Federal Response to COVID-19: Therapeutics Clinical Implementation Guide
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Clinical Implementation Guide Objectives

• Review available outpatient COVID-19 therapeutics used to treat eligible non-hospitalized patients who have mild to moderate symptoms of COVID-19.
• Summarize key information on COVID-19 therapeutics and support healthcare providers’ understanding of these therapies and how to implement their administration.
• Describe process for obtaining and reporting COVID-19 therapeutics products purchased by HHS/ASPR, including collaboration with state and territorial health departments, as well as national healthcare and medical organizations and associations to ensure efficient and equitable distribution.

IMPORTANT NOTE: The Clinical Implementation Guide will no longer be updated after February 2024.

See the latest information on all FDA authorized products under EUA https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
COVID-19 Therapeutics under Emergency Use Authorization (EUA)

- In certain types of emergencies, the FDA can issue an emergency use authorization (EUA), to provide more timely access to critical medical products (including medicines and tests) that may help during the emergency when there are no adequate, approved, and available alternative options.

- The EUA process is different than FDA approval, clearance, or licensing because the EUA standard may permit authorization based on significantly less data than would be required for approval, clearance, or licensing by the FDA. This enables the FDA to authorize the emergency use of medical products that meet the criteria within weeks rather than months to years. Since EUA products are not approved and, thus, do not have labeled indications, “off-label use” or the use of the product outside of the EUA authorization is not permitted.

- EUAs are in effect until the emergency declaration ends but can be revised or revoked. The need will be evaluated during the emergency, availability of new data on the product’s safety and effectiveness, or as products meet the criteria to become approved, cleared, or licensed by the FDA.

- Products packaged under the EUA must be prescribed/administered in accordance with the EUA even if the product receives FDA approval.
COVID-19 Therapeutics: Resources for Health Care Professionals and Public Health Officials

**ASPR’s Response to COVID-19 Therapeutics Website**
https://aspr.hhs.gov/COVID-19/therapeutics/Pages/default.aspx

**New and Notable: COVID-19 Therapeutics Announcements**
https://aspr.hhs.gov/COVID-19/Therapeutics/update/Pages/default.aspx
Module 1: COVID-19 Outpatient Therapeutics Overview
Who Is At Risk for Severe COVID-19?

COVID-19 Risk Continuum

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>LOWER RISK</th>
<th>HIGHER RISK</th>
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</thead>
<tbody>
<tr>
<td>&lt;30</td>
<td>30–49</td>
<td>50–69</td>
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<tr>
<td>≥70</td>
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<table>
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<th>Medical Conditions</th>
<th>LOWER RISK</th>
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<tr>
<td>None</td>
<td>1</td>
<td>2</td>
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<tr>
<td>1</td>
<td>3+</td>
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</table>

<table>
<thead>
<tr>
<th>Vaccination Status</th>
<th>LOWER RISK</th>
<th>HIGHER RISK</th>
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</thead>
<tbody>
<tr>
<td>Full vaccination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>plus boosting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full vaccination</td>
<td></td>
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</tr>
<tr>
<td>Partial vaccination</td>
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<td></td>
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<tr>
<td>Unvaccinated</td>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Immunosuppression</th>
<th>LOWER RISK</th>
<th>HIGHER RISK</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Corticosteroids</td>
<td>Solid organ transplant</td>
</tr>
<tr>
<td>Biologics (e.g., anti-tumor Necrosis factor)</td>
<td>Antimetabolites (e.g., mycophenolate)</td>
<td>Lymphodepletion (e.g., anti-CD20°)</td>
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<tr>
<td>Antimetabolites (e.g., mycophenolate)</td>
<td>AIDS</td>
<td>Stem cell transplant</td>
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<tr>
<td>Solid organ transplant</td>
<td>Lymphodepletion (e.g., anti-CD20°)</td>
<td>Hematological malignancy</td>
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Sociodemographic factors and non-pharmaceutical interventions affect exposure

Original illustration by Dr. William Werbel, adapted for the COVID-19 Real-Time Learning Network

# Summary of COVID-19 Preventative Agents & Treatments

<table>
<thead>
<tr>
<th>No Illness</th>
<th>Exposed</th>
<th>Mild to Moderate Symptoms&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Hospital Admission</th>
<th>ICU Admission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline health status, no infection&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Per CDC Close Contact Criteria</td>
<td>Not hospitalized for COVID&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Not hospitalized for reason other than COVID</td>
<td>Not hospitalized for COVID, not on oxygen</td>
</tr>
</tbody>
</table>

**COVID19 Vaccines**
None currently authorized for use in any U.S. state or territory.

**Exposed**
None currently authorized for use in any US state or territory.

**Mild to Moderate Symptoms<sup>1</sup>**

*Oral Antivirals*
- Paxlovid (nirmatrelvir + ritonavir, Pfizer)
- Lagevrio (molnupiravir, Merck) – Alternative

**IV Antiviral**
- Veklury® (remdesivir, Gilead)

**Hospital Admission**
- Hosp. for reason other than COVID
- Hospitalized for COVID, not on oxygen
- Hospitalized, on oxygen

**ICU Admission**
- Hospitalized, high flow oxygen/ non-invasive ventilation
- Hospitalized, mechanical ventilation/ ECMO

**Please see NIH Current Inpatient Therapies**
(https://www.covid19treatmentguidelines.nih.gov/therapies/)

Patient assistance programs support continued access post commercialization

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<sup>1</sup> Convalescent Plasma EUA
https://www.fda.gov/media/141478/download
High titer convalescent plasma is authorized for specific immunocompromised patients.

<sup>2</sup> Refer to individual product Fact Sheets for authorization details

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<sup>*HHS distribution</sup>

<sup>**Commercially available**</sup>

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<sup>#Be sure to check latest updates on inpatient care</sup>

Therapeutic Management of Nonhospitalized Adults With COVID-19

Therapeutic Management of Hospitalized Adults With COVID-19
The COVID-19 Treatment Guidelines Panel (the Panel) recommends the following anti-SARS-CoV-2 therapies as preferred treatments for COVID-19. These drugs are listed in order of preference:

- Nirmatrelvir co-packaged with ritonavir (Paxlovid) (AIIa)
- Remdesivir (Veklury) (BIIa)

Alternative therapy. For use when the preferred therapies are not available, feasible to use, or clinically appropriate.

- Molnupiravir (Lagevrio) (CIIa)
NIH: Patient Prioritization for Treatment

• These guidelines\(^1\) are for use only when logistical constraints limit the availability of therapies.

• Remdesivir is a recommended option if nirmatrelvir co-packaged with ritonavir cannot be used.

• Some treating facilities may not have the ability to provide a 3-day course of remdesivir intravenous infusions to all eligible patients. In these situations, prioritizing patients who will benefit the most from the therapy becomes necessary.

• Prioritization strategy includes 4 factors: age, vaccination status, immune status, and clinical risk factors.

\(^1\)NIH Prioritization Guidelines https://www.covid19treatmentguidelines.nih.gov/overview/prioritization-of-therapeutics/
### Tier Risk Group

<table>
<thead>
<tr>
<th>Tier</th>
<th>Risk Group</th>
</tr>
</thead>
</table>
| 1    | • Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); or  
    | • Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with additional risk factors). |
| 2    | • Unvaccinated individuals not included in Tier 1 who are at risk of severe disease (anyone aged ≥65 years or anyone aged <65 years with clinical risk factors) |
| 3    | • Vaccinated individuals at risk of severe disease (anyone aged ≥65 years or anyone aged <65 years with clinical risk factors) |

**Note:** Vaccinated individuals who are not up to date with their immunizations are likely at higher risk for severe disease; patients within this tier who are in this situation should be prioritized for treatment.

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1 NIH Prioritization Guidelines https://www.covid19treatmentguidelines.nih.gov/overview/prioritization-of-therapeutics/
Recommendations for Special Populations: Immunocompromised & Pediatrics
NIH Guidelines for Patients Who are Immunocompromised

- All people who are moderately or severely immunocompromised should receive COVID-19 vaccination.

- All close contacts of people who are immunocompromised are strongly encouraged to be up to date on vaccination against COVID-19.

- There is insufficient evidence for recommendation for or against the use of SARS-CoV-2 serologic testing to assess for immunity or to guide clinical decision about using COVID-19 vaccines or PrEP for certain people.

