Drug Coverage Policy

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Coverage Policy Number..... 2016
Policy Title.....COVID-19 Drug and Biologic Therapeutics

COVID-19 Drug and Biologic Therapeutics

- Gohibic® (vilobelimab intravenous injection – InflaRx)
- Infliximab (infliximab intravenous infusion – multiple manufacturers)
- Lagevrio™ (molnupiravir capsules – Merck)
- Pemgarda™ (pemivibart injection – Invivyd, Inc.)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Disease Overview

Coronavirus disease 2019 (COVID-19) is a respiratory illness that can spread from person-to-person. Many types of human coronaviruses exist, including some that commonly cause mild upper-respiratory tract illnesses. COVID-19 is a new disease, caused by a novel (new) coronavirus that has not previously been seen in humans. Current symptoms reported for patients with COVID-19 have included mild to severe respiratory illness with fever, cough, and difficulty breathing.[8]

National Institute of Health (NIH) COVID-19 Treatment Guidelines - Clinical Spectrum of SARS-CoV-2 Infection

In general, adults with SARS-CoV-2 infection can be grouped into the following severity of illness categories[9]:

- **Asymptomatic or Presymptomatic Infection**: Individuals who test positive for SARS-CoV-2 using a virologic test (i.e., a nucleic acid amplification test [NAAT] or an antigen test) but who have no symptoms that are consistent with COVID-19.

- **Mild Illness**
  - Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have shortness of breath, dyspnea, or abnormal chest imaging
  - Or the absence of viral pneumonia ad hypoxemia, can be managed in ambulatory care setting or at home

- **Moderate Illness**
  - Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have an oxygen saturation (SpO_2) ≥94% on room air at sea level.
  - Or those individuals with viral pneumonia, but without hypoxemia

- **Severe Illness**: Individuals who have SpO_2 <94% on room air at sea level, a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO_2/FiO_2) <300 mm Hg, a respiratory rate >30 breaths/min, or lung infiltrates >50%.

- **Critical Illness:** Individuals who have respiratory failure, septic shock, and/or multiple organ dysfunction.

GOHIBIC

Gohibic is a recombinant chimeric monoclonal antibody that selectively binds complement component C5a, thereby inhibiting C5a-mediated inflammatory signaling and downstream neutrophil activation implicated in severe COVID-19–associated lung injury and systemic inflammation.[5] Gohibic received Emergency Use Authorization (EUA) for the treatment of hospitalized adults with COVID-19 when treatment is initiated within 48 hours of receipt of invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO).[5]
The authorization for Gohibic is based on randomized controlled trial data demonstrating a reduction in 28-day and 60-day all-cause mortality when added to standard of care in critically ill, mechanically ventilated patients with COVID-19.[5]

Gohibic limitations of authorized use include the following:[5]

- Gohibic is authorized for use only in adults (≥18 years of age).
- Gohibic is authorized only for patients hospitalized with COVID-19 who require IMV or ECMO.
- Treatment must be initiated within 48 hours of starting IMV or ECMO.
- Gohibic is not authorized for use in non-hospitalized patients.
- Gohibic is not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- Use is limited to administration in accordance with the EUA-authorized dosing regimen.

INFLIXIMAB

Infliximab is a chimeric monoclonal antibody that binds tumor necrosis factor-alpha (TNF-α), a key pro-inflammatory cytokine involved in immune-mediated tissue injury.[6,7] In the context of COVID-19, infliximab has been evaluated for use in COVID-19–associated multisystem inflammatory syndrome in children (MIS-C) that is refractory to first-line immunomodulatory therapy.[6,7]

MIS-C is a post-infectious hyperinflammatory condition temporally associated with SARS-CoV-2 infection and characterized by fever, laboratory evidence of inflammation, and multisystem organ involvement.[6,7] Clinical practice guidelines and systematic reviews support the use of infliximab as a second-line biologic agent in patients with severe or refractory MIS-C who fail to respond adequately to intravenous immunoglobulin (IVIG) and glucocorticoids.[6,7]

Infliximab limitations of use in COVID-19–associated MIS-C include the following:[6,7]

- Use is limited to pediatric or adolescent patients (<21 years of age) diagnosed with MIS-C.
- Infliximab is used only for refractory disease following IVIG and glucocorticoid therapy.
- Infliximab should not be used concurrently with anakinra.
- Infliximab is not indicated for treatment of acute viral COVID-19 infection.
- Infliximab is not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.

