

COVID-19 THERAPEUTICS HANDBOOK

For Providers & Dispensing Partners

0. Context for this document and table of contents

This handbook consolidates essential information on federally-procured, state-allocated COVID-19 therapeutics. With this handbook, the Department aims to equip providers and dispensing partners to comply with federal and state requirements, help achieve equitable allocation of COVID-19 therapeutics across Pennsylvania, and ensure that lifesaving treatments effectively reach patients in need. This document will be revised periodically to reflect changes in process, procedure, or guidance at the state or federal level. The Department will share updated versions of the document when major changes occur, but providers should reference the current version of the document at the Department's [COVID-19 Treatment & Preventive Options webpage](#) for the most up-to-date version.

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1. Overview of therapeutic products

1.1 Summary of state-allocated therapeutic products

There are currently three types of therapeutics authorized for outpatient use that are procured by the U.S. government and distributed at the state level. A more detailed side-by-side overview can be found [here](#). See [here](#) for a clinical decision aid.

	Pre-exposure Prophylaxis (PrEP)	Monoclonal Antibodies (mAbs) ³	Oral antivirals (OAVs)	
Product	Evusheld	Bebtelovimab	Paxlovid⁵ & Renal Paxlovid⁶	Lagevrio (molnupiravir)
Manufacturer	AstraZeneca	Eli Lilly	Pfizer	Merck
Treatment window	Pre-exposure ⁴	Within 7 days of symptom onset	Within 5 days of symptom onset	Within 5 days of symptom onset
Patient COVID-19 status	Negative COVID-19 test with no known exposure	Positive COVID-19 test	Positive COVID-19 test	Positive COVID-19 test
Efficacy ¹	83% reduction in the risk of developing COVID-19 symptoms ⁱ	Reduction of risk in high-risk patients (clinical trial ongoing) ⁱⁱ	88% reduction in hospitalizations/deaths ⁱⁱⁱ	30% reduction in hospitalizations/deaths ^{iv}
Route of admin.	Intramuscular injection (2)	IV infusion	Orally (Twice daily, 5 days)	Orally (Twice daily, 5 days)
Indications	Immunocompromised patients and those not able to be fully vaccinated with any available COVID-19 vaccines due to a history of severe reactions; age 12+	Non-hospitalized patients when oral antivirals are not available, feasible to use, or clinically appropriate; age 12+	Non-hospitalized patients with mild to moderate COVID-19; age 12+	Non-hospitalized patients with mild to moderate COVID-19; age 18+
Possible adverse side effects ²	1) Allergic reaction 2) Cardiac events	1) Allergic reaction 2) Injection-related reaction	1) Allergic reactions 2) Liver problems 3) Resistance to HIV meds	1) Allergic reactions 2) Diarrhea 3) Nausea 4) Dizziness
FDA status	EUA	EUA	EUA	EUA
Resources	Link here	Link here	Link here	Link here

- Sources: i) [AstraZeneca](#), ii) [NIH](#), iii) [Pfizer](#), iv) [Merck](#)
- Non-exhaustive; key side effects noted in FDA product fact sheets
- The following mAbs have been suspended as these treatments are highly unlikely to be active against the Omicron BA.1/BA.2 variant: bamlanivimab and etesevimab (bam/ete), REGEN-COV, & sotrovimab. Refer to [fda.gov](#) for latest info
- Per [FDA 2/24/22](#): “Previously, the authorized Evusheld dosage was 150 mg of tixagevimab & 150 mg of cilgavimab administered as 2 separate consecutive intramuscular injections, with repeat doses every six months while SARS-CoV-2 remains in circulation. With this EUA revision, FDA has increased the initial authorized dose to 300 mg of tixagevimab & 300 mg of cilgavimab. Patients who have already received the previously authorized dose (150 mg of tixagevimab & 150 mg of cilgavimab) should receive an additional dose of 150 mg of tixagevimab & 150 mg of cilgavimab as soon as possible. The recommended timing for repeat dosing cannot be provided at this time.” Refer to [fda.gov](#) for latest info
- [Paxlovid patient eligibility screening checklist tool](#) is available for prescribers
- FDA updated the Paxlovid [EUA](#) to authorize an additional dose pack presentation with appropriate dosing for patients with moderate renal impairment. The new package option contains 150 mg nirmatrelvir and 100 mg ritonavir per dosage, in contrast to 300 mg nirmatrelvir and 100 mg ritonavir per dosage in the standard packaging. Providers can re-submit the DOH [enrollment form](#) to request Renal Paxlovid and indicate estimated patient panel size