- Management of COVID-19 in individuals who are moderately to severely immunocompromised:
  - Patients should be treated quickly with appropriate COVID-19 therapeutics
  - Decisions regarding stopping or reducing the doses of immunosuppressive drugs in patients with COVID-19 should be made in consultation with the appropriate specialists; When selecting treatments for COVID-19, clinicians should consider factors such as the underlying disease, the specific immunosuppressants being used, the potential for drug-drug interactions, and the severity of COVID-19

Veklury (Remdesivir)

- Pediatric patients **28 Days of Age and Older and weighing 3 kg to less than 40 kg**
  
  * Pediatric patients less than 12 years of age but weighing 40kg or greater receive Veklury at the adult dose

# NIH Guidelines For Therapeutic Management in Non-hospitalized Children With COVID-19

## Risk of Severe COVID-19

<table>
<thead>
<tr>
<th>Risk of Severe COVID-19</th>
<th>Panel’s Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic, Regardless of Risk Factors</td>
<td>• Provide supportive care (AIII).</td>
</tr>
<tr>
<td>High Risk&lt;sup&gt;a,b&lt;/sup&gt;</td>
<td>• Use 1 of the following options (listed in order of preference):&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>▪ Nirmatrelvir co-packaged with ritonavir (Paxlovid) within 5 days of symptom onset (BIII)</td>
</tr>
<tr>
<td></td>
<td>▪ Remdesivir within 7 days of symptom onset (CIII)</td>
</tr>
<tr>
<td>Intermediate Risk&lt;sup&gt;b,d&lt;/sup&gt;</td>
<td>• There is insufficient evidence to recommend either for or against the use of any antiviral therapy. Consider treatment based on age and other risk factors.</td>
</tr>
<tr>
<td>Low Risk&lt;sup&gt;b,e&lt;/sup&gt;</td>
<td>• Manage with supportive care alone (BIII).</td>
</tr>
</tbody>
</table>

### Panel’s Recommendations:

- **Aged 12-17 years**
  - • Provide supportive care (AIII).

- **Aged <12 years**
  - • Provide supportive care (AIII).

### Notes:

- *Molnupiravir is not authorized by the FDA for use in children aged <18 years and should not be used.*
- *See Table 3b for the Panel’s framework for assessing the risk of progression to severe COVID-19 based on patient conditions and COVID-19 vaccination status.*
- *Initiate treatment as soon as possible after symptom onset.*
- *The relative risk of severe COVID-19 for intermediate-risk patients is lower than the risk for high-risk patients but higher than the risk for low-risk patients.*
- *Low-risk patients include those with comorbid conditions that have a weak or unknown association with severe COVID-19. Patients with no comorbidities are included in this group.*

Additional Tools to Assist in COVID-19 Outpatient Therapeutic Selection

- NIH’s COVID-19 Treatment Guidelines - What’s new

- NIH Therapeutic Management of Nonhospitalized Children With COVID-19

- CDC Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals

- CDC COVID Data Tracker
  https://covid.cdc.gov/covid-data-tracker/#variant-proportions
  The CDC monitors and publishes variant information

- Clinical Decision Aid
  https://aspr.hhs.gov/COVID-19-Therapeutics/Outpatient-Therapeutics-Clinical-Decision-Aide/Pages/default.aspx

- Side-by-Side Overview of Outpatient Therapeutics

- ASPR COVID-19 Therapeutics
  https://aspr.hhs.gov/COVID-19-Therapeutics/Pages/default.aspx
Module 2: Product Information
Products for Treatment of Mild-to-Moderate COVID-19: Preferred Therapies per NIH Guidelines
Paxlovid (nirmatrelvir co-packaged with ritonavir) – Pfizer Oral Antiviral (Preferred)*

*Note both EUA (while supply remains) and NDA labeled Paxlovid is available

Fact Sheet for Healthcare Providers for Paxlovid (nirmatrelvir co-packaged with ritonavir) https://www.fda.gov/media/155050/download
Paxlovid (nirmatrelvir co-packaged with ritonavir)

Product Information

- FDA Fact Sheets and Prescribing Information
  - Paxlovid provider fact sheet https://www.fda.gov/media/155050/download
  - Fact Sheet for Patients, Parents and Caregivers https://www.fda.gov/media/155051/download

- Manufacturer’s Resources:
  - Pharmacist Instruction Sheet

- Prescribing Resources:
  - Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers https://www.fda.gov/media/158165/download
  - Important Prescribing and Dispensing Information https://www.fda.gov/media/155071/download
  - University of Liverpool COVID-19 Drug Interactions Checker https://covid19-druginteractions.org

- Safety Reporting:
  - Pfizer Safety Reporting http://www.pfizersafetyreporting.com/
Paxlovid (nirmatrelvir co-packaged with ritonavir) Emergency Use AUTHORIZATION

- Paxlovid EUA authorized for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg), who are at high risk for progression to severe COVID-19, including hospitalization or death
- Initiated as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset
- Paxlovid includes: nirmatrelvir (a SARS-CoV-2 main proteases inhibitor) co-packaged with ritonavir (a CYP34A inhibitor)
- PAXLOVID is not authorized for use as pre-exposure or post-exposure prophylaxis for prevention of COVID-19
- Paxlovid (nirmatrelvir co-packaged with ritonavir) may be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which Paxlovid (nirmatrelvir co-packaged ritonavir) belongs (i.e., anti-infectives). Pharmacists are also authorized under the EUA to prescribe Paxlovid under certain conditions

Fact Sheet for Healthcare Providers for Paxlovid (nirmatrelvir co-packaged with ritonavir) https://www.fda.gov/media/155050/download
Paxlovid (nirmatrelvir co-packaged with ritonavir)
FDA APPROVAL

• On May 25, 2023, FDA approved a New Drug Application (NDA) for Paxlovid for the treatment of mild to moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. 

  ▪ Paxlovid Prescribing Information
    https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217188s000lbl.pdf

• Paxlovid also remains authorized under EUA to ensure continued access for all eligible patients to the current supply of Paxlovid, including adult patients

  ▪ EUA fact sheet for health care providers https://www.fda.gov/media/155050/download

• The Emergency Use Authorization (EUA) continues to authorize Paxlovid to treat certain eligible pediatric patients, a patient population that is not covered under the approved NDA for Paxlovid at this time. Note: EUA-labeled Paxlovid will no longer be authorized for emergency use after March 8, 2024, however the Paxlovid EUA will continue to authorize emergency use of NDA-labeled Paxlovid for pediatric patients (12 years of age and older weighing at least 40 kg). 

• NDA-labeled Paxlovid (nirmatrelvir tablets and ritonavir tablets) continues to be available from the federal government at no cost for federal Entities
Paxlovid (nirmatrelvir co-packaged with ritonavir) – Pharmacist Prescribing Authorization under EUA

As outlined in the EUA, Paxlovid may also be prescribed for an individual patient by a state-licensed pharmacist under the following conditions:

• Sufficient information is available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient, to assess renal and hepatic function; and

• Sufficient information is available, such as through access to health records, patient reporting of medical history, or consultation with a health care provider in an established provider-patient relationship with the individual patient, to obtain a comprehensive list of medications (prescribed and non-prescribed) that the patient is taking to assess for potential drug interaction.

Fact Sheet for Healthcare Providers for Paxlovid (nirmatrelvir co-packaged with ritonavir) https://www.fda.gov/media/155050/download
The state-licensed pharmacist should refer an individual patient for clinical evaluation (e.g., telehealth, in-person visit) with a physician, advanced practice registered nurse, or physician assistant licensed or authorized under state law to prescribe drugs, if any of the following apply:

- Sufficient information is not available to assess renal and hepatic function.
- Sufficient information is not available to assess for a potential drug interaction.
- Modification of other medications is recommended due to a potential drug interaction.
- Paxlovid is not an appropriate therapeutic option based on the authorized Fact Sheet for Healthcare Providers or due to potential drug interactions for which recommended monitoring would not be feasible.

