## Side-by-Side Overview of Therapeutics Authorized or Approved for the Prevention of COVID-19 Infection or Treatment of Mild-Moderate COVID-19

This table is a quick reference summarizing key information for available pre-exposure prophylaxis (PrEP) for preventing COVID-19 infection and for all outpatient therapies currently authorized or approved in the United States for treatment of mild-moderate COVID-19.1 This resource will be regularly reviewed and updated.

For full details, please review the Fact Sheets for Healthcare Providers for each product (links below).

### MONOClonal Antibodies (mAbs)

<table>
<thead>
<tr>
<th>PRODUCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evusheld (tixagevimab/cilgavimab)</td>
</tr>
<tr>
<td>bebtelovimab</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prevention (PrEP)</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventative (PrEP)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### IV Antivirals

<table>
<thead>
<tr>
<th>PRODUCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Veklury (remdesivir)</td>
</tr>
<tr>
<td>Paxlovid (nirmatrelvir/ritonavir)</td>
</tr>
<tr>
<td>Lagevrio (molnupiravir)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prevention (PrEP)</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>Treatment</td>
</tr>
</tbody>
</table>

### Oral Antivirals

<table>
<thead>
<tr>
<th>PRODUCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paxlovid (nirmatrelvir/ritonavir)</td>
</tr>
<tr>
<td>Lagevrio (molnupiravir)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prevention (PrEP)</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>Treatment</td>
</tr>
</tbody>
</table>

### Mechanism of Action

- **mAb against conserved epitope of spike protein; blocks viral entry**
- **mAb against spike protein; blocks viral attachment to host cells**
- **Nucleotide analog ribonucleic acid (RNA) polymerase inhibitor that halts viral replication**
- **Viral protease inhibitor that halts viral replication**
- **Nucleoside analog that inhibits viral replication by viral mutagenesis**

### Treatment Efficacy per Clinical Trials

- **77% reduction in developing symptomatic COVID-19**
- **Symptomatic improvement and Day 5 reduction in viral load vs. placebo**
- **87% reduction in hospitalizations/deaths**
- **88% reduction in hospitalizations/deaths**
- **30% reduction in hospitalizations/deaths**

### Activity Against SARS-CoV-2 Variants

<table>
<thead>
<tr>
<th>PRODUCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evusheld Healthcare Provider Fact Sheet</td>
</tr>
<tr>
<td>bebtelovimab Healthcare Provider Fact Sheet</td>
</tr>
<tr>
<td>Veklury package insert</td>
</tr>
<tr>
<td>Paxlovid Healthcare Provider Fact Sheet</td>
</tr>
<tr>
<td>Lagevrio Healthcare Provider Fact Sheet</td>
</tr>
</tbody>
</table>

### Authorized Use(s)

- **Pre-exposure prophylaxis (PrEP)**
- **Treatment of mild-moderate COVID-19**
- **Treatment of mild-moderate COVID-19**
- **Treatment of mild-moderate COVID-19**
<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>MONOCLONAL ANTIBODIES (mAbs)</th>
<th>IV ANTIVIRALS</th>
<th>ORAL ANTIVIRALS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preventative (PrEP)</td>
<td>Treatment</td>
<td>Treatment</td>
</tr>
<tr>
<td>Evusheld (tixagevimab/cilgavimab)</td>
<td>Adult and pediatric patients (at least 12 years of age and older weighing at least 40 kg) 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, and who have moderate to severe immune compromise or for those who any EUA or approved vaccine is not recommended.</td>
<td>FDA-approved for: Adults and pediatric patients (28 days of age and older weighing at least 3 kg) at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by the U.S. Food and Drug Administration (FDA) are not accessible or clinically appropriate</td>
<td>Adults and pediatric patients (12 years of age and older weighing at least 40 kg) at high risk for progressing to severe COVID-19, including hospitalization or death</td>
</tr>
<tr>
<td>bezlotozumab</td>
<td>Adult and pediatric patients (at least 12 years of age and older weighing at least 40 kg) who are not currently infected with SARS-CoV-2, and who have moderate to severe immune compromise or for those who any EUA or approved vaccine is not recommended.</td>
<td></td>
<td>Adults patients age 18 and older at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate</td>
</tr>
<tr>
<td>Veklury (remdesivir)</td>
<td></td>
<td>Positive SARS-CoV-2 viral test Baseline renal function required under EUA for pediatric patients Pediatric patients (greater than 28 days old and weighing at least 3 kg) must have an estimated glomerular filtration rate (eGFR) determined. Before starting and during treatment as clinically appropriate, perform renal and hepatic laboratory testing Assess prothrombin time before starting and monitor as clinically appropriate</td>
<td>Positive SARS-CoV-2 viral test</td>
</tr>
<tr>
<td>Paxlovid (nirmatrelvir/ritonavir)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lagevrio (molnupiravir)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Eligible Population(s)**

