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine. In addition, on November 17, 2021 the CDC and FDA issued emergency use instructions to provide information about the use of the vaccine as an additional primary series dose or as a booster dose in certain individuals who completed vaccination with certain non-FDA-authorized or -approved COVID-19 vaccines. ([13] FDA, 2022).

Antiviral Treatments

Veklury (remdesivir)

Veklury (remdesivir) is approved for use in patients who are hospitalized; adults and pediatric patients (12 years of age and older, weighing 40 kilograms or more [approximately 88 pounds]) ([1] FDA, 2021). Veklury, the first FDA approved treatment for COVID-19, should be administered in a hospital or other healthcare setting capable of providing acute care comparable to inpatient hospital care. Originally in May 2020, Veklury was authorized under an EUA. To continue use in the pediatric population previously covered under the EUA, the FDA revised the EUA for Veklury to authorize use 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. Ongoing clinical trials are assessing the safety and efficacy of Veklury for pediatric patients. In addition, Veklury's approval was strengthened by the FDA's analysis of three randomized, controlled clinical trials; each included those hospitalized with mild-to-severe COVID-19. Side effects may include: increased levels of liver enzymes (a sign of liver injury) and allergic reactions which may include changes in blood pressure and heart rate, low blood oxygen level, fever, shortness of breath, wheezing, swelling (lips, eyes, under the skin), rash, nausea, sweating or shivering. ([8] FDA, 2020). The FDA most recently expanded the approved indications for Veklury. These now include adult and pediatric patients 12 and over with positive SARS-CoV-2 viral testing and who are not hospitalized and have mild-to-moderate disease at risk of progression. Molina addresses this in our COVID-19 Pharmacy policy *Veklury(remdesivir) – C20763-A.*

Paxlovid (nirmatrelvir)

In December 2021, the FDA issued an EUA for Pfizer's Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use). Indications for use are for mild-to-moderate COVID-19 infection in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms or about 88 pounds). Patients should have a positive test result and are at high risk for progression to severe COVID-19 (such as hospitalization or death). Available by prescription only, Paxlovid should be initiated as soon as possible after diagnosis and within five days of symptom onset. ([9] FDA, 2021).

Nirmatrelvir inhibits a SARS-CoV-2 protein to stop the virus from replicating; ritonavir slows nirmatrelvir's breakdown to help keep it in the body longer period and at higher concentrations. It is administered as three tablets (two tablets of nirmatrelvir and one tablet of ritonavir) taken together orally twice a day for five days (total 30 tablets). Paxlovid has not received authorization for use over five consecutive days. Paxlovid is not authorized for the pre-exposure or post-exposure prevention of COVID-19. It is not for initiation of treatment in those requiring hospitalization due to severe or critical COVID-19. Side effects include impaired sense of taste, diarrhea, high blood pressure and muscle aches. Interactions may occur when taking Paxlovid at the same time as other drugs. Drug resistance may occur in those taking Paxlovid and who have uncontrolled or undiagnosed HIV-1 infection. Ritonavir should be used with caution in patients with preexisting liver diseases, liver enzyme abnormalities or liver inflammation as it may cause liver damage. In addition, Paxlovid is not recommended for those with severe kidney or severe liver impairment. Patients with moderate renal impairment require a reduced Paxlovid dose. ([9] FDA, 2021).

Molnupiravir

On December 23, 2021 the FDA issued an EUA for Merck's molnupiravir for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing, 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 drug is available by prescription only and should be initiated as soon as possible after diagnosis of COVID-19 (within five days of symptom onset). Authorization was not given for use in patients younger than 18 years of age as it may affect bone and cartilage growth. In addition, molnupiravir is not authorized for pre- or post-exposure prevention of COVID-19 or for initiation of treatment in patients hospitalized due to COVID-19 because benefit of treatment has not been observed in people when treatment started after hospitalization due to COVID-19. ([10] FDA, 2021).