Fact Sheet for Healthcare Providers for Paxlovid (nirmatrelvir co-packaged with ritonavir) https://www.fda.gov/media/155050/download
Paxlovid (nirmatrelvir co-packaged with ritonavir)

**Dosage and Administration**

- **eGFR > 60 mL/min**: 300 mg nirmatrelvir (two 150 mg tablets) co-packaged with 100 mg ritonavir (one 100 mg tablet) taken together twice daily for 5 days.
- **Dose reduction for moderate renal impairment eGFR > 30 mL/min to < 60 mL/min**: 150 mg nirmatrelvir (one 150 mg tablet) co-packaged with 100 mg ritonavir (one 100 mg tablet) taken together twice daily for 5 days.
- **eGFR <30 mL/min**: currently not recommended
- **Severe hepatic impairment (Child-Pugh Class C)**: currently not recommended

**Contraindications and Precautions**

- **History of clinically significant hypersensitivity reactions to the active ingredients or any other components.**
- **Co-administration with drugs highly dependent on CYP3A for clearance may result in life-threatening reactions**
- **Co-administration with potent CYP3A inducers may result in reduced nirmatrelvir plasma concentrations and potential loss of virologic response.**
- **The concomitant use of Paxlovid (nirmatrelvir co-packaged with ritonavir) and certain other drugs may result in potentially significant drug interactions.**
- **Hepatic transaminase elevations, hypersensitivity reactions, clinical hepatitis, and jaundice have occurred in patients receiving ritonavir.**
- **Paxlovid (nirmatrelvir co-packaged with ritonavir) use may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection.**

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1 Liverpool Covid-19 interaction checker https://covid19-druginteractions.org/
Fact Sheet for Healthcare Providers for Paxlovid (nirmatrelvir co-packaged with ritonavir) https://www.fda.gov/media/155050/download
Paxlovid (nirmatrelvir co-packaged with ritonavir) Patient Eligibility Screening Checklist Tool for Prescribers

Medical History

- Mild to moderate COVID-19 with symptom onset within 5 days
- Age $\geq 12$ years of age and weighing at least 40 kg (if utilizing product under EUA)
- Adult (if utilizing approved product)
- Has one or more risk factors for progression to severe COVID-19
  
- Not requiring hospitalization due to severe or critical COVID-19 at treatment initiation
- No known or suspected severe renal impairment (eGFR < 30 mL/min)
  
  ▪ Note that a dose reduction is required for patients with moderate renal impairment (eGFR $\geq30$-$<60$ mL/min); see the Fact Sheet for Healthcare Providers.
- No known or suspected severe hepatic impairment
- No history of clinically significant hypersensitivity reactions to the active ingredients (nirmatrelvir or ritonavir) or other components of the product

Fact Sheet for Healthcare Providers for Paxlovid (nirmatrelvir co-packaged with ritonavir) https://www.fda.gov/media/155050/download
See table in Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers https://www.fda.gov/media/158165/download
Concomitant Medications

- **Assess patient’s home medication list for drug-drug interactions**
- See table in [Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers](https://www.fda.gov/media/158165/download)
- **HMG-CoA reductase inhibitors (statins)**
  - Patient is taking lovastatin or simvastatin, which are contraindicated with Paxlovid coadministration: The statin can be held 12 hours prior to the first dose of Paxlovid treatment, held during the 5 days of treatment, and restarted 5 days after completing Paxlovid.
  - Patient is taking atorvastatin or rosuvastatin: Temporary discontinuation of atorvastatin and rosuvastatin during treatment with Paxlovid should be considered depending on statin dose. Atorvastatin and rosuvastatin do not need to be held prior to or after completing Paxlovid.
- **Hormonal contraceptives containing ethinyl estradiol:** Patient is taking a hormonal contraceptive containing ethinyl estradiol: The need for an additional non-hormonal method of contraception during the 5 days of Paxlovid treatment and until one menstrual cycle after stopping Paxlovid should be recommended.
- **Medications for HIV-1 Treatment:** Patient is taking medications for the treatment of HIV-1 infection: With the exception of maraviroc, HIV antiretroviral medications can be co-administered with Paxlovid without dose adjustment, but arranging follow-up by the HIV care provider to monitor for side effects is recommended.

Other Drugs with Established and Other Potentially Significant Drug Interactions with Paxlovid

- See table in [Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers](https://www.fda.gov/media/158165/download)

*Prescriber is encouraged to include a note to the pharmacist in the prescription stating:

Please fill prescription by [insert date]. This prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.
# Paxlovid (nirmatrelvir co-packaged with ritonavir) Patient Eligibility Screening Checklist Tool for Prescribers (Table)

## PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

**Other Drugs with Established and Other Potentially Significant Drug Interactions with PAXLOVID (listed alphabetically by generic name)**

### Interaction Codes:

- **XXX**: Coadministration of this drug with PAXLOVID is CONTRAINDIATED. For further information, refer to the Fact Sheet for Healthcare Providers and the individual Prescribing Information for the drug.

- *******: Coadministration of this drug with PAXLOVID should be avoided and/or holding of this drug, dose adjustment of this drug, or special monitoring is necessary. Consultation with the prescriber of the potentially interacting drug is recommended. For further information, refer to the Health Care Provider Fact Sheet and the individual Prescribing Information for the drug.

### Drug Interactions Table

<table>
<thead>
<tr>
<th>Drug</th>
<th>Drug Class</th>
<th>Interaction Code</th>
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<tbody>
<tr>
<td>abemaciclib</td>
<td>Anticancer drug</td>
<td>XXX</td>
</tr>
<tr>
<td>aflduzosin</td>
<td>Alpha 1-adrenergic</td>
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<td>amiodipine</td>
<td>Calcium channel blocker</td>
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<td>apalsetamide</td>
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<td>colchinine</td>
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<td>cyclosporine</td>
<td>Immunosuppressant</td>
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<td>dalfuzirgan</td>
<td>Anticoagulants</td>
<td>***</td>
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<tr>
<td>dasabuvir</td>
<td>Hepatitis C direct act</td>
<td>***</td>
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<tr>
<td>dasatinib</td>
<td>Anticancer drug</td>
<td>XXX</td>
</tr>
<tr>
<td>dexamethasone</td>
<td>Systemic corticosteriod</td>
<td>***</td>
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<tr>
<td>prinapril</td>
<td>Antipsyhotic</td>
<td>***</td>
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<tr>
<td>prinidone</td>
<td>Antipsyhotic</td>
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<tr>
<td>propafenone</td>
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<td>propoxyphenone</td>
<td>Antipsyhotic</td>
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<td>quinaprine</td>
<td>Antipsyhotic</td>
<td>***</td>
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<tr>
<td>quinidine</td>
<td>Antipsyhotic</td>
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</tr>
<tr>
<td>ranitidine</td>
<td>Antipsyhotic</td>
<td>***</td>
</tr>
</tbody>
</table>

See table in [Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers](https://www.fda.gov/media/158165/download)
Additional Paxlovid (nirmatrelvir co-packaged with ritonavir) Prescribing Resources

- University of Liverpool COVID-19 Drug Interactions
  https://covid19-druginteractions.org/checker

- FDA PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers
  https://www.fda.gov/media/158165/download

- Pfizer Drug Interaction Checker
  https://www.pfizermedicalinformation.com/drug-interaction-checker?product=PAXLOVID%E2%84%A2+%7C+nirmatrelvir+tablets%3B+ritonavir+tablets

- NIH COVID-19 Treatment Guidelines – Nirmatrelvir Co-Packaged with Ritonavir (Paxlovid)
  https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ritonavir-boosted-nirmatrelvir--paxlovid-
Paxlovid (nirmatrelvir co-packaged with ritonavir)
Formulation and Packaging – EUA Product

Standard Dose
300 mg nirmatrelvir; 100 mg ritonavir: Each carton contains 30 tablets divided in 5 daily dose blister cards. Each blister card contains 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

Reduced Dose (Renal)
150 mg nirmatrelvir; 100 mg ritonavir: Each carton contains 20 tablets divided in 5 daily dose blister cards. Each blister card contains 2 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

Note: EUA-labeled Paxlovid will no longer be authorized for emergency use after March 8, 2024

Paxlovid (nirmatrelvir co-packaged with ritonavir)
Formulation and Packaging – Commercial NDA-labeled

**Standard Dose**
300 mg nirmatrelvir; 100 mg ritonavir: Each carton contains 30 tablets divided in 5 daily dose blister cards. Each blister card contains 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

**Reduced Dose (Renal)**
150 mg nirmatrelvir; 100 mg ritonavir: Each carton contains 20 tablets divided in 5 daily dose blister cards. Each blister card contains 2 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

**Viral RNA Rebound**

- Post-treatment increases in SARS-CoV-2 RNA levels (i.e., viral RNA rebound) in nasopharyngeal samples were observed on Day 10 and/or Day 14 in a subset of Paxlovid and placebo recipients, irrespective of COVID-19 symptoms. The frequency of detection of post-treatment viral RNA rebound varied according to analysis parameters but was generally similar among Paxlovid and placebo recipients, regardless of the rebound definition used. A similar or smaller percentage of placebo recipients compared to Paxlovid recipients had nasopharyngeal viral RNA results < LLOQ (lower limit of quantitation) at all study timepoints in both the treatment and post-treatment periods.

- Post-treatment viral RNA rebound was not associated with the primary clinical outcome of COVID-19-related hospitalization or death from any cause through Day 28 following the single 5-day course of Paxlovid treatment. Post-treatment viral RNA rebound also was not associated with drug resistance as measured by Mpro sequencing. The clinical relevance or exact incidence of post-treatment increases in viral RNA following Paxlovid or placebo treatment is unknown at this time.

- Viral RNA rebound is not specific to Paxlovid or Lagevrio and has been seen in placebo recipients.

***Not exclusive to Paxlovid***

See Microbiology (12.4): Viral RNA Rebound of Fact Sheet for Healthcare Providers: EUA for Paxlovid https://www.fda.gov/media/155050/download

Paxlovid (nirmatrelvir co-packaged with ritonavir)
Product Information & Ordering Logistics

• **EUA Status:** EUA for pediatric patients (12 years of age and older weighing at least 40 kg) is active: NDA-labeled Paxlovid will be used – Active

• **Procurement:** USG purchased and commercially available.