- **Pre-exposure Initiate within 7 days of symptom onset**
- **Initiate within 7 days of symptom onset**
- **Initiate within 7 days of symptom onset**
- **Initiate within 5 days of symptom onset**

**Prescribing Window**

- **Pre-exposure**
- **Initiate within 7 days of symptom onset**
- **Initiate within 7 days of symptom onset**
- **Initiate within 5 days of symptom onset**

**Testing Requirements**

- None
- Positive SARS-CoV-2 viral test
- Positive SARS-CoV-2 viral test
- Positive SARS-CoV-2 viral test

**History Requirements**

- Not specified
- Not specified
- Not specified
- Assessment of pregnancy status

**Limitations of Authorized Use**

- Not authorized for: For treatment of COVID-19
- For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.
- In individuals who have received a COVID-19 vaccine, Evusheld should be administered at least two weeks after vaccination.

- Not authorized for: Patients less than 12 years of age and less than 40 kg
- Patients who are hospitalized due to COVID-19
- Patients who require oxygen therapy due to COVID-19
- Require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 and are on chronic oxygen therapy and/or respiratory support due to underlying non-COVID-19 related comorbidity

- N/A
- Not authorized for: Patients requiring hospitalization due to severe or critical COVID-19.
- Pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- Use for longer than 5 consecutive days.
- Pre-exposure or post-exposure prophylaxis for prevention of COVID-19

- Not authorized for: Patients less than 18 years of age
- Initiation in patients who are hospitalized due to COVID-19.
- Use for longer than 5 consecutive days.
- Pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>Preventative (PrEP)</th>
<th>Treatment</th>
<th>Treatment</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evusheld (tixagevimab/cilgavimab)</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Ritonavir may reduce the efficacy of combined hormonal contraceptives. Patients should use an effective alternative contraceptive method or an additional barrier method of contraception.</td>
</tr>
<tr>
<td>Veklury (remdesivir)</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Not recommended for use during pregnancy because may cause fetal harm when given to pregnant individuals based on animal reproduction studies. Authorized for use in pregnancy only if benefits would outweigh risks for the individual patient; documentation requirements apply. Females of childbearing potential should be advised of potential risk to a fetus and should use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of Lagevrio. Males of reproductive potential who are sexually active with females of childbearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.</td>
</tr>
<tr>
<td>Paxlovid (nirmatrelvir/ritonavir)</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Lagevrio (molnupiravir)</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

**Family Planning Considerations**

- For Evusheld: None
- For Veklury: None
- For Paxlovid: None
- For Lagevrio: None

**Contraindications**

- For Evusheld: Individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of Evusheld
- For Veklury: Patients with a history of clinically significant hypersensitivity reactions to Veklury or any components of the product. Consider discontinuing Veklury if ALT levels increase to greater than 10 times the upper limit of normal. Discontinue Veklury if ALT elevation is accompanied by signs or symptoms of liver inflammation.
- For Paxlovid: Individuals with significant hypersensitivity reactions to any component of Paxlovid. Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions. Co-administration with potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance.
- For Lagevrio: None

**Administration Route(s)**

- Evusheld: IM Injection
- Veklury: IV Injection, IV Infusion
- Paxlovid: Oral
- Lagevrio: Oral
<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>MONOCLONAL ANTIBODIES (mAbs)</th>
<th>IV ANTIVIRALS</th>
<th>ORAL ANTIVIRALS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preventative (PrEP)</td>
<td>Treatment</td>
<td>Treatment</td>
</tr>
<tr>
<td>Evusheld (tixagevimab/cilgavimab)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>bebtelovimab</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Veklury (remdesivir)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paxlovid (nirmatrelvir/ritonavir)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lagevrio (molnupiravir)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Dosage**

**Initial Dose:** 300 mg of tixagevimab and 300 mg of cilgavimab administered as two separate consecutive intramuscular injections (preferably one in each of the gluteal muscles, one after the other).

- **Dosing for those who initially received 150 mg of tixagevimab and 150 mg of cilgavimab**
  - Initial dose ≤ 3 months ago: 150 mg of tixagevimab and 150 mg of cilgavimab ASAP
  - Initial dose > 3 months ago: 300 mg of tixagevimab and 300 mg of cilgavimab ASAP

**Repeat Dose:**

The SARS-CoV-2 variants that will be circulating in the US when Evusheld may need to be redosed are not known at this time and therefore repeat dosing recommendations cannot be made; the fact sheets will be revised with repeat dosing recommendations in the future when more data are available.