2. Enrolling in DOH therapeutics network

2.1 Enrollment overview

- **DOH enrollment:** To begin the process of receiving federally-procured, state-distributed COVID-19 therapeutics products, including oral antiviral medications, monoclonal antibodies for treatment, and/or monoclonal antibodies for pre-exposure prophylaxis, providers will need to complete the Pennsylvania [therapeutics enrollment form](#).
- **Enrollment FAQ:**

Q. If I am a current therapeutics provider, do I need to fill out this form?

A. Yes. We are asking that all providers – both current and new – fill out this form. This will ensure consistent and complete record keeping by DOH, especially as federal partners streamline all therapeutics into a single system.

Q. If I am a retail pharmacy and only want to provide oral antivirals, do I need to fill out this form?

A. It depends. Retail pharmacies that are part of one of the Federal Retail Pharmacy Partnership for Therapeutics (FRPP-T) chains who only want to provide oral antivirals should **not** fill out the form; please contact your network leadership for access to this product. Other retail pharmacies that are not part of one of these networks should fill out a form, as should network pharmacies that want to administer mAbs for treatment or mAbs for PrEP.

Q. If my site wants to add or change therapeutics we are receiving, how should we indicate that?

A. A provider should indicate in their initial submission any therapeutics that they want to administer/dispense, including any products currently being administered/dispensed. If a provider wishes to change the products they administer/dispense in the future, they should email covidtherapeutics@pa.gov to notify DOH of this change and update the enrollment form to reflect any additions/removals.

In addition to completing the enrollment form, providers will need a verified account on the federal Health Partner Ordering Portal (HPOP) system to receive federally procured, state distributed COVID-19 therapeutics.

3. Setting up an account on the Health Partner Ordering Portal (HPOP)

3.1 Health Partner Order Portal (HPOP) - information for providers

- **The Health Partner Ordering Portal (HPOP) is a web-based tool developed by HHS for managing and reporting key metrics associated with the distribution and administration of vaccines, therapeutics, and diagnostics.** For providers who are not already registered on HPOP, DOH can assist them to set up their HPOP accounts once they have completed the PA DOH therapeutics [enrollment form](#).
- **When completing DOH's therapeutics enrollment form and registering with HPOP, providers should answer all questions as accurately as possible, even when optional** – this includes information on patient panel size in each age group & average number of doses administered each week. This information helps optimize allocations.
- **The term “providers” describe all organizations that administer therapeutics to patients and customers.** This includes individual stores within a pharmacy chain (e.g., Walgreens store #1234) and organizations such as hospitals, clinics, doctors' offices, dialysis centers, and local pharmacies.
- **Logging in to HPOP:** After DOH creates a provider contact in HPOP for a new provider, they will receive a registration email from vpop-no-reply@cdc.gov that will contain a registration link that **expires after 72 hours**. Providers need to open the registration link and set up their password and two-factor authentication. **If they miss the 72-hour deadline to register, they can contact cars_helpdesk@cdc.gov.** Once providers have set up their HPOP accounts, their designated contact person should have access to the [Provider Portal](#) for management of inventory and information, including addresses, licensing, and operating hours.

4. Using Direct Ordering Request (DOR) to request therapeutics

4.1 Overview of Direct Ordering Request (DOR)

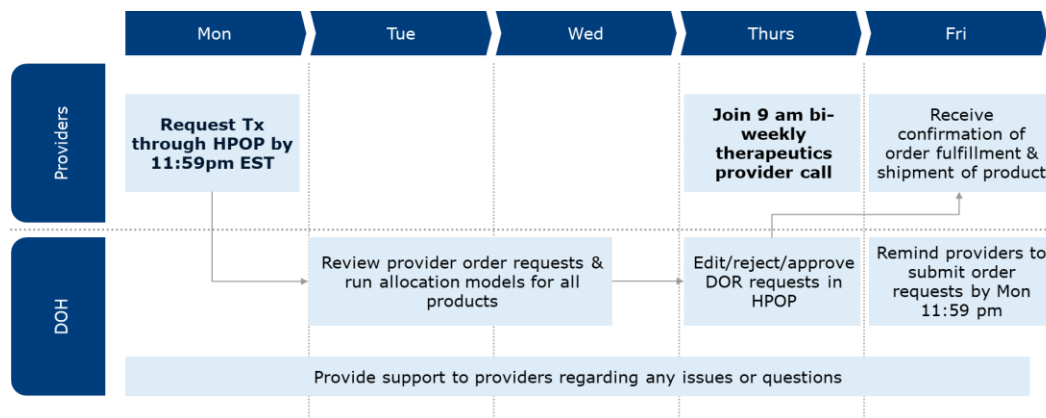
- **Direct Ordering Request (DOR)** allows a provider to request a specific therapeutic allotment by submitting an order in HPOP. As of 06/06/2022, DOH has been using DOR to allocate all federally distributed therapeutics (Evusheld, Bebtelovimab, Paxlovid, and Lagevrio) across providers in Pennsylvania.

