COVID-19 Therapeutics Program
Therapeutics Onboarding

Last Updated November 1, 2022

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. Evusheld is a long-acting monoclonal antibody for moderate to severely immunocompromised individuals available under EUA. 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**	**Evusheld**	**Bebtelovimab**
Purpose	Preferred treatment of mild-to-moderate COVID-19	Alternative treatment of mild-to-moderate COVID-19 when preferred methods are not feasible	Prevention of COVID-19 in special populations	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	12 years of age and older weighing more than 40kg	12 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	Given to individual not infected with or recently exposed to COVID-19	Must be given within 7 days of symptom onset
Storage	Store at USP controlled room temperature (20°C to 25°C (68°F to 77°F), Excursions permitted	Store at USP controlled room temperature (20°C to 25°C (68°F to 77°F), Excursions permitted between 15°C to 30°C	Store in a refrigerator 2ºC to 8ºC (36ºF to 46ºF). If immediate administration is not possible, the	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)	(59°F to 86°F)	total time from vial puncture to administration must not exceed 4 hours: in a refrigerator at 2ºC to 8ºC (36ºF to 46ºF), or o at room temperature up to 25ºC (77ºF)	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.	Prescribed by physicians, advanced practice registered nurses, physician assistants.	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.	Limited eligible patient population: moderate to severely immune compromised	Commercially available through AmerisourceBergen (cannot procure through MDH).

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

New 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 D). 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.

Evusheld

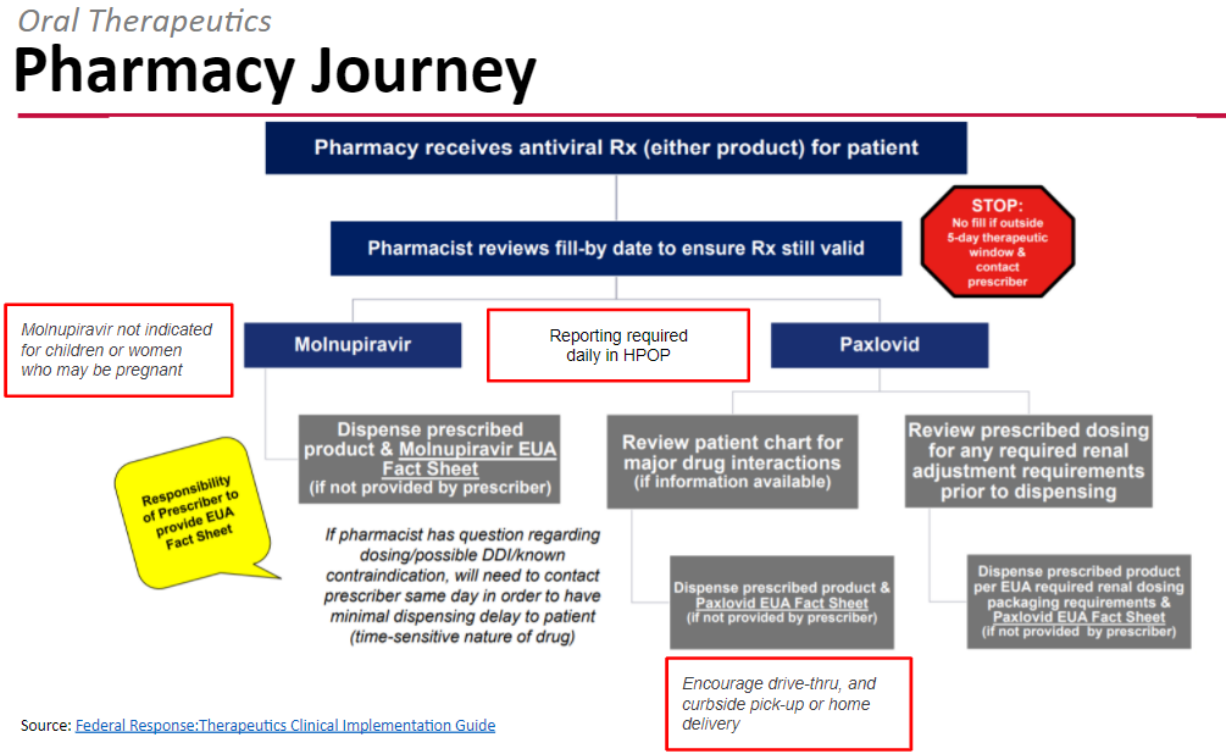
New Evusheld Dispensing Site Requirements

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

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.