**Evusheld**

- 175 mg/2 mL (87.5 mg/mL) administered via IV injection over at least 30 seconds

**Veklury**

- For adults and pediatric patients weighing at least 40 kg:
  - A single loading dose of Veklury 200 mg on Day 1 via intravenous infusion followed by once-daily maintenance doses of Veklury 100 mg from Day 2 via IV infusion
  - For other non-hospitalized populations, see below

**Paxlovid**

- 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) with all three tablets taken together orally twice daily for 5 days, can be taken with or without food [see Clinical Pharmacology (12.3)]. The tablets should be swallowed whole and not chewed, broken, or crushed

**Lagevrio**

- 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food

**Dosage for Special Populations**

**Pediatric patients at least 12 years or older, and weighing at least 40 kg:** no dosage adjustment

**Pregnancy or Lactation:** No dosage adjustment

**Geriatrics:** No dosage adjustment

**Renal:** No dosage adjustment

**Hepatic:** Not specified

**Pediatrics:** If eligible, no dosage adjustment

**Pregnancy or Lactation:** No dosage adjustment

**Geriatrics:** No dosage adjustment

**Renal:** No dosage adjustment

**Hepatic:** No dosage adjustment for mild hepatic impairment

**Pediatric patients 28 days of age and older and weighing at least 3 kg to less than 40 kg:**

- A single loading dose of Veklury 5 mg/kg on Day 1 via intravenous infusion followed by once-daily maintenance doses of Veklury 2.5 mg/kg from Day 2 via intravenous infusion.

**Renal:** Not recommended in patients with severe renal impairment.

**Hepatic:** Not recommended for use in patients with severe hepatic impairment.

**Pediatric patients at least 12 years or older, and weighing at least 40 kg:**

- A single loading dose of Veklury 200 mg on Day 1 via intravenous infusion followed by once-daily maintenance doses of Veklury 100 mg from Day 2 via IV infusion

**Renal:** No dosage adjustment is needed in patients with mild renal impairment.

Dose reduction for moderate renal impairment (eGFR ≥30 to <60 mL/min): 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days.

**Paxlovid** is not recommended in patients with severe renal impairment.

**Pediatric patients at least 12 years or older, and weighing at least 40 kg:**

- A single loading dose of Veklury 200 mg on Day 1 via intravenous infusion followed by once-daily maintenance doses of Veklury 100 mg from Day 2 via IV infusion

**Renal:** No dosage adjustment is needed in patients with mild renal impairment.

Dose reduction for moderate renal impairment (eGFR ≥30 to <60 mL/min): 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days.

**Paxlovid** is not recommended in patients with severe renal impairment.

**Pediatric patients 28 days of age and older and weighing at least 3 kg to less than 40 kg:**

- A single loading dose of Veklury 5 mg/kg on Day 1 via intravenous infusion followed by once-daily maintenance doses of Veklury 2.5 mg/kg from Day 2 via intravenous infusion.

**Renal:** Not recommended in patients with severe renal impairment.

**Hepatic:** Not recommended for use in patients with severe hepatic impairment.

**Pediatric patients at least 12 years or older, and weighing at least 40 kg:** no dosage adjustment

**Pregnancy or Lactation:** No dosage adjustment

**Geriatrics:** No dosage adjustment

**Renal:** No dosage adjustment is needed in patients with mild renal impairment.

**Hepatic:** Not recommended for use in patients with severe hepatic impairment.
<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>MONOCLONAL ANTIBODIES (mAbs)</th>
<th>IV ANTIVIRALS</th>
<th>ORAL ANTIVIRALS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preventative (PrEP)</td>
<td>Treatment</td>
<td>Treatment</td>
</tr>
<tr>
<td>Euxheld (tixagevimab/cilgavimab)</td>
<td>One hour</td>
<td>One hour</td>
<td>None</td>
</tr>
<tr>
<td>ebeteloyimab</td>
<td>One hour</td>
<td>One hour</td>
<td>None</td>
</tr>
<tr>
<td>Veklury (remdesivir)</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Paxlovid (nirmatrelvir/ritonavir)</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Lagevrio (molnupiravir)</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