4.2 Weekly DOR workflow and cadence

- To request a specific product, providers must submit their DORs via HPOP by **Monday 11:59 pm**. DOH reviews submitted DORs on a **weekly cycle**, and they may approve, deny, or adjust the order request made by the provider. Approved order requests are then sent to AmerisourceBergen for distribution.

The figure below illustrates the weekly cadence for providers to request and receive product. Bold text denotes key deadlines and meetings.

Figure 1: Weekly DOR cadence



Note: Providers can submit requests any day/time during the week, but order requests will close for weekly review/processing on Monday at 11:59 pm; DOR process is for non-FRPP partners only – FRPPs that would like to request additional products from the state threshold to supplement their federal allotment, should email covidtherapeutics@pa.gov by Monday 11:59 pm for a given cycle.

4.3 Provider checklist for DOR

For a smooth DOR process, providers must:

- **Set up & verify an HPOP account:** Log into provider portal, update address/hours, validate license information and expiration date, etc.
- **Submit requests within deadline:** Submit all order requests for products into HPOP by Monday 11:59 pm
- **Report utilization:** Report utilization and on-hand inventory of products daily

4.4 Creating an order request using DOR – step by step guide

1. To place an order request, click the green “Create Order” or black “Create External Order” button on the Therapeutic Orders panel at the top left of the Provider screen.
2. You will then be prompted to select the therapeutics you want to order (e.g., Paxlovid) and the quantities. If the product you want to order is unavailable as an option, it might be because you did not select that particular product as one you would like to provide/administer when completing the DOH enrollment form. Email covidtherapeutics@pa.gov indicating your interest to provide this product and update your enrollment form to reflect the change in the products you would like to provide.
3. If your order request is complete, review and confirm your order, then submit; otherwise select “add another therapeutic” and continue. When satisfied with the order request, select Submit.
4. The requested order should now appear under Therapeutic Orders along with its status (more information on order status below). Order requests submitted in error can be canceled by emailing covidtherapeutics@pa.gov.

Note: a created order request **does not guarantee that the order will be distributed to the provider**. Allocation decisions are dependent on weekly supply of therapeutics from the federal government and requests may not be fulfilled in their entirety when supply is constrained. DOH will review all order requests, assess the state of therapeutics supply in the Commonwealth, and make allocation decisions accordingly.

Figure 2: Placing a direct order request for therapeutics

1 Therapeutic Orders Create Order

TX-HHX-186238 (04/13/2022 08:28)	SUBMITTED >
Total Order Lines: 2	
TX-HHX-173838 (03/31/2022 13:12)	CANCELLED >
Total Order Lines: 1	
TX-HHX-173819 (03/31/2022 12:28)	TRANSMITTED >
Total Order Lines: 2	

2 Select Therapeutic

- Bebtelovimab (0002-7589-01)
- Evusheld (0310-7442-02)
- Paxlovid (0069-1085-30)
- Lagevrio (molnupiravir) (0006-5055-06)
- Renal Paxlovid (0069-1101-20)
- Sotrovimab (0173-0901-86)

Note - Only Therapeutics which have been allocated will be available to order!

Select Quantity

Paxlovid (0069-1085-30)
For the treatment of mild-to-moderate COVID-19 in certain adults and pediatric patients

Minimum Shipping Units **1** Maximum Shipping Units **200**

Remaining Shipping Units (Maximum - Submitted) **200**

1 Shipping Units (20 courses)	2 Shipping Units (40 courses)
3 Shipping Units (60 courses)	4 Shipping Units (80 courses)
5 Shipping Units (100 courses)	6 Shipping Units (120 courses)

3 Review & Confirm ✕

Line No.	Therapeutic	Generic Description	Quantity
1	Paxlovid	For the treatment of mild-to-moderate COVID-19 in certain adults and pediatric patients	2 Shipping Units (40 courses) ✕

Cancel
Add another therapeutic
Submit

4 Therapeutic Orders Create Order

TX-PAA-301178 (05/31/2022 11:37)	SUBMITTED
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Note: This view will only be displayed in the Therapeutic Orders section of the portal when DOH has granted therapeutic ordering permission to the providers.