Monoclonal Antibody Treatments ([2] CMS, 2021)

As of December 23, 2021, the FDA authorized the following investigational monoclonal antibody product under emergency use authorization (EUA) for pre-exposure prophylaxis of COVID-19:

- Tixagevimab co-packaged with cilgavimab, administered as two separate consecutive intramuscular injections. *Issued by the EUA on December 8, 2021; latest update was December 20, 2021).*

In addition, the FDA authorized the use of this monoclonal antibody combination for the pre-exposure prophylaxis of COVID-19 in adults and pediatric patients (12 years and older weighing at least 40 kg) when:

- The individual is not currently infected with SARS-CoV-2.
- The individual has not had a known recent exposure to an individual infected with SARS-CoV-2.
- One of the following apply:
  - The individual may not mount an adequate immune response to the COVID-19 vaccine due to a moderately or severely compromised immune system due to a medical condition or because they received immunosuppressive medications or treatments.
  - The individual is not recommended to get vaccinated with any available COVID-19 vaccine, according to the approved or authorized schedule, due to a history of severe adverse reaction (for example, severe allergic reaction) to a COVID-19 vaccine.

The FDA authorized the following additional investigational monoclonal antibody therapies under EUA:

- Casirivimab and imdevimab, administered together. *Issued by the EUA issued on November 21, 2020; latest update was November 17, 2021. This was revised on January 24, 2022 due to unlikely activity against the widely circulating Omicron variant.*
- Bamlanivimab and etesevimab, administered together. *Issued by the EUA issued on February 9, 2021; latest update was December 3, 2021. This was revised on January 24, 2022 due to unlikely activity against the widely circulating Omicron variant.*
- Sotrovimab. *Issued by the EUA issued on May 26, 2021; latest update was on December 16, 2021.*
- Tocilizumab. *Issued by the EUA on June 24, 2021.*

The FDA authorized use of these monoclonal antibody therapies to treat mild-to-moderate COVID-19 in adults and pediatric patients when the patient has a positive COVID-19 test result and is at high risk for progressing to severe COVID-19, hospitalization, or both.

For additional information on monoclonal antibody treatments, visit CMS ([3] CMS, 2022). The National Institutes of Health (NIH) (2021) also published *The COVID-19 Treatment Guidelines Panel's Statement on Therapies for High-Risk, Non-Hospitalized Patients With Mild to Moderate COVID-19* (available here). This guidance includes information on monoclonal antibodies and oral antiviral agents.

COVERAGE POLICY

Molina considers the following criteria to be in effect until the United States Department of Health and Human Services (HHS) determines that the outbreak of COVID-19 associated with the national public health emergency is contained. Molina will waive co-pays and cost share for the following:

Medicaid

NOTE: Beginning in late January 2022, each residential household can order one (1) set of four (4) free at-home COVID-19 tests. Shipping is free. Please visit the CovidTests.gov for the most current information.

1. Diagnostic Laboratory Testing (including PCR and antigen tests) **may be covered** when ordered by a physician, non-physician practitioner, pharmacist, or other authorized health care professional when **ONE** of the following is met: ([4] CMS, 2022; [5] CMS, 2021). ***Please refer to your State's Medicaid Agency for the most up to date information (see Appendix for links).***

   a. Molecular or Antigen In Vitro Diagnostic Tests **are covered with no cost share** when **ALL** of the following are met:
      - Member is referred to or receives a COVID-19 test from a licensed / authorized provider; **AND**
      - Test is approved by the FDA or issued EUA **AND**
      - High or medium complexity test is performed by a laboratory that is accredited by Clinical Laboratory Improvement Amendments (CLIA) or is a CLIA-waived laboratory (per test instructions).

   There is no limit to the number of tests when prescribed by a licensed provider.

   See the Limitations and Exclusions section below for non-covered tests.

2. **COVID-19 Vaccine(s) and Booster Administration.** Coverage includes administration at any approved location for all Medicaid lines of business. Prior authorization is not needed.

3. **Monoclonal Antibody Treatments.** Includes bamlanivimab, or casirivimab and imdevimab for Members who meet the following criteria:
   a. Have tested positive for COVID-19; **OR**
   b. Have a mild to moderate case of COVID-19; **OR**
   c. Are at high risk of progressing to a severe case of COVID-19 and/or at high risk of hospitalization.

4. **Medically Necessary Hospitalizations.** This includes stays for patient's diagnosed with COVID-19 who may have otherwise been discharged from the hospital after an inpatient stay, but instead need to stay in the hospital under quarantine. Hospital deductibles will be the responsibility of the Member and copays / coinsurance applies.

5. **Office Visits, Urgent Care Visits, and ED Visits.** Applies when a rendered diagnosis is specifically related to COVID-19. Visits for other symptoms or diagnoses will not have co-pay or cost share removed, including not removing cost share for other laboratory testing (besides COVID-19 testing), x-rays, or other add-on testing.