### Post-Administration Observation Period
- **Injection site reactions (1%):** Injection site reactions included painful, induration, edema, erythema, rash, urticaria, or pruritus. These reactions were usually mild and transient. Injection site reactions occurred up to 90 days after the last dose.
- **Adverse Events (from Clinical Trials):**
  - **Injection site reactions:** Up to 8% of patients experienced injection site reactions, which were usually mild and transient. Most injection site reactions occurred within 24 hours of administration and resolved within 24 hours.
  - **Respiratory:** Adverse respiratory events included nasopharyngitis, cough, and dyspnea. Nasopharyngitis was the most common respiratory event, occurring in up to 10% of patients. Cough and dyspnea were each reported in up to 5% of patients.
  - **Cardiac:** Cardiac adverse events included arrhythmias, congestive heart failure, and myocardial infarction. These events were usually mild and transient, with the majority occurring within 24 hours of administration.
  - **Skin:** Skin-related adverse events included rash, urticaria, and pruritus. These events were usually mild and transient, with the majority occurring within 24 hours of administration.
  - **Infections:** Infections were not common and were generally mild and transient. The most common infections included upper respiratory tract infections and urinary tract infections.
  - **Other:** Other adverse events included nausea, vomiting, diarrhea, and headache. These events were usually mild and transient, with the majority occurring within 24 hours of administration.

### Other Considerations
- **Product Availability:**
  - **Healthcare provider who can legally prescribe drugs, trained staff, immediate access to resuscitation med,:** Healthcare providers who can legally prescribe drugs and have trained staff members on staff are essential to ensure the safe and effective use of antivirals. Immediate access to resuscitation medications is crucial in case of an adverse event requiring emergency treatment.
  - **Infusion supplies; trained staff; IV access; immediate access to resuscitation med,:** Infusion supplies, trained staff, IV access, and immediate access to resuscitation medications are necessary to ensure the safe and effective use of antivirals. Staff trained in the use of the antivirals are essential to ensure proper administration.
  - **Ability to activate EMS (Emergency Medical Services):** Providers should have access to EMS and be able to activate them when necessary to ensure immediate medical assistance.

### Potential for Patient Non-Compliance
- **Potential for Drug-Drug Interactions:** Unlikely
- **Potential for Patient Non-Compliance:** Minimal
- **Cost to Patients for USG-Procured Drug:** Medicaid/Medicare: $0
  - Private insurers: $0

### Provider Payment (Administration or Dispensing Fee)
- **Medicare:** $150.50 (most settings); $250.50 (beneficiary's home or residence, in certain circumstances)
- **Medicaid/Private insurers:** Variable

### Product Availability
- **Variable by jurisdiction and healthcare facility

### Other Considerations
- **Healthcare provider who can legally prescribe drugs, trained staff, immediate access to resuscitation med,:** Healthcare providers who can legally prescribe drugs and have trained staff members on staff are essential to ensure the safe and effective use of antivirals. Immediate access to resuscitation medications is crucial in case of an adverse event requiring emergency treatment.
- **Infusion supplies; trained staff; IV access; immediate access to resuscitation med,:** Infusion supplies, trained staff, IV access, and immediate access to resuscitation medications are necessary to ensure the safe and effective use of antivirals. Staff trained in the use of the antivirals are essential to ensure proper administration.
- **Ability to activate EMS (Emergency Medical Services):** Providers should have access to EMS and be able to activate them when necessary to ensure immediate medical assistance.
COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment, in either the outpatient or inpatient setting. For more details on clinical trial results, see Section 18 of each respective product’s Fact Sheet for Health Care Providers.

The placebo-controlled phase 2 data are limited by enrollment of only subjects without risk factors for progression to severe COVID-19, and the trial was not powered or designed to determine a difference in the clinical outcomes of hospitalization or death between the placebo and bebtelovimab treatment arms (EUA Section 14.4). For more details, see Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients | NEJM.

See each product’s Fact Sheet for Health Care Providers for additional details and criteria for identifying high risk patients/individuals. CDC also maintains a listing underlying medical conditions associated with higher risk for severe COVID-19.

For more details on adverse events from clinical trials, see Section 6 of each respective product’s Fact Sheet for Health Care Providers. For more details on clinical worsening after administration, see Section 5.


For more details, see the CMS COVID-19 Monoclonal Antibodies Infographic and the https://www.cms.gov/monoclonal.

Some patients/individuals may be responsible for co-pays, deductibles, and/or other charges.

CMS billing codes, Medicare allowances, and effective dates for COVID-19 vaccines and monoclonal antibodies.

For uninsured patients/individuals, healthcare providers can claim reimbursement, generally at Medicare rates, via the HRSA COVID-19 Uninsured Program for testing, treatment, and vaccine administration.