The typical allocation timeline is as follows:

	State Therapeutics Team Actions	Partner Site Actions
Monday	• Receive weekly allocation from Federal government	• HPOP Reporting (courses administered and courses on hand) • Deadline for Direct Order Requests
Tuesday	• Create draft allocation for all sites	
Wednesday	• Receive approval for draft allocation from department leadership	
Thursday	• Final requests approved, adjusted, or denied in HPOP • Biweekly: Host Stakeholder Call	• HPOP Reporting (courses administered and courses on hand) • Biweekly: Attend Stakeholder Call

Friday, Saturday, Sunday	• Product ships to sites from distributor • As needed: Provider Update Memo distributed	• 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

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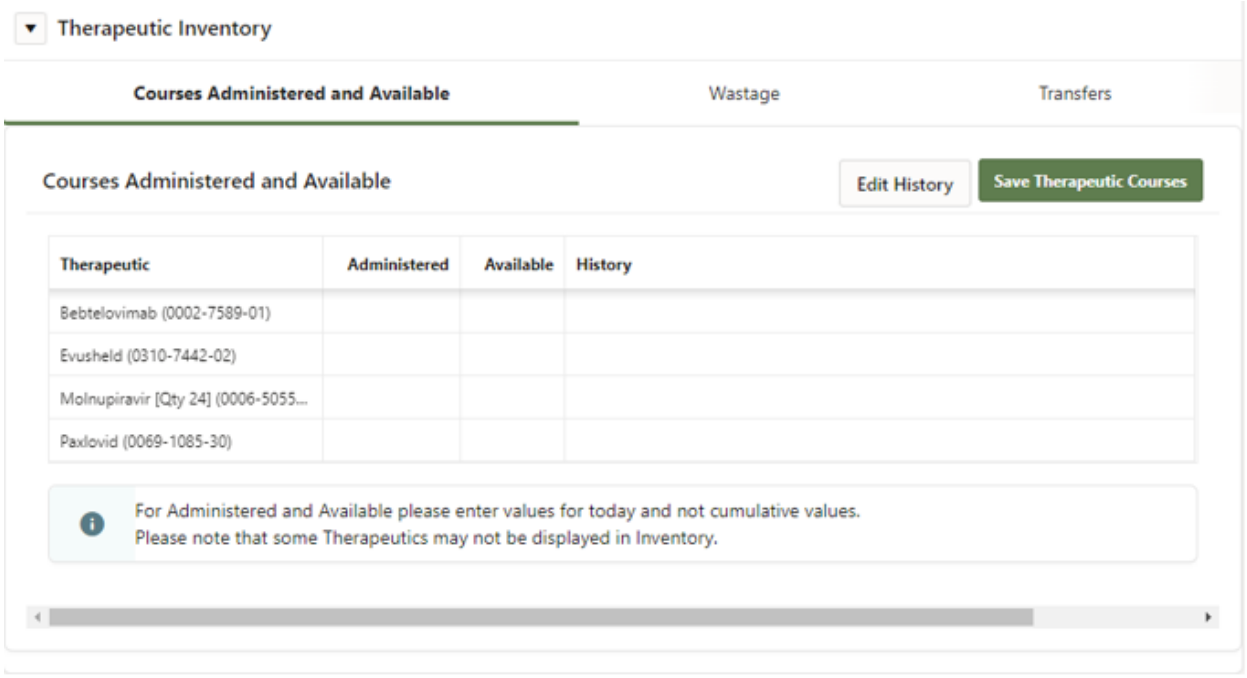
Appendix A: HPOP Reporting Instructions For Enrolled Partners