LAGEVRIO

Lagevrio is a nucleoside analogue that inhibits SARS-CoV replication by viral mutagenesis.[1] It was issued Emergency Use Authorization for the treatment of mild to moderate COVID-19 in adults who are at high risk for progressing to severe COVID-19, including hospitalization and death, and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate.

Lagevrio limitations of authorized use include the following:[1]

- Lagevrio is not authorized for use in patients < 18 years of age.
- Lagevrio is not authorized for initiation of treatment in patients hospitalized due to COVID-19. Benefit of treatment has not been observed when treatment was initiated after hospitalization due to COVID-19.
- Lagevrio is not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- Lagevrio is not authorized for use longer than 5 consecutive days.

PEMGARDA

Pemgarda is a recombinant human monoclonal antibody that acts as a SARS-CoV-2 spike protein-directed attachment inhibitor, preventing viral binding to the human ACE2 receptor.

Pemgarda received Emergency Use Authorization (EUA) for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents (12 years of age and older weighing at least 40 kg) with moderate-to-severe immune compromise who are unlikely to mount an adequate immune response to COVID-19 vaccination.[2]

Pemgarda is authorized for use only in individuals who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2. Pemgarda is not FDA-approved and is authorized only for the duration of the public health emergency declaration under section 564 of the Federal Food, Drug, and Cosmetic Act.[2]

Pemgarda limitations of authorized use include the following[2]:

- Pemgarda is not authorized for the treatment of COVID-19.
- Pemgarda is not authorized for post-exposure prophylaxis for prevention of COVID-19.
- Pemgarda is not a substitute for COVID-19 vaccination in individuals for whom vaccination is recommended.
- Pemgarda is authorized for use only when circulating SARS-CoV-2 variants remain susceptible based on FDA-reviewed surveillance data.

DOSING

The recommended dose is as follows [1,2,5–7]:

- Gohibic: 800 mg intravenously, initiated within 48 hours of intubation, followed by repeat dosing during hospitalization for a maximum of six doses.[5]

- Infliximab is administered as a single intravenous dose of 5–10 mg/kg for refractory MIS-C.[6,7]

- Lagevrio: 800 mg (four 200 mg capsules) taken orally once every 12 hours for 5 days.[1]

- Pemgarda: 4,500 mg administered as a single intravenous infusion approximately every 3 months.
  - Repeat dosing should be timed from the date of the most recent Pemgarda dose.
  - Pemgarda should be administered at least 2 weeks after COVID-19 vaccination, if recently vaccinated.[2]

Availability

Gohibic is supplied as single-dose vials for intravenous infusion and is administered in the inpatient hospital setting under EUA conditions.[5]

Infliximab is supplied as an intravenous infusion product and is administered in the inpatient hospital setting.[6,7]

Lagevrio is supplied as 200-mg capsules packaged in a bottle of 40 capsules.[1]

Pemgarda is supplied as 500 mg/4 mL single-dose vials for intravenous infusion and is administered in a healthcare setting with appropriate monitoring due to the risk of anaphylaxis. Pemgarda is available for use under Emergency Use Authorization conditions only.[2]

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for benefit coverage of Drugs or Biologics for the treatment, prevention, or management of Coronavirus Disease 2019 (COVID-19) and related symptoms. All approvals are provided for the duration noted below.

The use of infliximab for non-COVID-19 uses is addressed in a separate coverage policy. Please refer to the related coverage policy (Inflammatory Conditions – Infliximab Intravenous Products Prior Authorization Policy IP0660).