• **Eligibility information for product labeled under EUA:**
  - [ASPR Paxlovid page](https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Paxlovid/Pages/default.aspx)
  - [Frequently Asked Questions: FDA EUA for Paxlovid (FDA)](https://www.fda.gov/media/155052/download)
  - [Letter of Authorization](https://www.fda.gov/media/155049/download?attachment)

• **Indications and usage for product labeled under FDA approval**

• **To order:**
  - [Process for Ordering COVID-19 Therapeutics | HHS/ASPR](https://aspr.hhs.gov/HPOP/Pages/default.aspx)

• **Where to find:**
  - [Treatments Locator (hhs.gov)](https://treatments.hhs.gov/)
Veklury (remdesivir) – Gilead Antiviral for IV Infusion (Preferred)

Veklury Product Information
https://www.vekluryhcp.com/
Veklury (remdesivir) Product Information

• Prescribing Information & FDA Fact Sheets

• Manufacturer’s Resources:
  ▪ Website for Healthcare Providers https://www.vekluryhcp.com/
  ▪ Website for Patients https://www.veklury.com/

• Safety Reporting:
  ▪ Safety Reporting Email Safety_fc@gilead.com
  ▪ Report a Pregnancy Exposure https://covid-pr.pregistry.com
Veklury (remdesivir) – Outpatient Use

- FDA approved Veklury (remdesivir) for certain non-hospitalized adults and pediatric patients for treatment of mild-to-moderate COVID-19, including:
  - Adults and pediatric patients 28 days of age and older and weighing at least 3 kg, AND
  - Who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death
- The treatment course of Veklury (remdesivir) should be initiated as soon as possible after diagnosis of symptomatic COVID-19 has been made and within 7 days of symptom onset. The recommended total duration of treatment for non-hospitalized patients is 3 days.
- No dosage adjustment of Veklury is recommended in patients with any degree of renal impairment, including those on dialysis for adult and pediatric patients
  - Veklury may be administered without regard to the timing of dialysis in all patients
- No dosage adjustment of Veklury is recommended for patients with mild, moderate, or severe hepatic impairment (Child-Pugh Class A, B, or C)
  - The label still recommends:
    - Initial hepatic laboratory testing in all patients, before starting Veklury and during treatment as clinically appropriate
    - Discontinuation be considered if alanine transaminase (ALT) levels increase to 10 times the upper limit of normal or if ALT elevation is accompanied by signs or symptoms of liver inflammation.

Veklury (remdesivir)

Dosage and Administration

• Dosage:
  ▪ For adults and pediatric patients who weight > 40kg: **200 mg** on Day 1, followed by once-daily maintenance doses of **100 mg** from Day 2 administered only via intravenous infusion over 30 to 120 minutes.
  ▪ For pediatric patients 28 days of age and older and weighing 3 kg to less than 40 kg: **5 mg/kg** on Day 1 followed by **2.5 mg/kg** once daily from Day 2.

• Dosage Forms:
  ▪ For injection: **100 mg** of remdesivir as a lyophilized powder, in a single-dose vial.
  ▪ Injection: **100 mg/20 mL (5 mg/mL)** remdesivir, in a single-dose vial.

Contraindications and Precautions

• Contraindications:
  ▪ History of clinically significant hypersensitivity reactions to Veklury or any components of the product.
  ▪ Hypersensitivity including infusion-related and anaphylactic reactions.

• Pre-administration testing:
  ▪ Perform hepatic laboratory testing in all patients before starting Veklury and during treatment as clinically appropriate.
  ▪ Assess prothrombin time before starting Veklury and monitor as clinically appropriate.

• Increased risk of transaminase elevations with administration.

• Risk of reduced antiviral activity when co-administered with chloroquine phosphate or hydroxychloroquine sulfate.
Veklury (remdesivir) Pediatric Eligibility Criteria

• Pediatric patients **28 Days of Age and Older and weighing 3 kg to less than 40 kg***
• Mild-to-moderate COVID-19 and at high risk for progression to severe disease
• Initiate within **7 days of symptom onset**

* Pediatric patients less than 12 years of age but weighing 40kg or greater receive Veklury at the adult dose

### Veklury (remdesivir) Pediatric Dosing and Administration

<table>
<thead>
<tr>
<th>Body weight</th>
<th>Recommended dosage form</th>
<th>Loading dose (on Day 1)</th>
<th>Maintenance dose (from Day 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 kg to less than 40 kg</td>
<td>Veklury for injection, lyophilized powder Only</td>
<td>5 mg/kg</td>
<td>2.5 mg/kg</td>
</tr>
</tbody>
</table>

- Lyophilized powder: **100 mg** of Veklury (remdesivir) reconstituted with 19 mL of Sterile Water for Injection. The only approved dosage form of Veklury for pediatric patients weighing 3 kg to less than 40 kg is Veklury for injection (supplied as 100 mg lyophilized powder in vial).

- Further dilute to a concentration of 1.25 mg/mL using 0.9% sodium chloride
  - Small 0.9% sodium chloride infusion bags (e.g., 25, 50, or 100 mL) or an appropriately sized syringe should be used for pediatric dosing.

Veklury (remdesivir)
Recommended Rate of Infusion-Diluted Veklury for Injection Lyophilized Powder for Pediatric Patients Weighing 3 kg to Less than 40 kg

<table>
<thead>
<tr>
<th>Infusion Volume</th>
<th>Infusion Time</th>
<th>Rate of Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 mL</td>
<td>30 min</td>
<td>3.33 mL/min</td>
</tr>
<tr>
<td></td>
<td>60 min</td>
<td>1.67 mL/min</td>
</tr>
<tr>
<td></td>
<td>120 min</td>
<td>0.83 mL/min</td>
</tr>
<tr>
<td>50 mL</td>
<td>30 min</td>
<td>1.67 mL/min</td>
</tr>
<tr>
<td></td>
<td>60 min</td>
<td>0.83 mL/min</td>
</tr>
<tr>
<td></td>
<td>120 min</td>
<td>0.42 mL/min</td>
</tr>
<tr>
<td>25 mL</td>
<td>30 min</td>
<td>0.83 mL/min</td>
</tr>
<tr>
<td></td>
<td>60 min</td>
<td>0.42 mL/min</td>
</tr>
<tr>
<td></td>
<td>120 min</td>
<td>0.21 mL/min</td>
</tr>
<tr>
<td>7 mL</td>
<td>30 min</td>
<td>0.23 mL/min</td>
</tr>
<tr>
<td></td>
<td>60 min</td>
<td>0.12 mL/min</td>
</tr>
<tr>
<td></td>
<td>120 min</td>
<td>0.06 mL/min</td>
</tr>
</tbody>
</table>

1 See section 2.6 of [Veklury (remdesivir) Prescribing Information](https://www.gilead.com/-/media/files/pdfs/medicines/COVID-19/veklury/veklury_pi.pdf)
Operational Considerations for Outpatient Veklury Administration

• Infusion schedule and hours of operation:
  ▪ Infusion requires 3 consecutive days of administration
  ▪ Infusion sites need to have appropriate hours of operation to accommodate complete infusion cycle

• Pediatric-specific infusion:
  ▪ Providers credentialed in pediatrics
  ▪ Staff trained in assessment and management of pediatric patients

• Capacity for lab testing, liver function, and prothrombin time as clinically appropriate
Post-Veklury Administration Observation

• Per Veklury prescribing information, “Monitor patients during dose administration and observe for at least 1 hour after intravenous infusion or subcutaneous dosing is complete”.

• Provide education on follow-up, required isolation per CDC guidelines after COVID-19 exposure or diagnosis, red flags for seeking emergency care.

• Respond to severe adverse events/anaphylaxis.

• “Discharge” patient after one-hour post-administration observation if stable and without symptoms of severe adverse reaction, otherwise consider further observation or emergency department evaluation if clinical concern.