4.5 Tracking order status

Status of orders can be tracked in the Therapeutic Orders panel:

- Submitted – Order placed by or for Provider
- Processing – Order being reviewed by DOH
- Completed – Order approved by DOH and ready for distribution
- Cancelled – Order canceled by DOH users
- On-Hold – AmerisourceBergen (distributor) needs to create an account for the provider
- Transmitted – Distributor has downloaded order and is in process of packing and shipping
- Distributed – Order picked up by the distributor
- Shipped – Order has been shipped & shipping information has been provided by the distributor to HPOP

4.6 User guide

Provider guides with detailed instructions on creating DORs are available in HPOP under “Help” > “Documentation.”

5. Reporting therapeutics

5.1 Federal reporting requirements

According to federal guidelines, providers who receive products through DOH must report data on product utilization (courses administered) and stock on-hand (courses available) to the federal reporting systems. As of June 2022, the reporting requirements have been updated as follows:

- [Evusheld, Paxlovid, Lagevrio, & bebtelovimab](#): reporting required to **HPOP by 11:59 pm every Monday & Thursday**
- [Sotrovimab, bam/ete, & REGEN-COV](#) (not currently authorized as of June 2022): by **11:59 every Wednesday**
 - Long Term Care/ Skilled Nursing Facilities: NHSN
 - Hospitals/Hospital Pharmacies: HHSProtect/TeleTracking/Health Departments
 - Non-hospital facilities: HHS TeleTracking

5.2 Reporting product data in HPOP

To report data on utilization:

- Double-click the row under Courses Administered and Courses Available.
- Enter total number administered since the last report, and click “Save Therapeutic Courses.”
- After clicking “Save” you will see a short pop up indicating that the save operation completed successfully. The values you save will remain there until the system moves them to the History column, which happens once a day around midnight EST.
- If a person inadvertently enters an incorrect value, or transposes the Administered and Available numbers, they can edit and correct the data entry errors.

5.3 The importance of reporting

Your compliance with timely and accurate reporting of COVID-19 therapeutic utilization and stock on-hand will help (i) DOH understand how treatments are being utilized to optimize allocation and ensure equitable distribution across the state, and (ii) inform providers and patients of where to locate product, as data is published to [ASPR's COVID-19 Therapeutics Locator](#) and to [HealthData.gov](#). We appreciate your effort in ensuring access to lifesaving treatments.

6. Stocking therapeutics

6.1 Stocking therapeutics overview

DOH recommends that sites aim to build an inventory of therapeutics on-hand to cover at least several weeks of patient demand, rather than only account for immediate patient needs. While sites should not seek to stockpile beyond their ability to feasibly dispense the treatment before product expiration, keeping several weeks of supply on-hand is prudent given the dynamic nature of the pandemic and the therapeutics supply/demand environment. There are several benefits of building inventory of therapeutics outlined below, as well as considerations for storage and for returning and disposing of product when required.

6.2 Benefits of building stock on hand of therapeutics

- **Reach patients during brief treatment window:** there is limited time to quickly reach patients with COVID-19 therapeutics, especially as patients may defer testing until symptoms worsen and are required to consult with a physician for prescription. Current treatments are only effective within a short window after symptom onset:
 - 5 days for oral antivirals (Paxlovid, Lagevrio)
 - 7 days for monoclonal antibodies (Bebtelovimab)
- **Prepare for demand spikes:** new variants and surges can lead to rapid and sudden increases in demand for COVID-19 products, adding to the immediate need for therapeutics.
- **Avoid supply chain disruptions:** COVID-19-related supply chain issues across industries are limiting capabilities to expedite distribution.

6.3 Precautions for stocking COVID-19 therapeutics

- **Comply with product storage conditions:** Different therapeutic products require different storage and handling conditions:
 - Evusheld, Bebtelovimab: Store unopened vials in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Discard any unused portion. DO NOT FREEZE. DO NOT SHAKE.
 - Paxlovid, Lagevrio: 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).
- **Keep track of product shelf-lives:** if your facility has soon-expiring product on-hand that will not be used, consider an inter-facility transfer to [another site](#) to avoid wastage. Contact covidtherapeutics@pa.gov with questions.