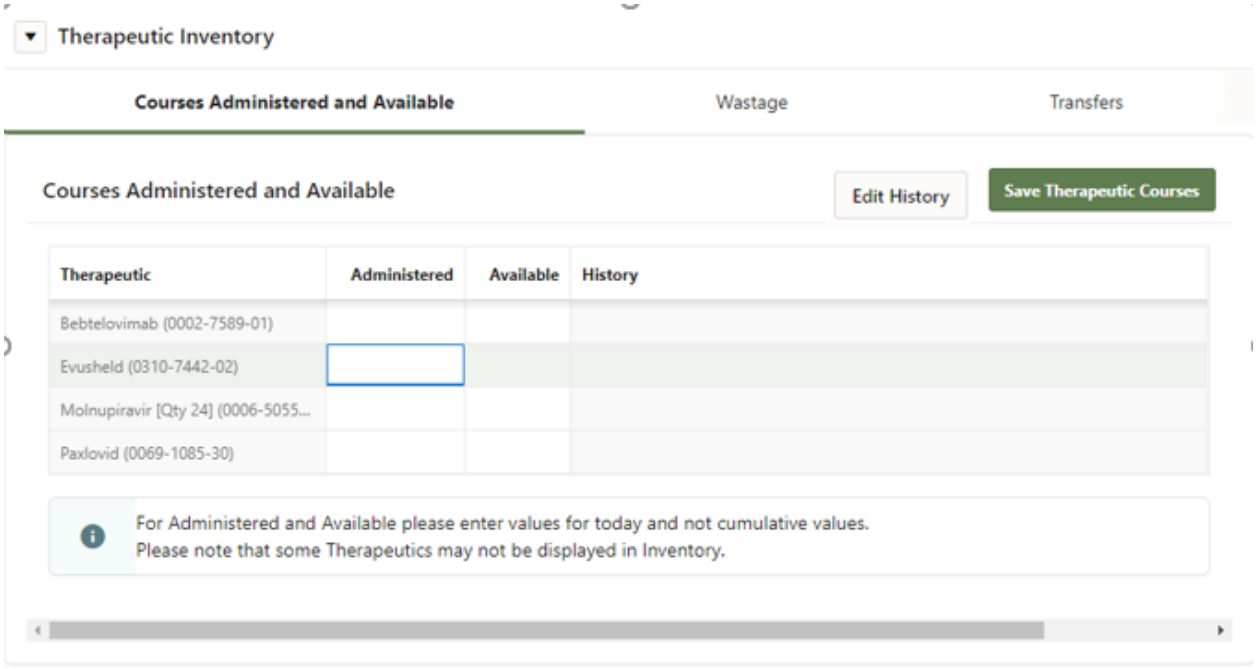
- Reporting is required on Mondays and Thursdays by 11:59pm, even if no product is dispensed.
- Reporting is ***cumulative since you last reported***.
    - So, if you start with 20 courses and use 1 course on Monday, and 4 courses on Tuesday, and 1 courses on Wednesday, your Monday reporting would be 1 course used and 19 on hand, while your Thursday reporting would be 5 courses used and 14 on hand.
- You do not have to report for products you do not receive. So, if your site never received a product, you do not have to report.

