



COVID-19 Therapeutics Program
Therapeutics Onboarding
Last Updated February 15, 2023

The Maryland Department of Health allocates oral antivirals to treat COVID-19 to participating entities such as pharmacies, urgent care clinics, primary care offices, and Federally Qualified Health Centers. The Federal government purchases the oral agents and sets an ordering threshold for states to order against, free of charge to the state. Currently there are two oral antivirals available under [Emergency Use Authorization](#)-- [Paxlovid](#) and [Molnupiravir](#). All are available for people with COVID-19 who have mild-to-moderate symptoms and are not hospitalized for COVID-19, and are provided free of charge to pharmacies and provider offices.

| | Paxlovid | Molnupiravir |
|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| Purpose | Preferred treatment of mild-to-moderate COVID-19 | Alternative treatment of mild-to-moderate COVID-19 when preferred methods are not feasible |
| Age/Weight Restriction | 12 years of age and older weighing more than 40kg | 18 years of age and older weighing more than 40kg |
| Required Timing | Must be given within 5 days of symptom onset | Must be given within 5 days of symptom onset |
| Storage | Store at USP controlled room temperature (20°C to 25°C (68°F to 77°F), Excursions permitted between 15°C to 30°C (59°F to 86°F) | Store at USP controlled room temperature (20°C to 25°C (68°F to 77°F), Excursions permitted between 15°C to 30°C (59°F to 86°F) |
| Prescriber restrictions | Prescribed by physicians, advanced practice registered nurses, physician assistants. Pharmacists may prescribe in limited circumstances. | Prescribed by physicians, advanced practice registered nurses, physician assistants. |
| Restrictions | Has significant drug interactions (see Appendix B); must be dosed renally (Renal Paxlovid also available as a dispensing option) | Not for use in patients less than 18 years of age, during pregnancy, or in lactating women. |

Oral Antivirals

Similar to other available therapeutics, sites may charge a dispensing fee for oral antivirals.

- [Oral Antiviral dispensing fee guidance from CMS](#)
- [COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured](#)
- [For Vaccines & Monoclonal Antibodies: Medicare Part B Payment Chart](#)

Oral Antiviral Dispensing Site Requirements

- 1) Sites must be able to offer home delivery, drive-thru, or curbside pickup services to support infection control. If in the Test to Treat program, must be able to dispense medications on site.
- 2) All sites must be able to complete twice-weekly reporting in HPOP (See Appendix A).
- 3) Enrollment in the program does not guarantee a type of product or quantity of product. State leadership will adjust levels of allocation as necessary to ensure coverage of COVID therapeutics.
- 4) Sites must be willing to transfer product to other locations as requested by the State therapeutics team.
- 5) Sites are responsible for reading all partner communication, including weekly updates and PowerPoint presentations.
- 6) Sites are responsible for submitting direct order requests to resupply (See Appendix B). If a site has an urgent need for more therapeutics, contact a member of the therapeutics team (contact at end of document).

Additional requirements for Test to Treat sites

- Must be able to offer testing, evaluation by a PA, advanced practice nurse, or Physician, and dispensing of therapeutics in the same location. Use of telehealth is appropriate.
 - Though pharmacists may prescribe antivirals in certain circumstances, these situations are more limited and MDH is seeking T2T sites that are available to all patients, not a limited subset.
- Must be able to accept new patients regardless of insurance status.
- Offer same or next day priority appointment for Test to Treat.
- Sites may bill for testing and evaluation, but may **not** charge for therapeutics themselves.
 - Sites may charge a dispensing fee to a patient's insurance, but the dispensing fee may not be passed to the patient.
- Sites must be publicly listed on Test to Treat locators linked below.