• To report SUSPECTED ADVERSE REACTIONS, contact Gilead Sciences, Inc. at 1-800-GILEAD-5 or FDA at 1-800-FDA-1088 or MedWatch (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program)

Managing Adverse Reactions to Veklury

• **Veklury should only be administered** in settings in which health care providers have immediate access to medications (e.g., epinephrine) to treat a severe infusion or hypersensitivity reactions, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

• Early identification of anaphylaxis. Symptoms may include:
  - Respiratory: hypoxia, dyspnea, wheezing, angioedema
  - Gastrointestinal: nausea, transaminase elevation
  - Cardiovascular: hypotension, hypertension, tachycardia, bradycardia
  - Skin/mucosal: rash
  - Neurologic: agitation, convulsions, altered mental status, sense of impending doom
  - Other: diaphoresis, shivering, fever
Managing Adverse Reactions to Infused Outpatient COVID Therapeutics: Medications and Equipment

- **Should be available** at all sites:
  - Epinephrine (e.g., prefilled syringe or autoinjector)
  - H1 antihistamine (e.g., diphenhydramine, cetirizine)
  - Blood pressure monitor

- **If feasible**, include at sites (not required):
  - Pulse Oximeter
  - Oxygen
  - Bronchodilator (e.g., albuterol)
  - H2 antihistamine (e.g., famotidine, cimetidine)
  - Intravenous fluids
  - Intubation kit
  - Pocket mask with one-way valve (CPR mask) sized for adults and children

Adapted from [CDC Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccine Sites](https://www.cdc.gov/vaccines/covid-19/downloads/IntermConsid-Anaphylaxis-covid19-vaccine-sites.pdf)
Veklury Storage and Preparation

Administration preparation process:
- Prepare sterile infusions in a manner consistent with local laws, regulations, guidelines and policies
- Obtain new vial(s) and/or IV bags if the drug product contains any visible particulate matter
- See Prescribing Information for reconstitution instructions

Needs for space to prepare infusion:
- Dedicated preparation area for sterile preparation

Acceptable equipment for Veklury drug storage:
- Refrigerated storage (2-8 °C)
- Temperature control mechanism including temperature monitoring process

Note: product can be prepared for infusion bedside by any qualified medical professional

Official Veklury Website https://www.vekluryhcp.com/dosing-and-admin/
Veklury (remdesivir): Product Information

• FDA Approved for certain COVID19 indications, outpatient and inpatient
• Procurement/Ordering:
  ▪ Commercially available through Gilead Pharmaceuticals https://www.gilead.com/remdesivir
  ▪ Veklury is available through multiple distributors.
    o Outpatient distribution: Amerisource Bergen and Cardinal
      - Non-hospital entities that can attest to the proper administration of Veklury in accordance with the label can order Veklury for outpatient use.
    o Inpatient hospital distribution: Hospitals should continue ordering Veklury through AmerisourceBergen Specialty Division, Cardinal Specialty, and McKesson Plasma & Biologics.
  ▪ Treatment Locator Tool include outpatients Veklury (remdesivir) providers that allows visibility of Veklury outpatient infusion sites on the -Treatments Locator (hhs.gov) to assist in matching patients at high risk of severe COVID-19 to the medications that can prevent disease progression
    Treatments Locator (hhs.gov) https://treatments.hhs.gov/  
    • Infusion sites can opt in using this simple online form. All that is needed from provider is location information and agreement to participate) https://hpop.hhs.gov/ords/r/ohrr/voluntary
      ▪ For provider sites that want to be removed from the locator, follow the opt in link, fill out the form and select to opt out before re-submitting. In order to opt out, please ensure you use the EXACT information previously used when provider opted in.
        HPoP Voluntary Reporting (hhs.gov) https://hpop.hhs.gov/ords/r/ohrr/voluntary
    • Sites are encouraged to offer outpatient Veklury, especially in collaboration with tertiary centers treating immunocompromised patients for whom Paxlovid may not be clinically appropriate (e.g., transplant centers, oncology, etc.) and for vulnerable pediatric patients not eligible for other outpatient treatments.
# Example of Patient Flow for Outpatient Intravenous Product

## Pre-treatment

- Confirm diagnosis of COVID-19 infection
- Discuss treatment with patient
  - Ensure patient meets treatment requirements and understands risks
- Schedule the patient to come in for treatment ASAP (3 consecutive days for Veklury)
  - Provide guidance on site visit protocols to patients
  - Provide patient education on what to expect with administration

**Pre-treatment steps should be completed via telemedicine as possible (~30 mins)**

## Treatment

- Pre-book time for administration space and follow clear protocol for coming onsite
  - Ensure operationally ready to receive and treat the patient
  - Use CDC recommended practices to minimize exposure to others
- Provide treatment to patient
  - Infusion duration up to ~1 hr\(^1\) with an additional 1 hr of observation post infusion (checks during infusion and observation)
  - Infusion pumps or gravity-based infusion acceptable
- Ensure preparation for administration reactions as unlikely but possible side effect
  - Infusion rate may be reduced based on patient circumstances
  - Ensure emergency action plan in place; ability to activate EMS if necessary, a requirement for administration under EUA

\(^1\)Contingent on product dilution, reference EUA fact sheet or prescribing information for dilution and infusion timing

## Post-treatment

- Discharge patient immediately following monitoring completion
  - Follow clear protocol to minimize risk of exposure to others
  - Schedule subsequent appointments for Veklury and ensure patient understands importance of completing medication course
- Post-treatment care encouraged to be via telemedicine as possible
  - Normal follow-up care, no special data tracking requirements
Products for Treatment of Mild-to-Moderate COVID-19: Alternative Therapies
Lagevrio (molnupiravir) – Merck Oral Antiviral (Alternative)

Lagevrio (molnupiravir) Product Information
https://www.molnupiravir-us.com/
Lagevrio (molnupiravir) Product Information

• FDA Fact Sheets
  ▪ Lagevrio (molnupiravir) provider fact sheet
    https://www.fda.gov/media/155054/download
  ▪ Lagevrio (molnupiravir) patient fact sheet
    https://www.fda.gov/media/155055/download
  ▪ Lagevrio (molnupiravir) patient fact sheet (Spanish): N/A

• Manufacturer’s Resources:
  ▪ Website for Healthcare Providers
    https://www.molnupiravir-us.com/hcp/
  ▪ Website for Patients
    https://www.molnupiravir-us.com/patients/

• Safety Reporting:
  ▪ DHCP Letter
    https://www.fda.gov/media/165071/download
  ▪ Report a Pregnancy Exposure
    https://covid-pr.pregistry.com
  ▪ FDA MedWatch
    https://www.accessdata.fda.gov/scripts/medwatch/index.cfm
  ▪ Safety Reporting Email
    dpoc.usa@msd.com
Lagevrio (molnupiravir) Authorization

• Lagevrio (molnupiravir) has been authorized by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults who are at high-risk for progression to severe COVID-19, including hospitalization or death, for whom alternative COVID-19 outpatient treatment options approved or authorized by FDA are not accessible or clinically appropriate.

• Not authorized for:
  ▪ Patients less than 18 years of age
  ▪ Initiation of treatment in patients requiring hospitalization due to COVID-19
  ▪ Use longer than 5 consecutive days

• Lagevrio (molnupiravir) may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which Lagevrio (molnupiravir) belongs (i.e., anti-infectives).

Fact Sheet for Healthcare Providers for Lagevrio (molnupiravir) https://www.fda.gov/media/155054/download
Dosage and Administration

- **800 mg** (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food.
- Take Lagevrio (molnupiravir) as soon as possible after a diagnosis of COVID-19 has been made, and within 5 days of symptom onset.
- Not authorized for use for longer than 5 consecutive days.
- For administration via nasogastric (NG) or orogastric (OG) Tube (12F or larger), refer to instructions within the EUA Fact Sheet, Section 2.3

Contraindications and Precautions

- No contraindications have been identified based on the limited available data on the emergency use of Lagevrio (molnupiravir) authorized under the EUA.
- Not recommended for use during pregnancy and not authorized for use in patients under 18 years of age.
- Hypersensitivity reactions, including anaphylaxis have been reported with Lagevrio (molnupiravir).
- If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue Lagevrio (molnupiravir).

Fact Sheet for Healthcare Providers for Lagevrio (molnupiravir) https://www.fda.gov/media/155054/download
Lagevrio (molnupiravir) Checklist Tool for Prescribers

**Patient Eligibility**

- Current diagnosis of mild to moderate COVID-19
- Age ≥ 18 years
- Alternate COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate
- High-risk\(^1\) criteria met
- Symptom onset within **5 days**\(^*\)
- Not hospitalized due to COVID-19

\(^*\)Prescriber is encouraged to include a note to the pharmacist in the prescription stating:

Please fill prescription by [insert date]. This prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.


Molnupiravir Checklist Tool for Prescribers: https://www.fda.gov/media/155118/download
Prescriber Requirements – All Patients

• Provide electronic or hard copy of patient fact sheet

• Document* that patient has received an electronic or hard copy of the patient fact sheet

• Review the information contained within the patient factsheet with the patient and counsel patient on the known and potential benefits and risks of Lagevrio (molnupiravir)

• Advise patients on need for contraception use as appropriate
  • Females of childbearing potential treated: 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 (molnupiravir)
  • Males of reproductive potential treated: if 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

• The prescribing healthcare provider and/or the provider’s designee must report all medication errors and serious adverse events potentially related to Lagevrio (molnupiravir) within 7 calendar days from the healthcare provider’s awareness of the event

*How and where documentation occurs is at the discretion of the prescribing health care provider and their clinical site.