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

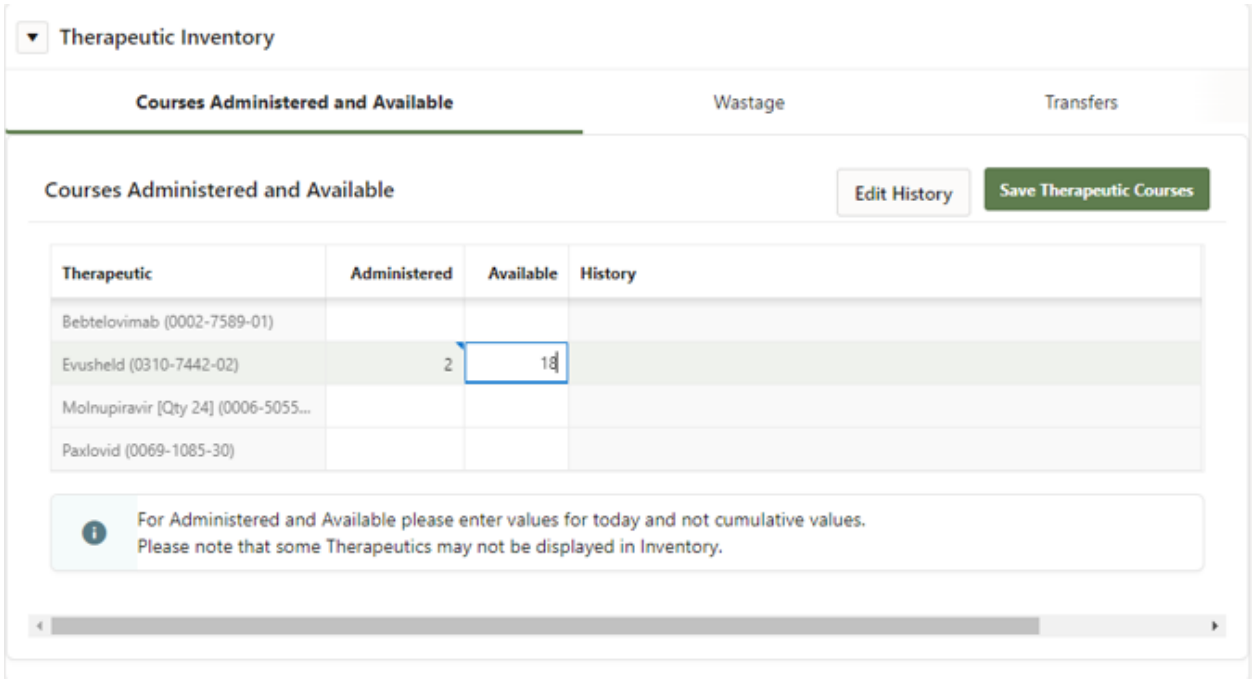


- Under “Courses Administered and Available” you will see the available products you can report for. As an example, we will report the following:
    - Evusheld: 2 courses administered, 18 available
    - Molnupiravir: 1 course administered, 40 available
    - Paxlovid: 0 courses administered, 20 available

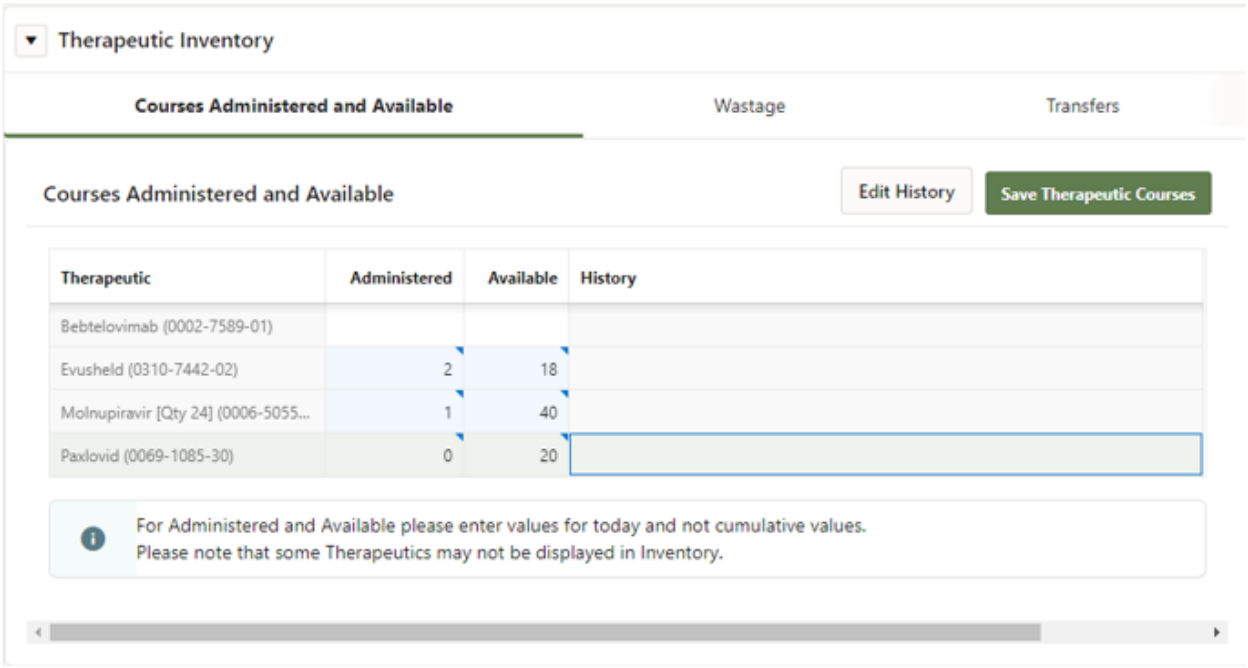
- Double click on the box that you need to edit, as below



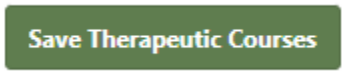
- Enter in the number of courses that you administered ***since you last reported,*** and the courses that remain available for patients. It will look like this:



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



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



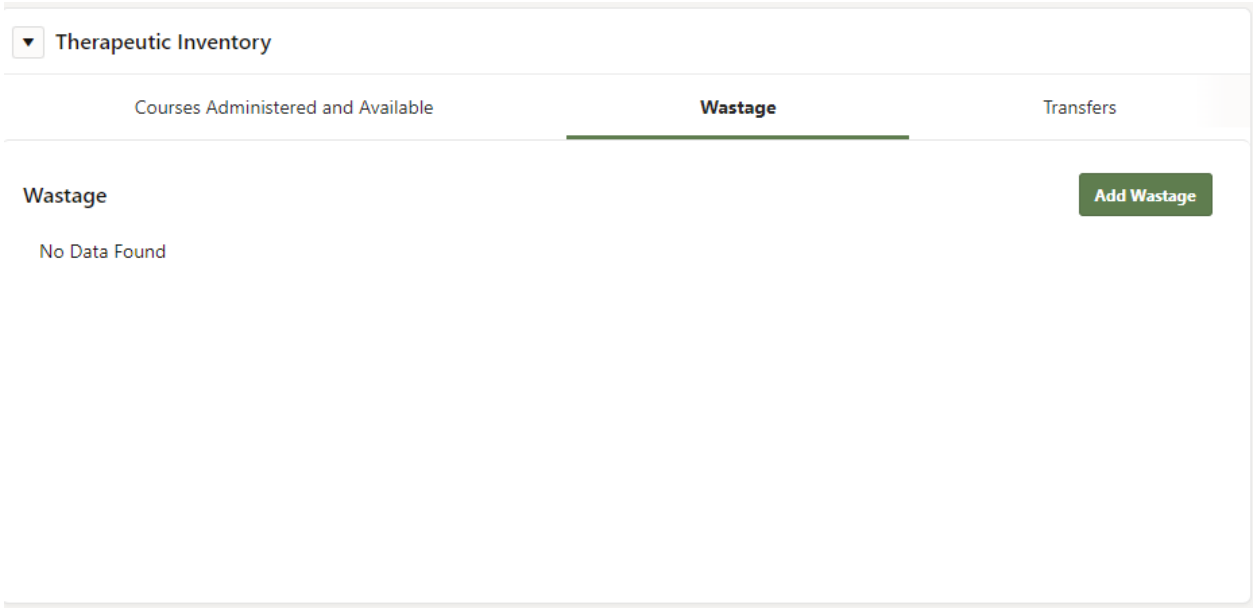
- **You're done!**

Editing Past Reporting

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

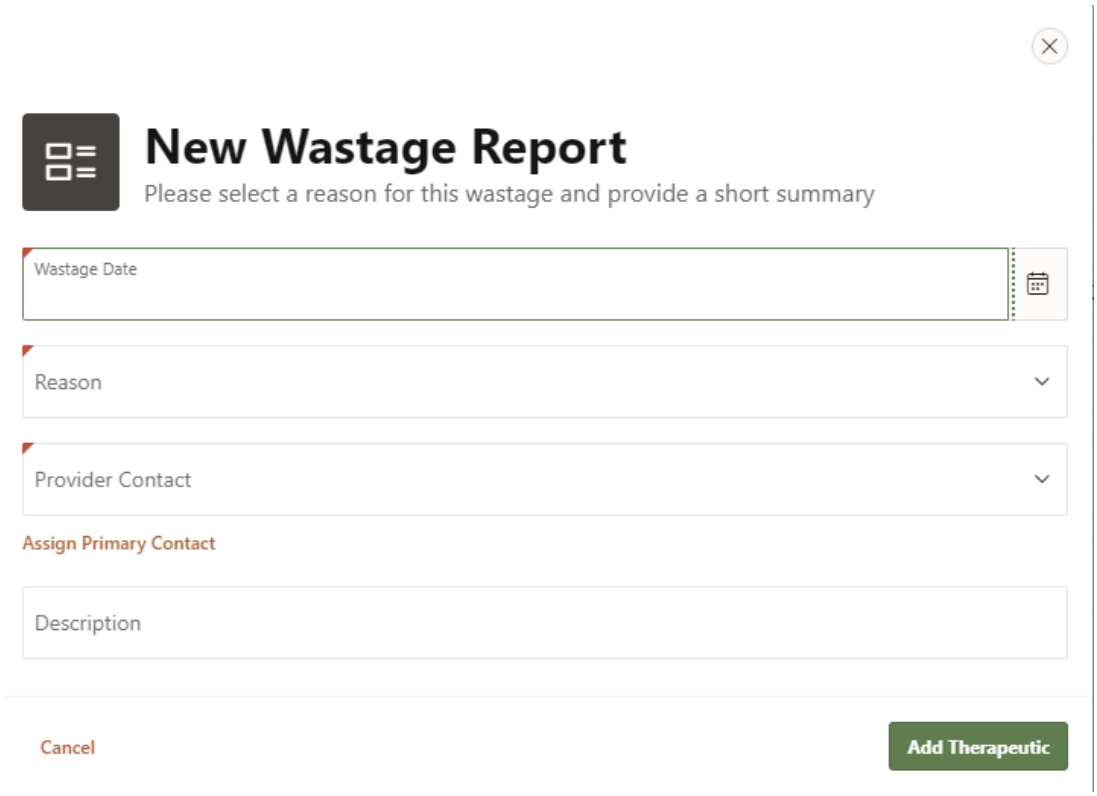
Reporting Wastage