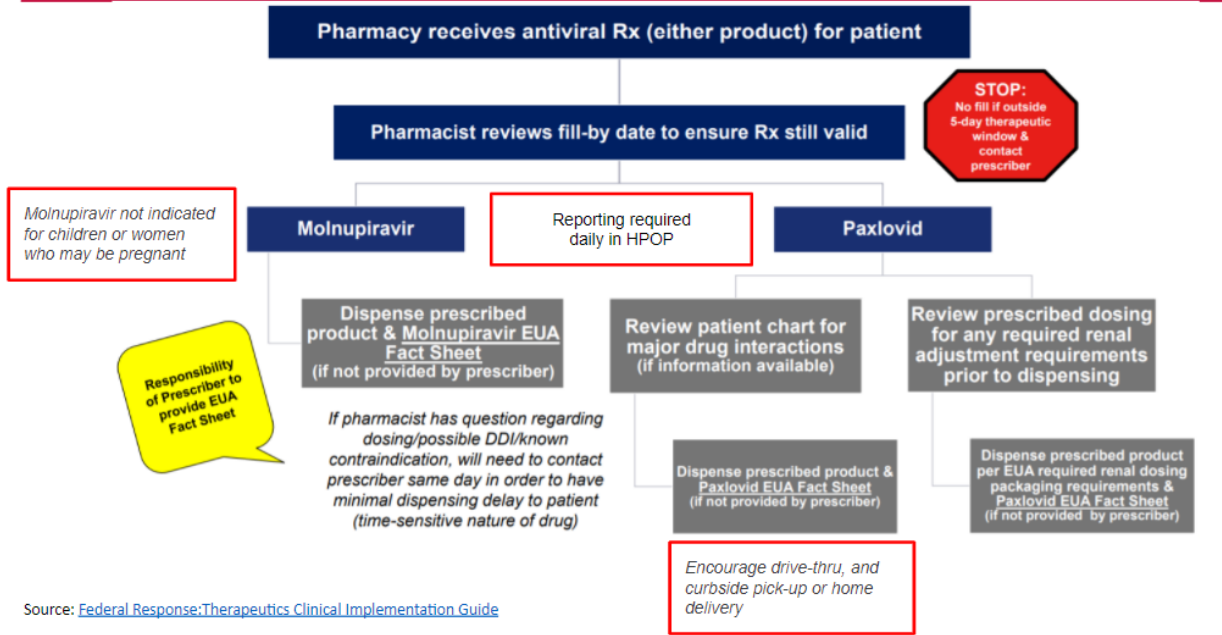
Federal Resources

- [COVID-19 Therapeutic Locator](#) (Maintained by HHS, this locator is updated based upon the information that you report in HPOP. If you do not report, you will be removed from the locator.)
- [Test to Treat Locator](#) (maintained by HHS, locator updated for Test to Treat sites only)
 - [Maryland Test to Treat Locator](#) (maintained by MDH, locator for T2T sites only)

- [Federal Response to COVID-19: Therapeutics Clinical Implementation Guide](#) (Outpatient Administration Guide for Healthcare Providers) (Slide 69)
 - Shows patient flow for oral antiviral therapies.

Oral Therapeutics

Pharmacy Journey



The typical order request processing timeline is as follows:

| | State Therapeutics Team Actions | Partner Site Actions |
|---------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Monday | <ul style="list-style-type: none"> • Receive weekly ordering threshold from Federal government | <ul style="list-style-type: none"> • HPOP Reporting (courses administered and available) • Deadline for Direct Order Requests (Monday 5PM) |
| Tuesday | <ul style="list-style-type: none"> • Assess all direct order requests | |
| Wednesday | <ul style="list-style-type: none"> • Final requests approved, adjusted, or denied in HPOP | |
| Thursday | <ul style="list-style-type: none"> • Biweekly: Host Stakeholder Call | <ul style="list-style-type: none"> • HPOP Reporting (courses administered and available) • Biweekly: Attend Stakeholder Call |
| Friday, Saturday, Sunday | <ul style="list-style-type: none"> • Product ships to sites from distributor • As needed: Provider Update Memo distributed | <ul style="list-style-type: none"> • Read any distributed memos from therapeutics team |

Program Enrollment

If your site is interested in enrolling in the therapeutics program to dispense oral antivirals, please complete the enrollment application form [at this link](#).