Molnupiravir Checklist Tool for Prescribers: https://www.fda.gov/media/155118/download
Prescriber Requirements – Individuals of Childbearing Potential

• Assess whether pregnant or not
  • Report of LMP in an individual who has regular menstrual cycles, uses a reliable method of contraception correctly and consistently or has had a negative pregnancy test
  • Negative pregnancy test (recommended but not required if other criteria are not met)
• If pregnant:
  • Counsel the patient regarding the known and potential benefits and potential risks of molnupiravir use during pregnancy
    • Document that the patient is aware of the known and potential benefits and potential risks of molnupiravir use during pregnancy
    • Make the individual aware of the pregnancy registry or 1-800-616-3791 https://covid-pr.pregistry.com/
• If not pregnant:
  • Make the individual aware of the pregnancy registry program and encourage them to participate should they become pregnant

Molnupiravir Checklist Tool for Prescribers: https://www.fda.gov/media/155118/download
Viral RNA Rebound

- Viral RNA Rebound Post-treatment increases in SARS-CoV-2 RNA shedding levels (i.e., viral RNA rebound) in nasopharyngeal samples were observed on Day 10, Day 15, and/or Day 29 in a subset of Lagevrio and placebo recipients in the Phase 3 MOVe-OUT trial. **Approximately 1% of both Lagevrio and placebo recipients had evidence of recurrent COVID-19 symptoms coinciding with a rebound in viral RNA levels in nasopharyngeal samples.**

- Post-treatment viral RNA rebound **was not associated with the primary clinical outcome of hospitalization or death** through Day 29 following the single 5-day course of Lagevrio treatment. Post-treatment viral RNA rebound also **was not associated with the detection of cell culture infectious virus** in nasopharyngeal swab samples.

- Viral RNA rebound is not specific to Lagevrio or Paxlovid and has been seen in placebo recipients.  

  ***Not exclusive to Lagevrio***

Lagevrio (molnupiravir):
Product Information & Ordering Logistics

- **EUA Status:** Currently under Emergency Use Authorization
- **Procurement:** USG purchased and commercially available
- **Eligibility information:**
  - [ASPR Lagevrio page](https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Lagevrio/Pages/default.aspx)
  - [Frequently Asked Questions: FDA EUA for Lagevrio (FDA)](https://www.fda.gov/media/155056/download)
- **To order:**
  - [Process for Ordering COVID-19 Therapeutics | HHS/ASPR](https://aspr.hhs.gov/HPOP/Pages/default.aspx)
- **Where to find:**
  - [Treatments Locator (hhs.gov)](https://treatments.hhs.gov/)
Module 3: Oral Antiviral Administration
Patient Flow for Antiviral Oral Therapies
(When product not available onsite)

Assessment and Prescribing

- Confirm diagnosis of COVID-19 infection
- Discuss treatment with patient
  - Ensure patient meets treatment requirements and understands risks
- Prescribe therapy for patient & provide the medication fact sheet
  (for product under EUA)

Visit Discharge

- Prescription provided to the patient
  - Ensure patient understands medication therapy being provided
  - Ensure medication therapy being dispensed complies with federal/state dispensing laws
- Discuss treatment with patient
  - Ensure patient meets treatment requirements and understands risks
- Prescribe therapy for patient & provide the medication fact sheet
  (for product under EUA)
  - Document required patient assessment in medical record
  - Provide patient education on medication therapy being prescribed
- Determine locations medication is available in local area.

Post-visit

- Pharmacist receives or prescribes patient prescription
  - Pharmacy should prioritize the prescription fill and ensure timely turnaround to support same day start for therapy
  - Pharmacist verifies prescription is appropriate for patient. Any concerns are clarified with prescribing provider
- Pharmacy staff dispenses product to the patient
  - Patient is counseled on medication therapy and reminded to start immediately
- Patient to begin prescribed therapy immediately and continue x 5 days
- Patient to report any adverse effect to FDA MedWatch
  - Patients that present for hospital visit may continue their prescribed antiviral during hospitalization (at discretion of provider)

Treatments Locator (hhs.gov) https://treatments.hhs.gov/
Test to Treat: About the Program

• Overall goal of Test to Treat program is to increase access to COVID-19 oral therapeutics, particularly for individuals who don’t have ready access to a health care provider.

• Sites with Test to Treat services give patients the option to get tested, get assessed by a healthcare provider, and receive treatment – all in one visit.

• COVID-19 treatments delivered as part of Test to Treat Program (Paxlovid and Lagevrio) must be taken within 5 days of initial COVID-19 symptoms.

• Helps close gap between positive COVID-19 test and receiving treatment for those eligible.

• An individual’s healthcare providers remain the first option for care; Test to Treat sites are one additional access point.

• Find Test to Treat locations on the Treatments Locator http://treatments.hhs.gov/
The Treatments Locator displays pharmacies, clinics, and other locations with safe and effective COVID-19 medications.

Users can find locations offering Test to Treat, telehealth, home delivery, and testing services for eligible patients.

Locations participating in the U.S. Government Patient Assistance Program operated by Pfizer offering free Paxlovid for eligible patients are included on this website. [https://paxlovid.iassist.com/](https://paxlovid.iassist.com/)

For questions regarding this site, contact 1-800-232-0233 (TTY 888-720-7489).
Module 4: Facilitating Patient Access
Access to OAVs

- Pharmacy partners are encouraged to **order commercial product to ensure that there is adequate supply to meet demand for oral antivirals**
  - There should be no gap between depletion of USG-distributed product and commercial product
- Anyone facing difficulty in access at the pharmacy counter should be directed to the patient assistance programs available to support access to [Paxlovid (PAXCESS)](https://www.paxlovid.com/paxcess) and [Lagevrio (Merck Helps)](https://www.merckhelps.com/LAGEVRIO)
- Through the Paxlovid PAP operated by Pfizer, individuals covered under federal programs, such as Medicare or Medicaid, and uninsured patients have a free access option to Paxlovid through 2024. Eligible uninsured and uninsured have a free access option beyond 2024
- Commercially insured can access the co-pay savings program
- **Medical professionals, pharmacy and plan partners should take steps to ensure patients understand the full range of options**
  - **Guide patients to enroll** – to ensure little to no cost for patient, encourage enrollment/awareness at every opportunity (eg, prior to pharmacy engagement)
Continued Access to Paxlovid

• Medicare, Medicaid, and uninsured patients will continue to receive Paxlovid at no charge through December 2024 using the USG Patient Assistance Program (USG PAP) operated by Pfizer
  ▪ Includes all patients publicly insured through Medicare (with or without Part D, Part B, or Part C and inclusive of Medicare Advantage), Medicaid/CHIP, TRICARE, and patients insured through the VA Community Care Network
  ▪ Uses USG-procured supply (commercial, NDA-labeled)

• Separately, federal entities (HRSA, IHS, VA, DoD, others) will have continued access to USG-procured Paxlovid supply for their patients, similar to how they have accessed Paxlovid to date

• USG-procured Paxlovid may also be used to support state, local, tribal, or territorial special programs targeting vulnerable populations on a case-by-case basis
  ▪ Reach out to your ASPR regional staff by email covid19.therapeutics@hhs.gov

• Concurrently, Pfizer is operating a Paxlovid Co-Pay Savings Program for eligible privately (commercially) insured patients https://www.paxlovid.com/enroll-in-co-pay-program
Continued Access to Lagevrio

- The Merck Patient Assistance Program (a 501c3 non-profit organization) provides Lagevrio free of charge to patients who meet its eligibility criteria and who, without assistance, could not otherwise afford the product. https://merckhelps.com/LAGEVRIO
  - This product is **ONLY available through an URGENT NEED request**. Your Health Care Provider must call 800-727-5400 and tell the program representative that they are making an Urgent Need Request for LAGEVRIO. The program representative will provide necessary instructions. Your Health Care Provider must follow the program representative's instructions to make your request. You may also check your eligibility on MerckHelps. https://merckhelps.com/LAGEVRIO

- In addition, USG-procured Lagevrio will continue to be distributed to certain federal entities, including HRSA-supported health centers, Indian Health Service, and others until USG supply is depleted.
Module 5:
Reimbursement
• Oral antivirals for COVID-19 that meet the statutory requirements at section 1860D-2(e) of the Social Security Act and are not otherwise excluded from coverage must be covered by Part D plans, either as a formulary product or through the formulary exception process consistent with 42 CFR § 423.578(b).

• Consistent with the November 4, 2022, memorandum CMS continues to encourage Part D sponsors to add at least one oral antiviral for COVID-19 that meets the definition of a Part D drug to their Contract Year (CY) 2024 formulary on a preferred or $0 cost-sharing tier, as available in the plan benefit structure.