1) Navigate to the "Wastage" tab under "Therapeutic Inventory"



2) Click “Add Wastage” button

3) Add your wastage report information



4) Click “Add Therapeutic”

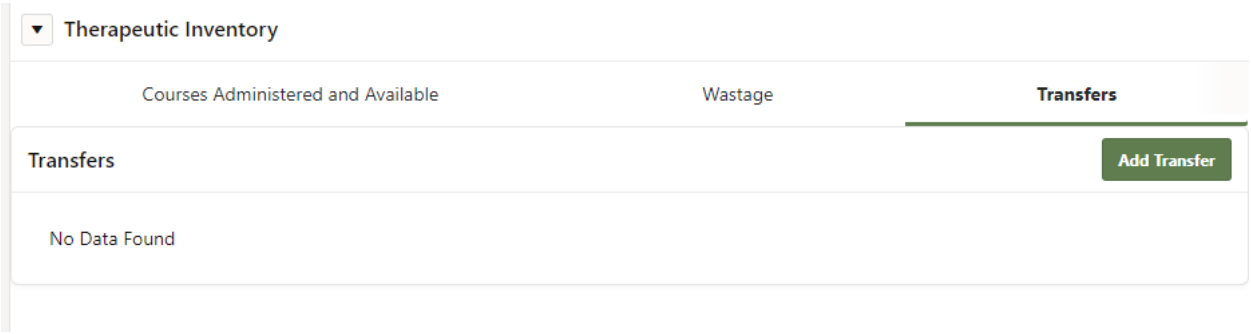
5) Your wastage report is submitted

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.