Product-specific coverage criteria for Drugs or Biologics used for the treatment, prevention, or management of COVID-19 and related symptoms are listed in below table:

Product	Criteria
Gohibic (vilobelimab)	**Gohibic is considered medically necessary when the following criteria are met (1):** 1. **COVID-19 – Hospitalized.** Patient meets **ALL** of the following (A, B, C, D, and E): A. Patient is 18 years of age or older B. Patient is hospitalized with a diagnosis of COVID-19 with positive results from direct SARS-CoV-2 viral testing (for example, molecular [PCR], or antigen [ELISA] laboratory methods) C. Patient requires invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO) D. Medication is administered within 48 hours of receiving IMV or ECMO E. Gohibic must be used in accordance with the authorized Health Care Provider Fact Sheets **Dosing**. 800 mg intravenous (IV) followed by repeat dosing during hospitalization for a maximum of six doses. **Any other use is considered not medically necessary.**
Infliximab	**Infliximab is considered medically necessary when the following criteria are met (1):** 1. **COVID-19 Associated Refractory Multisystem Inflammatory Syndrome in Children (MIS-C).** Patient meets **ALL** of the following (A, B, C, D, and E): A. Patient is less than 21 years of age B. Patient meets **ONE** of the following (i or ii): i. Patient is positive for current or recent SARS-CoV-2 infection by molecular [PCR], antigen [ELISA] laboratory methods), or serology results ii. COVID-19 exposure within the 4 weeks prior to onset of symptoms C. Patient continues to display the following symptoms and laboratory findings despite intravenous immunoglobulin (IVIG) and glucocorticoid therapy (i, ii and iii): i. Fever (> 100.4°F for ≥ 24 hours, or report of subjective fever lasting ≥ 24 hours)

	ii. Laboratory evidence of inflammation including, but not limited to, at least **ONE** of the following: elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, D-dimer, ferritin, lactate dehydrogenase (LDH), interleukin-6 (IL-6), or neutrophils, or reduced lymphocytes or albumin levels. iii. Evidence of clinically severe illness that requires hospitalization with multisystem (i.e., > 2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic, or neurological) D. Other causes have been excluded E. Infliximab will not be used in combination with anakinra **Dosing**. Up to 5 - 10 mg/kg intravenous (IV) **given one time**. **Any other use in the management of COVID-19 is considered not medically necessary.**
Lagevrio™ (molnupiravir)	**Lagevrio is considered medically necessary when the following criteria are met (1):** 1. **COVID-19**. Patient meets **ONE** of the following (A or B): A. Initial Therapy. Approve if patient meets **ALL** of the following (i, ii, iii, iv and v): i. Patient is 18 years of age or older ii. Patient has a diagnosis of mild to moderate COVID-19 with positive results of direct SARS-CoV-2 viral testing (for example, molecular [PCR], or antigen [ELISA] laboratory methods) iii. Patient is at high risk for progressing to severe COVID-19 Note: The following medical conditions or other factors may place adults and pediatric patients (12 to 17 years of age weighing at least 40 kg) at high risk for progression to severe COVID-19: • Older age (for example ≥ 65 years of age) • Obesity or being overweight (for example, adults with BMI >25 kg/m^2, or if 12 to 17 years of age, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm) • Chronic kidney disease • Diabetes • Immunosuppressive disease or immunosuppressive treatment • Cardiovascular disease (including congenital heart disease) or hypertension • Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension) • Sickle cell disease

	• Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies) • Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19]) • Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19, and authorization of molnupiravir under the EUA is not limited to the medical conditions or factors listed above iv. Alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate (for example, Paxlovid) v. Molnupiravir must be in accordance with the authorized Health Care Provider Fact Sheets B. Previously received molnupiravir, then **ALL** of the following (i, ii, and iii): i. Patient is experiencing a repeat diagnosis of COVID-19 with positive results of direct SARS-CoV-2 viral testing (for example, molecular [PCR], or antigen [ELISA] laboratory methods) ii. This is a second diagnosis unrelated to the initial diagnosis of COVID-19 treated with molnupiravir. iii. Alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate (for example, Paxlovid) **Any other use is considered not medically necessary, including the following (this list may not be all inclusive):** 1. **Less than 18 years of age.** 2. **Initiation of treatment in patient requiring hospitalization due to COVID-19.** Patient requiring hospitalization due to severe or critical COVID-19 after starting treatment with Paxlovid may complete the full 5-day treatment course per the healthcare provider's discretion. 3. **Pre-Exposure or Post-Exposure Prophylaxis for prevention of COVID-19.** 4. **For use longer than 5 consecutive days.**
Pemgarda (pemivibart)	**Pemgarda is considered medically necessary when the following criteria are met (1):** **1. Pre-exposure Prophylaxis of Coronavirus Disease 2019 (COVID-19).** Approve for 1 month if the patient meets **ALL** of the following (A, B,C and D): A. Patient is ≥ 12 years of age B. Patient is ≥ 40 kg (88 lbs) C. According to the prescriber, patient is currently not infected with SARS-CoV-2 and has not had a known recent exposure to a patient infected with SARS-CoV-2