Submission of the form does not guarantee enrollment or supply of antivirals. **Your site must be approved by Maryland Department of Health leadership, and your account must be activated.**

If your site is approved, your site will receive two emails:

- 1) Email from HPOP about logging into the new portal that will eventually be used for viewing orders of the antivirals. This email expires after 72 hours and must be completed. The email will come from “VTrckS Provider Ordering Portal,” vpop-no-reply@cdc.gov.
- 2) Email from the Maryland therapeutics team notifying you of your enrollment.

You will be added to an email list from the Maryland Hospital Association (MHA), which will invite you to biweekly Therapeutics Stakeholder Update calls on Thursdays at 12pm. This will also be the email list where weekly distribution memos will be sent. You are responsible for reading these memos to keep up to date with program changes.

New sites typically receive their orders between 7-10 days after allocations are submitted.

MDH Therapeutics Team Contacts

Onboarding/Program Questions

Kara Stitcher (kara.stitcher@maryland.gov)

HPOP Login Assistance

For password reset, errors when logging in, etc.

HPOP.Support@hhs.gov

Appendix A: HPOP Reporting Instructions For Enrolled Partners

Reporting Courses Administered and Available

Reporting is required on Mondays and Thursdays by 11:59pm, even if no product is dispensed.

Reporting is ***cumulative since you last reported***.

Example: If you start with 20 courses and administered 1 course on Monday, and 4 courses on Tuesday, and 1 course on Wednesday, your Monday reporting would be 1 course administered and 19 available, while your Thursday reporting would be 5 courses administered and 14 available.

- 1) Log into HPOP at this link: <https://vpop.cdc.gov/provider/signin/>
- 2) Navigate to the section “Therapeutic Inventory”

The screenshot shows the 'Therapeutic Inventory' section in the HPOP system. It features three tabs: 'Courses Administered and Available' (selected), 'Wastage', and 'Transfers'. Below the tabs, there are two buttons: 'Edit History' and 'Save Therapeutic Courses'. A table with four columns is displayed: 'Therapeutic', 'Administered', 'Available', and 'History'. The table lists four therapeutics: Bebtelovimab (0002-7589-01), Evusheld (0310-7442-02), Molnupiravir [Qty 24] (0006-5055...), and Paxlovid (0069-1085-30). Below the table, an information box states: 'For Administered and Available please enter values for today and not cumulative values. Please note that some Therapeutics may not be displayed in Inventory.'

| Therapeutic | Administered | Available | History |
|--------------------------------------|--------------|-----------|---------|
| Bebtelovimab (0002-7589-01) | | | |
| Evusheld (0310-7442-02) | | | |
| Molnupiravir [Qty 24] (0006-5055...) | | | |
| Paxlovid (0069-1085-30) | | | |

For Administered and Available please enter values for today and not cumulative values.
Please note that some Therapeutics may not be displayed in Inventory.

- 3) Under “Courses Administered and Available” you will see the available products you can report for. As an example, we will report the following:
 - a) Molnupiravir: 1 course administered, 40 available
 - b) Paxlovid: 0 courses administered, 20 available
- 4) Double click on the box that you need to edit, as below

Therapeutic Inventory

Courses Administered and Available Wastage Transfers

Courses Administered and Available Edit History Save Therapeutic Courses

| Therapeutic | Administered | Available | History |
|-------------------------------------|----------------------|-----------|---------|
| Bebtelovimab (0002-7589-01) | | | |
| Evusheld (0310-7442-02) | <input type="text"/> | | |
| Molnupiravir [Qty 24] (0006-5055... | | | |
| Paxlovid (0069-1085-30) | | | |

For Administered and Available please enter values for today and not cumulative values. Please note that some Therapeutics may not be displayed in Inventory.