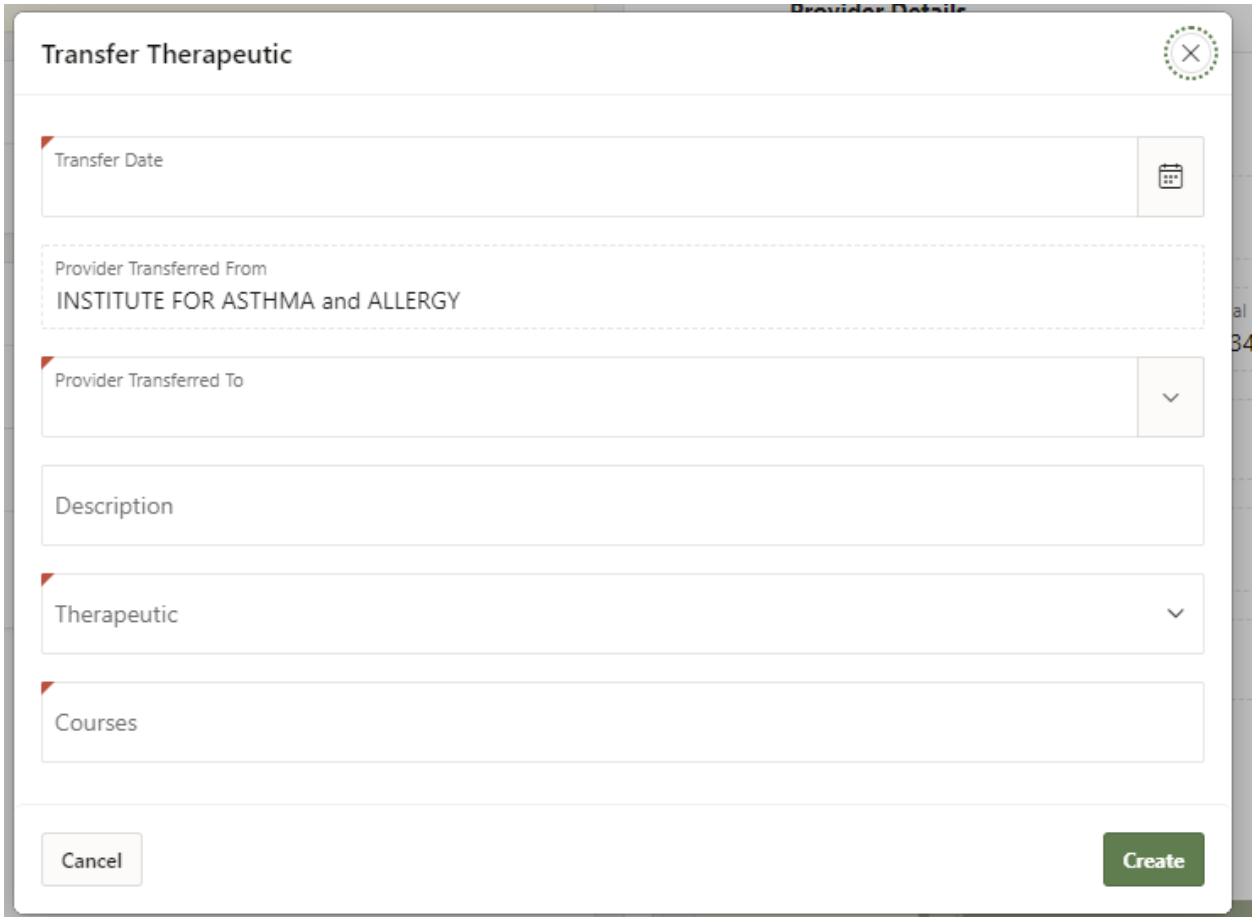
The **transferring** partner should submit the transfer report. So, if Hospital A transfers to Pharmacy B, then Hospital A records the transfer.

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



2) Click “Add Transfer”

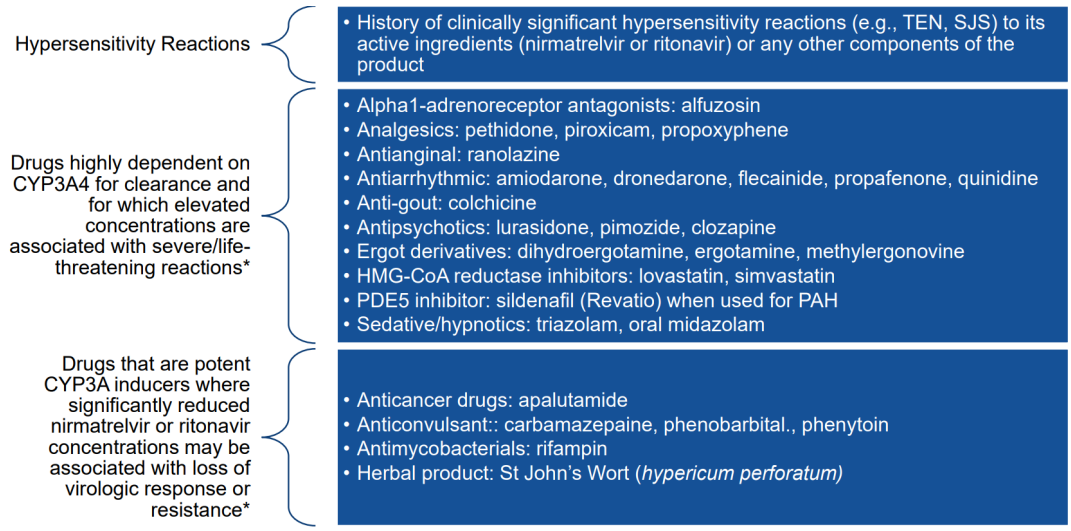
3) Fill out the requested information. Remember, the “Provider Transferred to” must be an existing site in HPOP to be populated.