	D. According to the prescriber, patient has moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and is unlikely to mount an adequate immune response to COVID-19 vaccination Note: Medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination include: active treatment for solid tumor and hematologic malignancies; hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia); receipt of solid-organ transplant or an islet transplant and taking immunosuppressive therapy; receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppressive therapy); moderate or severe primary immunodeficiency (e.g., common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome); advanced or untreated HIV infection (people with HIV and CD4 cell counts < 200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV); active treatment with high-dose corticosteroids (i.e., ≥ 20 mg prednisone or equivalent per day when administered for ≥ 2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, and biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents) **Dosing**. Approve a single 4,500 mg dose administered intravenous (IV) infusion, not more frequently than once every 3 months. **Any other use is considered not medically necessary, including the following** (this list may not be all inclusive)**:** 1. **For treatment of COVID-19.** Limitation of authorized use per the FDA. 2. **For post-exposure prophylaxis of COVID-19 in patients who have been exposed to someone infected with SARS-CoV-2.** Limitation of authorized use per the FDA. 3. **Pre-exposure prophylaxis vaccine substitution in patients for whom COVID-19 vaccination is recommended.** Limitation of authorized use per the FDA; Pre-exposure prophylaxis with Pemgarda is not a substitute for vaccination in patients for whom COVID-19 vaccination is recommended. Patients for whom COVID-19 vaccination is recommended, including patients with moderate-to-severe immune compromise

	who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination. 4. **Pemgarda administered < 2 weeks after COVID-19 vaccination.** Limitation of authorized use per the FDA; in patients who have recently received a COVID-19 vaccine, Pemgarda should be administered at least 2 weeks after vaccination.

APPENDIX
Active FDA Emergency Use Authorizations

Gohibic (vilobelimab)

Date	EUA Letter
4/12/2023	Re-issued.[10]
4/4/2023	The FDA issued an EUA on April 4, 2023, for emergency use of Gohibic (vilobelimab) for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV, or ECMO.[10]

Lagevrio (molnupiravir)

Date	EUA Letter
11/15/2023	Re-issued.[11]
10/27/2022	Re-issued.[11]
8/5/2022	Re-issued.[11]
12/23/2021	On December 23, 2021, the FDA issued an emergency use authorization for molnupiravir for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in certain adults who are at high-risk for progression to severe COVID-19, including hospitalization or death.[11]

Pemgarda (pemivibart)

Date	EUA Letter
8/26/2024	Re-issued.[12]
3/22/2024	On March 22, 2024, the FDA issued an emergency use authorization for Pemgarda for pre-exposure prophylaxis of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40kg).[12]

Withdrawn FDA Emergency Use Authorizations

Bamlanivimab

Date	EUA Letter
4/16/2021	The FDA revoked the EUA for bamlanivimab on April 16, 2021, that allowed for the investigational monoclonal antibody therapy bamlanivimab, *when administered alone*, to be used for the treatment of mild-to-moderate COVID-19 in adults and certain pediatric patients. Based on its ongoing analysis of emerging scientific data, specifically the sustained increase of SARS-CoV-2 viral variants that are resistant to bamlanivimab alone resulting in the increased risk for treatment failure, the FDA has determined that the known and potential

	benefits of bamlanivimab, when administered alone, no longer outweigh the known and potential risks for its authorized use. Therefore, the agency determined that the criteria for issuance of an authorization are no longer met and has revoked the EUA.[13]