5) Enter in the number of courses that you administered ***since you last reported,*** and the courses that remain available for patients. It will look like this:

Therapeutic Inventory

Courses Administered and Available Wastage Transfers

Courses Administered and Available Edit History Save Therapeutic Courses

| Therapeutic | Administered | Available | History |
|-------------------------------------|--------------|-----------|---------|
| Bebtelovimab (0002-7589-01) | | | |
| Evusheld (0310-7442-02) | 2 | 18 | |
| Molnupiravir [Qty 24] (0006-5055... | | | |
| Paxlovid (0069-1085-30) | | | |

For Administered and Available please enter values for today and not cumulative values. Please note that some Therapeutics may not be displayed in Inventory.

6) Continue to edit the boxes for each product you are reporting for.

Therapeutic Inventory

Courses Administered and Available Wastage Transfers

Courses Administered and Available Edit History Save Therapeutic Courses

| Therapeutic | Administered | Available | History |
|-------------------------------------|--------------|-----------|---------|
| Bebtelovimab (0002-7589-01) | | | |
| Evusheld (0310-7442-02) | 2 | 18 | |
| Molnupiravir [Qty 24] (0006-5055... | 1 | 40 | |
| Paxlovid (0069-1085-30) | 0 | 20 | |

For Administered and Available please enter values for today and not cumulative values. Please note that some Therapeutics may not be displayed in Inventory.

7) When you're finished, click the green button "Save Therapeutic Courses"

Save Therapeutic Courses

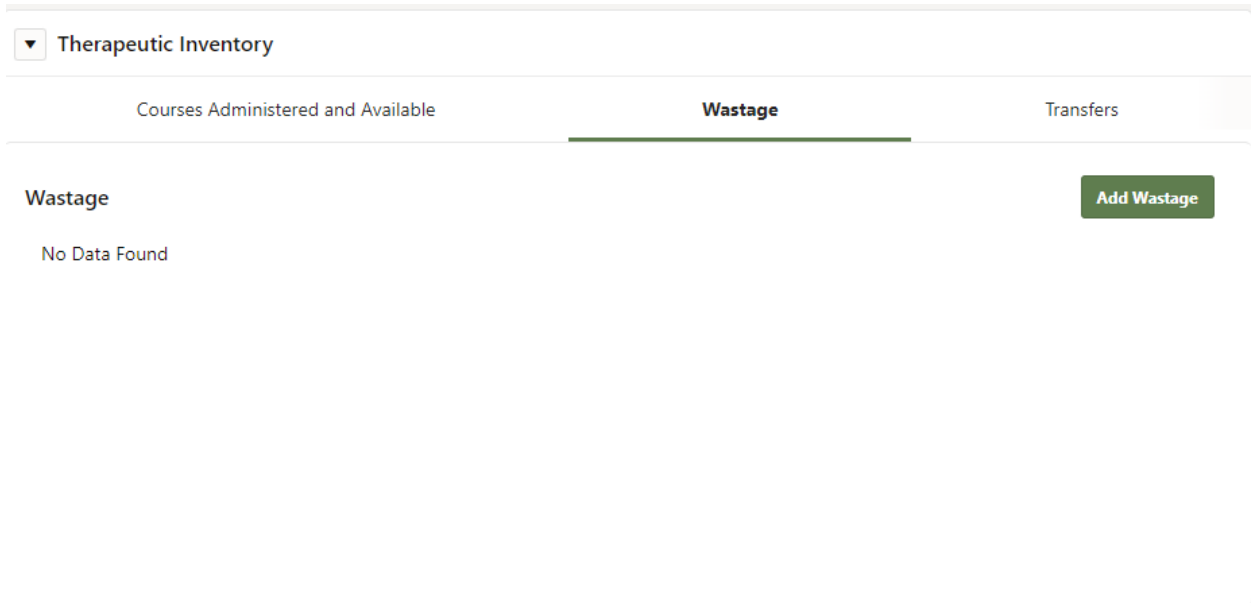
8) You're done!

Editing Past Reporting

If you entered incorrect inventory information, please select the "edit history" button and amend the entry that needs correction.