4) Click “Create” to record the transfer

Appendix B: Paxlovid Drug-Drug Interactions

Paxlovid Contraindications



*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 C: Other Resources

HPOP Login Assistance (Password Reset, errors when logging in): cars_helpdesk@cdc.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

Appendix D: Direct Order Request Instructions

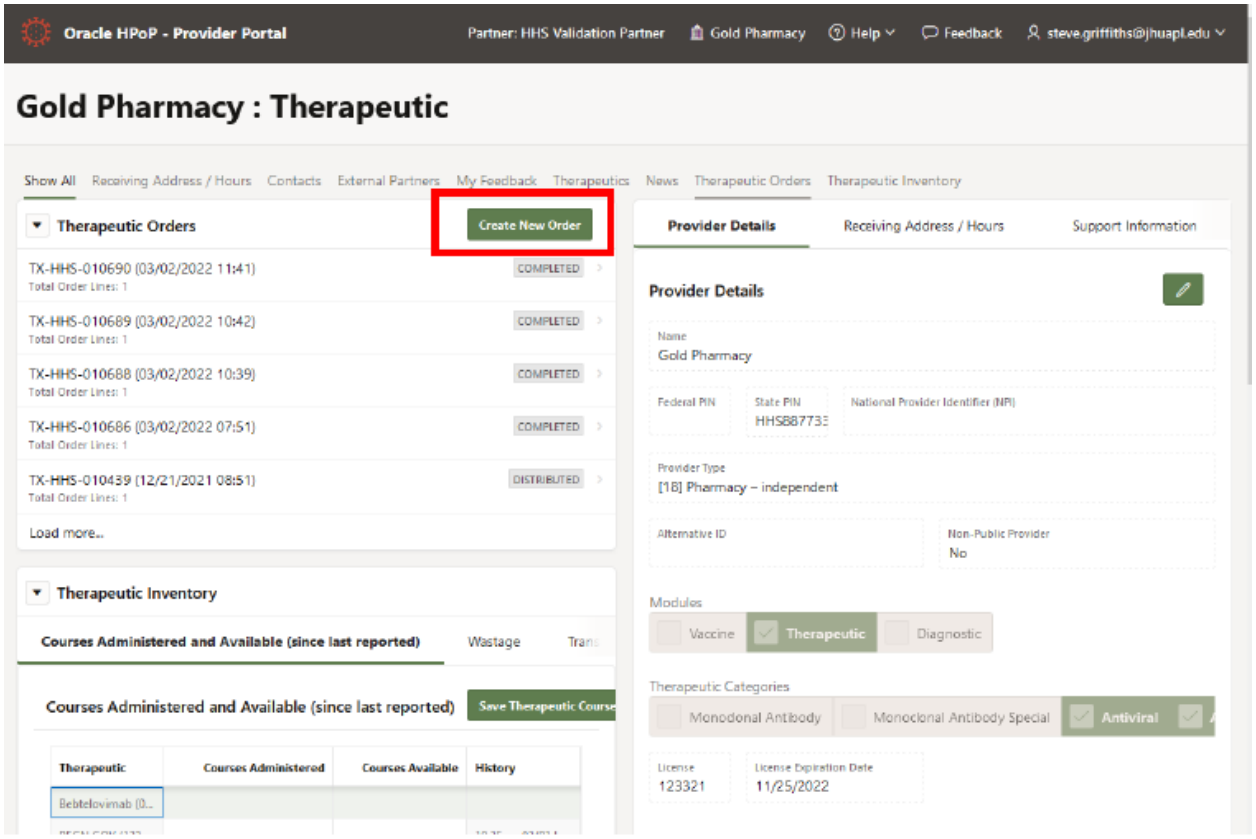
Providers enrolled in HPOP are able to complete “direct order” in HPOP. This means that a provider can request a supply of therapeutic medication that Maryland will approve, modify, or reject. All “orders” can be thought of as “requests” because they still need Maryland Department of Health approval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



3) Select the therapeutic you are interested in obtaining. Please note that you can only request product for which you have **already** been approved. So, a site that has never been approved to supply Evusheld will not be able to submit an order for Evusheld. If you would like to obtain a new therapeutic, you must contact the COVID Therapeutics Team to request authorization.
4) Select the quantity of shipping units. Each product is ordered in different increments, and cannot be customized.
5) 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.
6) If you're finished with your order, click the green "submit" button.
7) 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.