Bamlanivimab and Etesevimab

Date	EUA Letter
1/24/2022	As of **1/24/2022,** the Centers for Disease Control and Prevention (CDC) estimated the proportion of COVID-19 cases caused by the Omicron variant to be above 50% in all U.S. Department of Health and Human Services (HHS) regions. **Due to these data, use of Bamlanivimab and Etesevimab is NOT authorized in any U.S. state or territory at this time.** Accordingly, and effective immediately, Assistant Secretary for Preparedness & Response (ASPR) has paused sotrovimab distribution to all U.S. states and territories. The FDA has updated the Fact Sheet for sotrovimab to reflect product use restrictions. [14]

Bebtelovimab

Date	EUA Letter
11/30/2022	As of **11/30/2022,** the Centers for Disease Control and Prevention (CDC) estimated the proportion of COVID-19 cases to be caused by the Omicron subvariant BQ.1 and BQ.1.1to be above 50% in all U.S. Department of Health and Human Services (HHS) regions. **Due to these data, use of bebtelovimab is NOT authorized in any U.S. state or territory at this time.** Accordingly, and effective immediately, Assistant Secretary for Preparedness & Response (ASPR) has paused bebtelovimab distribution to all U.S. states and territories. The FDA has updated the Fact Sheet for bebtelovimab to reflect product use restrictions. [15]

Casirivimab and Imdevimab (REGEN-COV)

Date	EUA Letter
1/24/2022	As of **1/24/2022,** the Centers for Disease Control and Prevention (CDC) estimated the proportion of COVID-19 cases caused by the Omicron variant to be above 50% in all U.S. Department of Health and Human Services (HHS) regions. **Due to these data, use of REGEN-COV is NOT authorized in any U.S. state or territory at this time.** Accordingly, and effective immediately, Assistant Secretary for Preparedness & Response (ASPR) has paused sotrovimab distribution to all U.S. states and territories. The FDA has updated the Fact Sheet for sotrovimab to reflect product use restrictions. [16]

Chloroquine phosphate, hydroxychloroquine sulfate

Date	EUA Letter
6/15/2020	The FDA revoked the EUA that allowed for chloroquine phosphate and hydroxychloroquine sulfate on June 15, 2020... The agency determined that the legal criteria for issuing a EUA are no longer met. Based on its ongoing analysis of the EUA and emerging scientific data, the FDA determined that chloroquine and hydroxychloroquine are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA. Additionally, in light of ongoing serious cardiac adverse events and other potential serious side effects, the known and potential

	benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks for the authorized use.[15]

Sotrovimab

Date	EUA Letter
4/5/2022	As of **4/5/2022,** the Centers for Disease Control and Prevention (CDC) estimated the proportion of COVID-19 cases caused by the Omicron BA.2 variant to be above 50% in all U.S. Department of Health and Human Services (HHS) regions. **Due to these data, use of sotrovimab is NOT authorized in any U.S. state or territory at this time.** Accordingly, and effective immediately, Assistant Secretary for Preparedness & Response (ASPR) has paused sotrovimab distribution to all U.S. states and territories. The FDA has updated the Fact Sheet for sotrovimab to reflect product use restrictions. [14]

Tixagevimab co-packaged with cilgavimab) Evusheld

Date	EUA Letter
1/26/2023	January 26, 2023: FDA reissued the December 8, 2022, letter in its entirety, to revise the scope of authorization to limit the use of Evusheld for pre-exposure prophylaxis of COVID-19 in the United States only when, based on available information including variant susceptibility to EVUSHELD and national variant frequencies, the combined frequency of non-susceptible variants nationally is less than or equal to 90%.[16] Data show Evusheld is unlikely to be active against certain SARS-CoV-2 variants. According to the most recent CDC Nowcast data, these variants are projected to be responsible for more than 90% of current infections in the U.S. This means that Evusheld is not expected to provide protection against developing COVID-19 if exposed to those variants. **Accordingly, Evusheld is NOT currently authorized in any U.S. region due to the high frequency of circulating SARS-CoV-2 variants that are non-susceptible to Evusheld.** Therefore, Evusheld may not be administered for pre-exposure prophylaxis for prevention of COVID-19 under the Emergency Use Authorization until further notice by the Agency.[16]

Coding Information

Drugs are typically covered under pharmacy benefit plans. Certain prescription drugs require an authorization for coverage to ensure that appropriate treatment regimens are followed. Medical drug coding and diagnosis codes, however, are generally not required for pharmacy claims submissions.