CMS Commercial COVID-19 oral antivirals memo
CMS Resources: Veklury Billing

- CMS created HCPCS (Healthcare Common Procedure Coding System) code J0248 for Veklury
  - J0248 represents 1mg, and you should report units to reflect the dosage you administered for each patient.

- Outpatient Billing Example: a provider administering Veklury (remdesivir) in the outpatient setting would bill J0248 for the product and could use the following CPT code for its administration:

- 96365 (Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour)
  - and if needed use: 96366 (Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure).

- Medicare Part B will provide payment for the drug and its administration under the applicable Medicare Part B payment policy when you provide it in the outpatient setting, according to the FDA approval and authorization. In most cases, your patient’s yearly Part B deductible and 20% co-insurance apply.

CMS Resources

CMS Resources:

- **CMS COVID-19 Monoclonal Antibodies** [https://www.cms.gov/monoclonal](https://www.cms.gov/monoclonal)
- **CMS COVID-19 toolkits** [https://www.cms.gov/covidvax](https://www.cms.gov/covidvax)
- **Guidance for the Expiration of the COVID-19 Public Health Emergency (PHE)**
- **Oral Antiviral NDC Numbers:**
  - Reduced Dose (Renal) Paxlovid: 0069-1101-20
  - Lagevrio (molnupiravir): 0006-5055-06, 0006-5055-07
- **Veklury (remdesivir) NDC Numbers:** 61958-2901-2 (lyophilized power for injection), 61958-2902-2 (aqueous-based solution for injection)

*Continue to check CMS website for most up to date information (www.CMS.gov)*
Module 6:
Product Returns
Inventory and Disposal Management for Transition to Traditional Commercial Distribution

**Lagevrio**
- USG-distributed supply should be dispensed to patients until depletion or expiration, whichever comes first
- USG-distributed supply cannot be returned/disposed of unless expired (first expiry February 2024, [ASPR searchable expiry database](https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/Product-Expiry.aspx))
- Once expired, should be disposed of through manufacturer’s return process or on site in accordance with all federal, state, and local regulations

**Paxlovid**
- Unexpired USG-distributed supply can be dispensed to patients while provider obtains commercial supply
- Providers with excess USG-distributed, EUA-labeled Paxlovid are encouraged to return product through the Pfizer returns process to facilitate a credit to USG. All returns should be initiated by mid February 2024, to ensure the product is received by February 29, 2024
- Any expired product (Pfizer's [searchable expiry database](https://www.paxlovidlotexpiry.com/)), should be disposed of through manufacturer’s return process or on site in accordance with all federal, state, and local regulations

**COVID-19 Therapeutics Transition Guide**
https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/COVID19-Tx-Transition-Guide.aspx
Data Reporting Requirements

In accordance with the COVID-19 Therapeutics Provider Agreement, providers are responsible for adhering to all requirements outlined in the agreement while dispensing USG-distributed product.

• Providers are expected to provide reporting of all USG-distributed courses that they received and should report inventory, administration/dispensing, and disposal data until the provider’s USG product inventory is fully reconciled.

• USG supply used to support the Paxlovid USG PAP program is not subject to provider agreement reporting requirements.

Learn more in the COVID-19 Therapeutics Transition Guide
https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/COVID19-Tx-Transition-Guide.aspx
Guidelines for Product Return/Disposal

- All USG distributed COVID19 Therapeutics are property of USG and must be used in accordance with the EUA.
- Sites of care cannot donate products to entities outside the U.S. or for use outside the U.S.
- After checking for true expiration date online, dispose of any expired product.
- Non-expired product not currently authorized for use is eligible for disposal or returns to the manufacturer if no longer able to be stored.
- No returns or disposal of non-expired product currently in distribution by the USG.

- Jurisdictions can transfer product to other jurisdictions/states/territories
- Doses of USG-product discarded on site and doses returned need to be recorded in HPOP
- If undamaged product needs to be disposed of, destroy it on-site in accordance with the HPOP attestation, or follow the returns instructions below:
  - Updated: For Paxlovid, visit Inmar or contact PaxlovidEUAreturns@inmar.com, 800-967-6148 http://www.paxlovideuareturns.com/
  - Updated: For Lagevrio select “Return Merchandise” or call the Merck Order Management Center at 800-MERCK-RX (800-637-2579). http://www.merckorders.com/
  - For bam and bam/ete, see The Lilly Return Goods Procedure for detailed guidance. Bebtelovimab returns are not being accepted. https://www.lillytrade.com/
  - For REGEN-COV, call 844-734-6643
  - For sotrovimab, see the GSK Returns Goods Policy http://www.gsk-ecs.com/
  - Visit Evusheld or call 1-833-EVUSHLD https://www.evusheld.com/
On Site Destruction of Expired or Unauthorized Product

• For licensed provider locations with destruction procedures in place that follow all federal, state, and local regulations, therapeutics can be destroyed on site only if:
  ▪ Guidelines are followed on what product can be destroyed
    • Only expired product or unauthorized product that can no longer be stored
    • No unexpired product that is currently authorized for use can be destroyed
  ▪ Sites are to follow established protocols for destruction and attest in HPOP to following all regulations
  ▪ Quantities of any product destroyed is recorded in HPOP

• The established returns process for each product is still an option for sites who do not have an established method for proper destruction or otherwise prefer to go through the returns process
  ▪ Returned product must also be recorded in HPOP
  ▪ This process has been enabled in HPOP
Module 7: Additional Resources
COVID-19 Vaccination after mAb Administration

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the US

• Non-hospitalized COVID-19 patients who previously received passive antibody therapy
  ▪ There is no longer any need to delay vaccination following receipt of monoclonal antibody or convalescent plasma beyond recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

• Hospitalized COVID-19 patients
  ▪ Follow guidelines from CDC Advisory Committee on Immunization Practices
    https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination
For sotrovimab, bam/ete, REGEN-COV, bebtelovimab, Evusheld

**HPOP**

Reporting required

- **once a month** by 11:59 pm ET on the last day of the month

**For Paxlovid and Lagevrio**

**HPOP**

Reporting required

- **at least twice a month** by 11:59 pm ET on the 15th and last day of the month

- Reporting stock on hand is the minimal requirement if a therapeutic has not been administered, transferred, or wasted within the reporting period

- Please ensure accurate reporting, including when there is a significant change to stock on hand, e.g., if a specific lot of therapeutics expires and is wasted

Sites with inventory of USG-purchased COVID-19 therapeutics must provide information on product utilization, wastage, returns, and stock on hand
Opting in to the Treatments Locator

• USG has developed a mechanism for providers to report commercial treatment locations voluntarily that will be visible in an expanded treatments locator tool.
  - As of November 27, sites could voluntarily upload commercially acquired inventory data for Paxlovid, Lagevrio, and outpatient Veklury via HPOP.
  - HPOP users can leverage their existing accounts to report, while non-HPOP users can report using the HPOP volunteer reporting website. https://hpop.hhs.gov/voluntary
  - If a site opts in, that site will become publicly visible on the Treatments Locator. https://treatments.hhs.gov/
  - We encourage sites to report commercial therapeutics as often as possible; reporting commercially distributed therapeutics at least every 14 days is requested to ensure the locator remains accurate.
  - After 60 days, sites will fall off the locator until commercial inventory is reported again.
  - Separately, USG-distributed product should continue to be entered in the appropriate HPOP reporting fields.

Learn more in the COVID-19 Therapeutics Transition Guide
https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/COVID19-Tx-Transition-Guide.aspx
Voluntary Reporting of Commercial Therapeutics

- HPOP users can use HPOP for voluntary reporting.
- Non-HPOP users can use the HPOP Volunteer Reporting website to voluntarily report availability of commercial therapeutics. https://hpop.hhs.gov/voluntary
COVID-19 Therapeutic Resources

• Administration for Strategic Preparedness and Response
  https://ASPR.HHS.gov

• For the latest information on all COVID-19 therapeutics, refer to:
  ▪ *ASPR’s COVID-19 Therapeutics Resources* https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/default.aspx

• Still have questions? Reach out to *HHS COVID 19 Therapeutics Email*
covid19therapeutics@hhs.gov
Module 8: Appendices
Appendix A: Outpatient Infusion Site Resources
Sample Staffing Models for Parenteral Therapeutic Administration

Examples of staff plans *(recommended positions may vary depending on the State’s scope of practice for Paramedics as it related to Subcutaneous and or Intravenous administration of medications)*

- **8 - 10 bed infusion/observation site**
  - 1 physician / advanced practitioner (present or available via telemedicine)
  - 2 Nurses
  - 1 Nurse or Paramedic
  - 2 Paramedics
  - 1 flex position – administrative/ logistics/ runner