Reporting Wastage

- 1) Navigate to the “Wastage” tab under “Therapeutic Inventory”

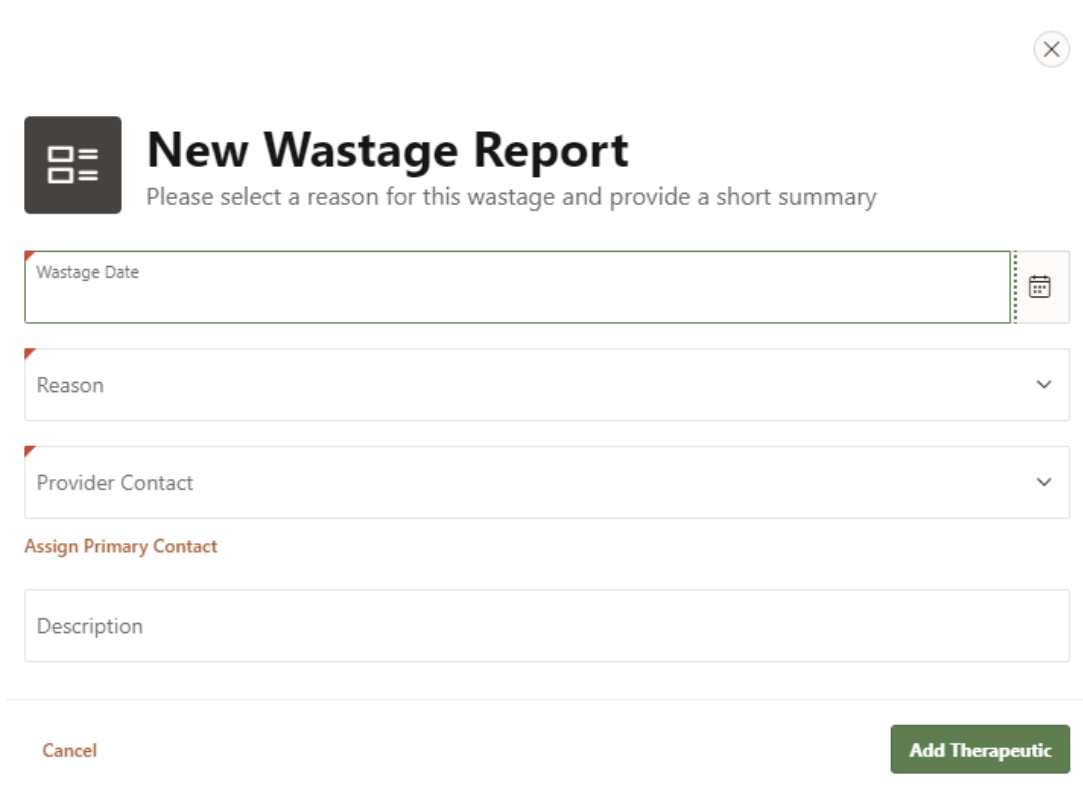


The screenshot shows a web interface for 'Therapeutic Inventory'. At the top, there is a dropdown menu set to 'Therapeutic Inventory'. Below it are three tabs: 'Courses Administered and Available', 'Wastage' (which is selected and highlighted with a green underline), and 'Transfers'. The main content area is titled 'Wastage' and contains the text 'No Data Found'. In the top right corner of this area, there is a green button labeled 'Add Wastage'.

- 2) Click “Add Wastage” button



- 3) Add your wastage report information



The screenshot shows a modal window titled 'New Wastage Report'. It has a close button (X) in the top right corner. Below the title is a sub-header with a menu icon and the text 'Please select a reason for this wastage and provide a short summary'. The form contains several input fields: 'Wastage Date' with a calendar icon, 'Reason' with a dropdown arrow, 'Provider Contact' with a dropdown arrow, and 'Description'. Below the 'Provider Contact' field is a section labeled 'Assign Primary Contact'. At the bottom left is a 'Cancel' button, and at the bottom right is a green 'Add Therapeutic' button.