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J1745	Injection, infliximab, excludes biosimilar, 10 mg
M0224	Intravenous infusion, pemivibart, for the pre-exposure prophylaxis only, for certain adults and adolescents (12 years of age and older weighing at least 40 kg) with no known SARS-CoV-2 exposure, who either have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments, includes infusion and post administration monitoring [effective 3/22/2024]
M0235†	Intravenous infusion, monoclonal antibody products with an indication for post-exposure prophylaxis or treatment of COVID-19, for hospitalized adults and/or pediatric patients 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, not otherwise classified, first dose [effective 10/1/2025]
M0236†	Intravenous infusion, monoclonal antibody products with an indication for post-exposure prophylaxis or treatment of COVID-19, for hospitalized adults and/or pediatric patients 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, not otherwise classified, second dose [effective 10/1/2025]
Q0224	Injection, pemivibart, for the pre-exposure prophylaxis only, for certain adults and adolescents (12 years of age and older weighing at least 40 kg) with no known SARS-CoV-2 exposure, and who either have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments, and are unlikely to mount an adequate immune response to COVID-19 vaccination, 4500 mg [effective 3/22/2024]
Q0235†	Injection, monoclonal antibody products with an indication for postexposure prophylaxis or treatment of COVID-19, for hospitalized adults and/or pediatric patients who are receiving systemic corticosteroids and require supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) only, not otherwise classified, 1 mg [effective 10/1/2025]
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA) 10 mg

†**Note:** Considered Medically Necessary when used to report Gohibic (vilobelimab) and medical necessity criteria outlined in this Coverage Policy are met.

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Revision Details

Summary of Changes	Review Date	Effective Date
Important changes in coverage criteria: • **Removed** Paxlovid tablets from the policy.	3/7/2024	5/1/2024
Important changes in coverage criteria: • **Removed** Veklury (remdesivir) and Kineret from the policy	4/11/2024	6/15/2024
Important changes in coverage criteria: • **Removed** Tocilizumab intravenous, Kevzara, Olumiant, and Xeljanz/Xeljanz medical necessity criteria from the policy.	9/19/2024	11/01/2024

Important changes in coverage criteria: • **Added** Pemgarda (pemivibart) coverage criteria consistent with Emergency Use Authorization issued on 8/26/2024 for use as pre-exposure prophylaxis of COVID-19 in certain adults and adolescents **Coding Information** **Updated** Coding**:** • **Added:** M0224 (effective 3/22/2024), Q0224 (effective 3/22/2024)	11/14/2024	11/14/2024
Coding Information: • **Updated** the description for HCPCS M0248 to include the note "effective until 6/30/2025"	-	6/1/2025
Coding Information: • **Added** HCPCS codes M0235, M0236 and Q0235 (effective 10/1/25) along with the coding note: o Considered Medically Necessary when used to report Gohibic (vilobelimab) and medical necessity criteria outlined in this Coverage Policy are met.	-	10/15/2025
Important changes in coverage criteria: • **Added** dosing information for Gohibic to policy. • **Removed** Intravenous Immunoglobulin (IVIG) medical necessity criteria from policy. **Coding Information** • **Added** the following HCPCS codes for infliximab and biosimilars: o J1745 Q5103 Q5104 Q5121 • **Removed** the following HCPCS codes because they have been deleted by CMS following FDA EUA revocations: o **Deleted** effective 4/17/2021 M0239 Q0239 o **Deleted** effective 12/14/2023 M0245 M0246 o **Deleted** effective 12/13/2024 M0220 M0221 M0222 M0223 M0240 M0241 M0243 M0244 M0247 M0248 Q0220 Q0222 Q0240 Q0243 Q0244 Q0245 Q0247 • **Removed** the ICD-10 diagnosis table • **Removed** the Experimental/Investigational/Unproven coding table, as all associated HCPCS codes have been deleted and are no longer billable.	4/30/2026	6/15/2026
Removed the Lagevrio quantity limitation criteria. The Lagevrio quantity limit criteria relocated to the new *Coronavirus – Oral Medications for Treatment of Coronavirus Disease 2019 (COVID-19) Drug Quantity Management Policy – Per Days (DQM047).*	10/01/2026	11/01/2026

The policy effective date is in force until updated or retired.

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