- **Single station or mobile visit Subcutaneous administration site**
  - 1 physician / advanced practitioner (present or available via telemedicine)
  - 1 Nurse / Paramedic per single mobile visit or single station

Average patient (door to door) visit can range from 80-120 minutes
# Infused Outpatient Therapeutics Site Suggested Supplies

## Infrastructure
- Seating area with appropriate spacing for patients to receive infusion
- Steel table for product preparation
- Privacy screens if needed
- Protocol/outline for patient flow (written protocol not required however patient flow and infection control should be addressed at each administration site)
- Emergency response plan (written plan not required, however all staff should be aware of the plan for emergency response)

## General supplies
- Infusion Reaction Kit
- Refrigerator
  - Optional to store prepared solution onsite
- Sharps container
- Biohazard disposal bag
- Trash bins and liners
- Disposable disinfecting wipes
- Hand sanitizer
- Thermometer probe covers (if required)
- 70% alcohol wipes
- Paper towels

## PPE
- NIOSH-certified, disposable N95 filter facepiece respirators or better
- Gloves in appropriate sizes
- Gowns
- Surgical face masks for patients
- Eye and face protection (e.g., goggles, safety glasses, face shields)

## Patient Intake
- Vital signs machine
- Pulse oximeter
- Thermometer
- Copies of eligibility checklist for treatment/PEP

## Administrative
- Site-specific documentation
- Patient fact sheets to provide each patient (copies in English, Spanish and other appropriate languages)

## Administration Supplies-Subcutaneous
- Alcohol wipes
- 3 or 5 mL luer lock syringes (4 required for each patient for subcutaneous administration)
- Appropriate needles for product preparation and subcutaneous administration
  - 21-gauge 1.5-inch needles for product transfer
  - 25- or 27-gauge needles for subcutaneous administration (4 per each patient course)

## Administration Supplies-Intravenous
- IV poles
- Alcohol wipes
- 2x2 gauze pads
- Adhesive bandages
- Medical tape
- Tegaderm bio-occlusive dressing
- Absorbent underpads (blue pads)
- Normal saline bags for mixing/administration- 50-250 mL
- IV administration sets:
  - For monoclonal antibody infusion: PVC infusion set with/without DEHP containing 0.2- or 0.22-micron polyethersulfone (PES) in-line filter
  - IV catheters
  - IV extension set tubing
  - 3mL saline syringes
  - Needles – stainless steel 18ga
  - Optional: Transilluminator (vein finder)
Site Preparation for Infused Outpatient COVID-19 Therapeutic Administration

• Collect administration site location(s), address, and points of contact
  ▪ For mobile or deployed teams, identify the point of contact at the administration site and make contact
  ▪ Site will need dedicated space for isolation of COVID-19 patients
  ▪ Rededication of existing clinical space is permitted under the CMS Hospital Without Walls Initiative

• Ensure a patient scheduling and referral process is in place
• Identify and understand which therapeutics will be administered
• Determine who is responsible for ordering infused therapeutic administration
  ▪ Referring provider
  ▪ On-site or telemedicine provider
  ▪ Standing order

• Brief administration team with site objectives
• Team training
  ▪ Site workflow
  ▪ Therapeutic Administration
  ▪ Managing adverse reactions with rescue medications on site as applicable

Appendix B: COVID-19 Convalescent Plasma
COVID-19 Convalescent Plasma EUA¹

• Eligibility Criteria
  ▪ The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies, for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment, in either the outpatient or inpatient setting.

• Not authorized for
  ▪ Treatment of immunocompetent patients with COVID-19 infection

• Contraindications
  ▪ Individuals with a history of severe allergic reactions or anaphylaxis to plasma transfusion

• Administration Considerations
  ▪ Administer according to standard institutional medical and nursing practices for the administration of plasma²

¹ Emergency Use Authorization of COVID-19 Convalescent Plasma https://www.fda.gov/media/141478/download
Fact Sheet for Healthcare Providers download (fda.gov) https://www.fda.gov/media/141478/download
NIH Guidelines Panel- COVID-19 Convalescent Plasma

• There is insufficient evidence for the Panel to recommend either for or against the use of high-titer CCP for the treatment of COVID-19 in hospitalized or nonhospitalized patients who are **immunocompromised**
  • Some panel members would use CCP to treat an immunocompromised patient with significant symptoms attributable to COVID-19 and with signs of active SARS-CoV-2 replication and who is having an inadequate response to available therapies. In these cases, clinicians should attempt to obtain high-titer CCP from a vaccinated donor who recently recovered from COVID-19 likely caused by a SARS-CoV-2 variant similar to the variant causing the patient’s illness

• There is insufficient evidence for the Panel to recommend either for or against the use of high-titer CCP for the treatment of COVID-19 in nonhospitalized patients who are **immunocompetent**

• The panel recommends **against** the use of CCP for the treatment of COVID-19 in hospitalized patients who are **immunocompetent**

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Outpatient COVID-19 Convalescent Plasma (CCP) Resources

- **Emergency Use Authorization of COVID-19 Convalescent Plasma**
  https://www.fda.gov/media/141478/download

- **Implementation of an Outpatient Covid-19 Convalescent Plasma Administration Program**

- **Early Outpatient Treatment for COVID-19 with Convalescent Plasma-NEJM**

- **New COVID-19 Treatments Add-On Payment (NCTAP) | CMS**
  - ICD-10-PCS Code: XW13325, XW14325 (Only applies to inpatient use)

- **Addendum A and Addendum B Updates | CMS**
  https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates
  - APC Code: 9540 / HCPCS Code: C9507 (Only applies to outpatient use)
Appendix C:
Formerly-Authorized Products
HHS continuously monitors emerging variants to assess their potential impacts on testing, treatments and vaccines, including susceptibility to therapeutics. There is potential for paused products to play a role in addressing future COVID-19 variants. Sites are encouraged to retain all product in the event that the below authorizations change in the future. For current variant data, refer to CDC Nowcast Projections https://covid.cdc.gov/covid-data-tracker/#variant-proportions.

### EUA Products Not Currently Authorized

<table>
<thead>
<tr>
<th>Product</th>
<th>Latest Status</th>
<th>Latest Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bebtelovimab</td>
<td>as of 30 November 2022, not authorized in any US region</td>
<td><a href="https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-30November2022.aspx">https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-30November2022.aspx</a></td>
</tr>
<tr>
<td>Sotrovimab</td>
<td>as of 05 April 2022, not authorized in any US region</td>
<td><a href="https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-5April2022.aspx">https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-5April2022.aspx</a></td>
</tr>
<tr>
<td>Bamlanivimab plus etesevimab</td>
<td>as of 14 of December 2023, EUA status revoked in US region</td>
<td><a href="https://www.fda.gov/media/174884/download?attachment">https://www.fda.gov/media/174884/download?attachment</a></td>
</tr>
</tbody>
</table>

Product Expiration Date Summary

- **Paxlovid**: First lot expiry July 31, most in field supply expiry is later
- **Lagevrio**: No lots have reached expiry, first expiry is Feb 9, 2024, last is Feb 27, 2025

<table>
<thead>
<tr>
<th>Therapeutic</th>
<th>First expiry</th>
<th>Last expiry</th>
<th>Extension</th>
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</thead>
<tbody>
<tr>
<td>Bamlanivimab¹</td>
<td>09/5/2022</td>
<td>5/22/2023</td>
<td>No further extension</td>
</tr>
<tr>
<td>Etesevimab¹</td>
<td>4/8/2022</td>
<td>5/16/2023</td>
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<tr>
<td>Regen-COV¹</td>
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</tr>
<tr>
<td>Evusheld</td>
<td>6/30/2023</td>
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<tr>
<td>Sotrovimab</td>
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<td>Extension possible</td>
</tr>
<tr>
<td>Bebtelovimab</td>
<td>7/11/2023</td>
<td>8/28/2024</td>
<td>Extension possible</td>
</tr>
</tbody>
</table>

¹All lots have expired. No expiry extension expected. Dispose of all product.

- For Paxlovid (nirmatrelvir co-packaged with ritonavir): Pfizer's [searchable expiry data](https://www.paxlovidlotexpiry.com/)
- For up-to-date information on expiration dates of all products: [ASPR searchable expiry database](https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/Product-Expiry.aspx)
Bamlanivimab and etesevimab reporting in HPOP

- Bamlanivimab and etesevimab can now be reported separately in HPOP, when needed
  - The products should be reported separately only when there is an excess of one component relative to a patient course
  - **When reporting separately**, each component should be reported **in proportion to the amount of the product previously used in a patient course**
  - In HPOP: 1 vial bam = 1 course bam ; 2 vials ete = 1 course ete
  - When remaining product is proportional to the previously used patient course, it should be reported together as bam/ete
    - In HPOP: 1 vial bam and 2 vials ete = 1 course bam/ete