- 4) Click “Add Therapeutic”



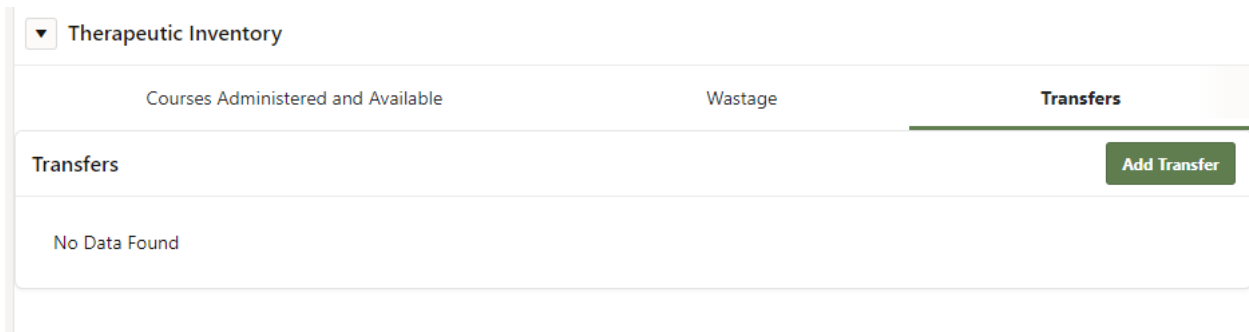
- 5) Your wastage report is submitted

Record Transfers

Transfers are from one physical location to another. Both sites must be enrolled as providers so they can continue to report. If your location would like to transfer to a location that is NOT enrolled in HPOP, they must be added before you can transfer.

The **transferring** partner should submit the transfer report. So, if Hospital A transfers to Pharmacy B, then Hospital A records the transfer.

- 1) Navigate to the “Transfer” tab under “Therapeutic Inventory”




- 2) Click “Add Transfer”




- 3) Fill out the requested information. Remember, the “Provider Transferred to” must be an existing site in HPOP to be populated.

Provider Details


Transfer Therapeutic

Transfer Date 

Provider Transferred From
INSTITUTE FOR ASTHMA and ALLERGY

Provider Transferred To 

Description

Therapeutic 

Courses

4) Click "Create" to record the transfer

Appendix B: Direct Order Request Instructions

Providers enrolled in HPOP are able to complete “direct order” in HPOP. This means that a provider can request a supply of therapeutic medication that Maryland will approve, modify, or reject. All “orders” can be thought of as “requests” because they still need Maryland Department of Health approval before they are submitted.

Program Requirements

- 1) Sites must submit orders for therapeutics no later than **5pm on Monday**. Orders will be approved, modified, or rejected by Friday of that same week. Sites should expect to receive orders the following week.
- 2) Sites must have reported within the past 7 days to be considered for approval.
- 3) Maryland Department of Health may modify or reject your request due to several factors, including but not limited to Federal supply availability, reporting history, and need to distribute products to areas with greater need.

Instructions for Submitting an Order in HPOP

- 1) Log in to HPOP at this link: <https://vpop.cdc.gov/provider/signin/>
- 2) Navigate to the section “Create new order”

The screenshot displays the Oracle HPOP - Provider Portal interface. At the top, the header includes the Oracle logo, the text "Oracle HPOP - Provider Portal", and navigation links for "Partner: HHS Validation Partner", "Gold Pharmacy", "Help", "Feedback", and a user profile for "steve.griffiths@jhuapl.edu". The main content area is titled "Gold Pharmacy : Therapeutic". Below this, there are several sections: "Therapeutic Orders" with a "Create New Order" button highlighted in a red box, "Therapeutic Inventory" with a "Save Therapeutic Course" button, and "Provider Details" with various fields for provider information. The "Therapeutic Orders" section lists several orders with their IDs, dates, and statuses (COMPLETED or DISTRIBUTED). The "Therapeutic Inventory" section shows a table with columns for "Therapeutic", "Courses Administered", "Courses Available", and "History". The "Provider Details" section includes fields for Name (Gold Pharmacy), Federal PIN, State PIN (HHS88773E), National Provider Identifier (NPI), Provider Type ([18] Pharmacy - independent), Alternative ID, Non-Public Provider (No), Modules (Vaccine, Therapeutic, Diagnostic), Therapeutic Categories (Monoclonal Antibody, Monoclonal Antibody Special, Antiviral), License (123321), and License Expiration Date (11/25/2022).