6. **Telemedicine.** Cost sharing will be waived for all video visits by in-network providers delivering (live video conferencing) related to COVID-19.

7. **90-day Prescription Volumes.** During State-declared emergencies, Molina allows up to three (3) early refills for 30 days' supply each when pharmacies submit the emergency codes.

Limitations and Exclusions

Testing

The following tests to detect COVID-19 infection **are not covered** when the above criteria are not met:
- Over the Counter (OTC) tests
- Tests that are non-diagnostic in nature

- In vitro testing (e.g., molecular, antigen, antibody) when performed for screening purposes for indications that include, but are not limited to:
  - Public health screening for the general population
  - To determine prevalence of community infection
- Molecular or antigen in vitro tests processed by a non-CLIA-accredited laboratory or non-FDA/EUA approved test.
- In vitro testing for the scenarios below that include, but are not limited to:
  - Work or educational purposes (including for pre-employment)
  - Sports participation
  - Physicals (routine and/or executive)
  - Travel
  - Armed Forces recruitment
  - Purposes related to insurance
  - Evaluation for disability
  - Unspecified encounter for administrative exam

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

CODING & BILLING INFORMATION ([8] CMS, 2020; Optum, n.d.)

CPT Codes

CPT	Description (Testing Codes)
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])
86408	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); screen
86409	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); titer
86413	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) Multi-step method
87426	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19)
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique
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 types A and B, multiplex amplified probe technique
87637	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique
87811	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
91308	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
0081A	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
0082A	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
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
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
0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed
0225U	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum
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
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
CPT	**Description (Vaccine Codes)**
0001A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; first dose
0002A	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
0011A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; first dose
0012A	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
0021A	Immunization administration by intramuscular injection of 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, $5x10^{10}$ viral particles/0.5mL dosage; first dose
0022A	Immunization administration by intramuscular injection of 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, $5x10^{10}$ viral particles/0.5mL dosage; second dose
0031A	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, $5x10^{10}$ viral particles/0.5mL dosage, single dose
91300	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
91301	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 us
91302	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, $5x10^{10}$ viral particles/0.5mL dosage, for intramuscular use

91303	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, $5x10^{10}$ viral particles/0.5mL dosage, for intramuscular use

HCPCS Codes

HCPCS	Description
C9803	Hospital outpatient clinic visit specimen collection for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source
G2023	Specimen collection for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source
G2024	Specimen collection for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source
U0001	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC
U0003	Infectious agent detection by nucleic acid (DNA or RNA); Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R

CODING DISCLAIMER. Codes listed in this policy are for reference 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. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

2/9/2022 Policy reviewed; updated Overview section including vaccine and pharmaceutical information; Coverage Policy section includes updated testing and pharmaceutical information; updated Reference section.
2/8/2021 Policy revised; removed language regarding waiving co-pays, cost share and refill timing; added clarifying statement: "Molina considers the following criteria to be in effect as long as global 'state of emergency' is declared for COVID-19 and will expire when the U.S. Department of Health and Human Services (HHS) determines that the outbreak of the 2019 novel Coronavirus (COVID-19) associated with the national public health emergency is contained."
3/9/2020 New policy. Includes applicable cost sharing and copay codes for the administration of the COVID-19 vaccine(s).

REFERENCES

Government Agencies

1. [1] Centers for Disease Control and Prevention (CDC). Variants of the virus. Available from CDC. Updated August 11, 2021. Accessed January 3, 2022.
2. [2] Centers for Disease Control and Prevention (CDC). Frequently asked questions. Available from CDC. Updated October 21, 2021.
3. [3] Centers for Disease Control and Prevention (CDC). COVID-19 information for specific groups of people. Available from CDC. Updated April 20, 2021. Accessed January 3, 2022.
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APPENDIX

Due to the changing nature of issues relating to COVID-19, it is the responsibility of the Provider or other reviewer of this policy to confirm their State's guidance on this topic. (Links were current at time of policy approval).

Arizona	California	Florida	Idaho	Illinois
Kentucky	Massachusetts	Michigan	Mississippi	New Mexico
New York	Ohio	So. Carolina – Provider	So. Carolina – Members	Texas
Utah	Virginia	Washington	Wisconsin	