Note: ASPR and FDA release periodic announcements about shelf-life extensions of COVID-19 therapeutics. Before disposing expired products, providers should verify whether the shelf life of these products have been extended. Updates on product expiry dates can be found [here](#).

6.4 Returning and disposing of therapeutic products

- **Please be aware of the following guidelines for returning products:**
 - All mAb products are property of the USG and must be used in accordance with EUA guidance.
 - FDA EUAs **only** apply to drug use in the U.S.: sites of care cannot donate products to entities outside the U.S. or for use outside the U.S.
 - Any returned product will be destroyed, as product integrity cannot be verified.
 - All sites should first check with respective state health department(s) to ensure product cannot be used elsewhere in the state or region.
 - Long-term utility of authorized mAb product is expected.

- Upon these considerations, if undamaged product needs to be returned, follow the below instructions:
 - For bam and bam/ete, see detailed guidance at [The Lilly Return Goods Procedure](#)
 - For REGEN-COV, call 844-734-6643
 - For sotrovimab, follow the [GSK Returns Goods Policy](#)
- Please be aware of the following guidelines for disposing of products:
 - Expired product can be disposed of per the facility's standard operating procedures (SOP) for disposing of expired product, but first check to ensure that no expiration date extensions were issued for that product.
 - Disposing of non-expired bam/ete, REGEN-COV or sotrovimab only due to the current suspended authorized use is not permissible, as we hope future variants will allow for the use of those products.
 - Reconstituted (diluted) product SHOULD NOT be returned and should be treated as waste per your facility's SOP.

7. Additional information

7.1 Online resources

- [DOH](#)
 - [COVID-19 Prevention and Treatment - Provider Portal](#)
 - [COVID-19 Prevention and Treatment Overview – General Public](#)
 - [Evusheld providers list in PA](#)
 - [Lagevrio \(molnupiravir\) providers list in PA](#)
 - [Paxlovid providers list in PA](#)
- [FDA](#)
 - [Evusheld fact sheet for healthcare providers](#)
 - [FDA authorizes revisions to Evusheld dosing](#)
 - [FDA updates Sotrovimab EUA](#) (*not authorized in U.S. as of 4/5/22*)
 - [Bebtelovimab fact sheet for healthcare providers](#)
 - [Paxlovid fact sheet for healthcare providers](#)
 - [Paxlovid patient eligibility screening checklist tool for prescribers](#)
 - [Lagevrio \(molnupiravir\) fact sheet for healthcare providers](#)
- [ASPR/HHS](#)
 - [COVID-19 Therapeutics Clinical Implementation Guide](#)
 - [COVID-19 Therapeutics Locator](#)
 - [COVID-19 Public Therapeutic Locator \(HealthData.gov\)](#)
 - [Side-by-side Overview of Outpatient Therapies for COVID-19](#)
 - [Process for Ordering COVID-19 Therapeutics](#)
 - [Federal Test to Treat Program](#)
 - [COVID-19 Test to Treat \(HealthData.gov\)](#)
 - [ASPR COVID-19 Test to Treat Locator](#)
- [CDC](#)
 - [Clinical Care Information for COVID-19](#)
 - [Guidance Documents for Healthcare Professionals](#)
 - [Clinical FAQs about COVID-19](#)

- **NIH**
 - [Treatment Guidelines](#)
 - [Statement on Patient Prioritization for Outpatient Therapies](#)
 - [Therapeutic Management of Hospitalized Adults with COVID-19](#)
 - [Therapeutic Management of Nonhospitalized Adults with COVID-19](#)
- **HPOP**
 - [HPOP Provider Portal](#)
 - [HPOP Provider Portal User Guide](#)
 - [ASPR HPOP overview](#)

7.2 HHS/ASPR COVID-19 therapeutics stakeholder updates

- Recurring call schedule [here](#)

7.3 HPOP help desk

- **CARS Helpdesk:** email cars_helpdesk@cdc.gov or call 833-748-1979.

7.4 DOH led provider/stakeholder calls

- Call for all providers, all therapeutic products: Biweekly, Thursdays 9 am
- If you wish to attend the calls, please email covidtherapeutics@pa.gov to be added

7.5 DOH contact information

- If you have any questions, contact us at covidtherapeutics@pa.gov