- 3) Select the therapeutic you are interested in obtaining. Please note that you can only request product for which you have **already** been approved. Select the quantity of shipping units. Each product is ordered in different increments, and cannot be customized.
- 4) Once you've saved your selected quantity, you can review your request.
 - a) You may delete your request and start again if you need to make a change.
 - b) If your site offers multiple therapeutics, you may add another therapeutic to your request.
- 5) If you're finished with your order, click the green "submit" button.
- 6) Your submitted order will appear in your "Therapeutic Orders" section, and will update as it is approved, modified, or rejected by Maryland Department of Health.

Appendix C: Paxlovid Drug-Drug Interactions (DDIs)

Paxlovid Contraindications

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hypersensitivity Reactions | <ul style="list-style-type: none">• History of clinically significant hypersensitivity reactions (e.g., TEN, SJS) to its active ingredients (nirmatrelvir or ritonavir) or any other components of the product |
| Drugs highly dependent on CYP3A4 for clearance and for which elevated concentrations are associated with severe/life-threatening reactions* | <ul style="list-style-type: none">• Alpha1-adrenoreceptor antagonists: alfuzosin• Analgesics: pethidone, piroxicam, propoxyphene• Antianginal: ranolazine• Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine• Anti-gout: colchicine• Antipsychotics: lurasidone, pimozide, clozapine• Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine• HMG-CoA reductase inhibitors: lovastatin, simvastatin• PDE5 inhibitor: sildenafil (Revatio) when used for PAH• Sedative/hypnotics: triazolam, oral midazolam |
| Drugs that are potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir concentrations may be associated with loss of virologic response or resistance* | <ul style="list-style-type: none">• Anticancer drugs: apalutamide• Anticonvulsant: carbamazepine, phenobarbital., phenytoin• Antimycobacterials: rifampin• Herbal product: St John's Wort (<i>hypericum perforatum</i>) |

*This is NOT a complete list of all DDIs. ALWAYS USE [CLINICAL TOOLS/DDI CHECKER](#) AND USE CLINICAL JUDGMENT.

For additional information see:

- [NIH COVID-19 Treatment Guidelines Panel's Statement on Paxlovid Drug-Drug Interactions](#)
- [PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers \(fda.gov\)](#)

Appendix D: Other Resources

HPOP Login Assistance (Password Reset, errors when logging in): HPOP.Support@hhs.gov

Paxlovid

- EUA: <https://www.fda.gov/media/155049/download>
- Fact Sheet for Health Care Providers: <https://www.fda.gov/media/155050/download>
- Fact Sheet for Patients: <https://www.fda.gov/media/155051/download>
- Fact Sheet for Patients (Spanish): <https://www.fda.gov/media/155075/download>
- FAQs for Paxlovid FDA EUA: <https://www.fda.gov/media/155052/download>
- [PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers \(fda.gov\)](#)

Molnupiravir

- EUA: <https://www.fda.gov/media/155053/download>
- Fact Sheet for Health Care Providers: <https://www.fda.gov/media/155054/download>
- Fact Sheet for Patients: <https://www.fda.gov/media/155055/download>
- Fact Sheet for Patients (Spanish): <https://www.fda.gov/media/155115/download>

Additional Resources

- [Side-by-Side Overview of Therapies Authorized for the Treatment of Mild-Moderate COVID-19](#)
- [Federal Response: Therapeutics Clinical Implementation Guide](#)