FAQs for COVID-19 Therapeutic Providers

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Therapeutics Overview

What are therapeutics?

COVID-19 therapeutics are drugs to help treat and care for patients who are diagnosed with COVID-19.

Early effective treatment of COVID-19 in patients at high risk of disease progression and severe illness can help avert progression to more serious illness or death, with the additional benefit of reducing the burden on healthcare systems. Several therapeutics are available under Emergency Use Authorization (EUA) for outpatient treatment to prevent the progression to severe COVID-19 infection in high risk patients. Clinicians should review the COVID-19 Treatment Guidelines (for Nonhospitalized Adults or for Hospitalized Adults), the NIH Coronavirus Disease 2019 (COVID-19) Treatment Guidelines and all available documentation for the individual therapy (see FDA for EUA, Fact sheets, additional documentation and instructions) for the latest guidelines.

What is an Emergency Use Authorization (EUA)?

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), when the Secretary of Department of Health and Human Services (US HHS) declares that an emergency use authorization is appropriate, FDA may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threats, including infectious disease, when certain criteria are met, including when there are no adequate, approved, and available alternatives.

Why are certain therapeutics being allocated?

Certain COVID-19 medications have been purchased by the US federal government (USG). When the demand for the medication far outstrips the supply, US HHS via the Office of the Assistant Secretary for Preparedness and Response (ASPR) moves to an allocation scenario, where providers place requests, instead of allowing direct ordering. ASPR has begun to transition specific product from allocation through the USG to a commercial market. For more information, see the ASPR COVID-19 Therapeutics.

What is the therapeutics allocation process?

US HHS allocates only therapeutics for non-hospitalized patients at high-risk of progressing to severe disease. Texas Department of State Health Services (DSHS) receives the quantity that has been allocated to Texas by U.S. HHS for each product and allocates to eligible providers.

Each cycle, DSHS reviews the current data including requested amounts, on-hand amounts, and reported utilization. This site-specific information is used with COVD-19 case counts and hospitalization information, population distribution, and geographic distribution of the facilities along with other considerations, such as access to healthcare, maintaining supply across weeks, and vulnerability of specific populations, and the appropriate use of each therapeutic.

Once the requests are reviewed and amended, the orders are placed with the distributor, AmerisourceBergen (ABC), who will ship the medications directly to the facility.

Which therapeutics are allocated by Texas DSHS?

The following therapeutics are currently allocated by Texas DSHS:

For treatment of symptomatic patients with mild to moderate COVID-19 illness:

- Paxlovid (Pfizer)
- Lagevrio (molnupiravir)(Merck)

These five products **are no longer authorized** for use in the US due to decreased efficacy against circulating variants.

- Bamlanivimab plus etesevimab (Eli Lilly)
- REGEN-COV (casirivimab/imdevimab) (Regeneron)
- Sotrovimab (GlaxoSmithKline)
- Bebtelovimab (Eli Lilly)
- Evusheld (AstraZeneca)

Which outpatient therapeutics are NOT allocated by Texas DSHS?

This outpatient treatment is available for purchase.

- Velkury (remdesivir)
  - Providers may wish to purchase Veklury (remdesivir) for patients who are unable to take one of the oral antiviral medications.
  - Hospitals can purchase Veklury through multiple distributors through the facility's normal procurement processes (Gilead Resource Call Center at 1-800-226- 2056).
  - Non-hospitals can purchase from AmerisourceBergen (Outpatient Product Information Guide including ordering).
  - Providers may order this medication for outpatient administration through their normal procurement channels (see https://www.vekluryhcp.com/).

How do I find COVID-19 Therapeutics and Test to Treat Locator Tools?

To find locations with COVID-19 therapeutics on hand and Test to Treat locations, please visit the following sites:

- U.S. HHS COVID-19 Therapeutic Locator
- ASPR Test to Treat Locator

If you provide **outpatient Veklury (Remdesivir) infusions,** U.S Health and Human Services (HHS) has requested that you register your site on their HHS COVID-19 Therapeutics Locator to assist in matching patients at high risk of severe COVID-19 to the medications that can prevent disease progression.

- HHS and DSHS are requesting healthcare partners who order Veklury (remdesivir)for outpatient use to sign up to have their location listed on the HHS COVID-19 Therapeutics Locator
- Any infusion site opting into this initiative will be featured on the COVID-19 Therapeutics Locator as an outpatient Veklury provider
  - Only information provided by the infusion site will be visible on the locator
  - Infusion sites can opt out of being on the locator at any time

To have your site listed on the Outpatient Veklury (remdesivir) Locator, please click here to provide your information.

Where can providers find more information about each of the therapeutics allocated by the state?

Providers should be familiar with the Fact Sheets and associated documents for each product they offer. Documentation for each product is available from DSHS at COVID-19 Therapeutics – Product Information including the FDA and from manufacturers' websites and resources.

How are therapeutics allocations made?

Your site is eligible to receive only the therapeutics for which DSHS has enrolled your facility to receive. All providers must follow the EUA for the therapeutic(s) they administer or prescribe. Being an enrolled provider does not guarantee an allocation. Allocations are made based on population distribution, geographic distribution, disease burden, utilization, and available quantities of the product.

What are the requirements to enroll for each therapeutic?

Oral Antivirals

Sites that dispense the oral antivirals MUST have a valid Texas Pharmacy license. If your pharmacy was associated with one of the federal partners for vaccines, please contact that partner to gain access to the oral antiviral medication.

Monoclonal antibodies

As of August 22, 2022, there are no monoclonal antibodies for outpatient treatment that are being allocated by DSHS.

How much do the therapeutics costs?

Therapeutics have been purchased by the federal government and are distributed to providers at no cost. Providers may not charge for the cost of the therapeutic for any USG-purchased product but may seek reimbursement for the administration or dispensing fee from Medicaid, Medicare, and commercial insurance companies. Providers may not pass the cost for the dispensing fee for oral antivirals to the patient. Questions on billing may be addressed with the DSHS webpage https://www.dshs.texas.gov/coronavirus/therapeutics-providers.aspx#billcode.

Requesting Therapeutics

What is HPOP?

The Health Partner Ordering Portal (HPOP) is a system developed and maintained by US HHS. The HPOP Provider Portal is used by providers to order all therapeutics that are allocated through the state. Providers will request the therapeutics they are approved for, and DSHS will approve, deny, or edit requests based on allocation allotted.

Which therapeutics use HPOP?

- Paxlovid (Pfizer)
- Renal Paxlovid (Pfizer)
- Lagevrio (molnupiravir)(Merck)

Unauthorized therapeutics in HPOP for reporting ONLY:

- Bamlanivimab plus etesevimab (Eli Lilly)
- REGEN-COV (casirivimab/imdevimab) (Regeneron)
- Sotrovimab (GlaxoSmithKline)
- Bebtelovimab (Eli Lilly) **ONLY USG PROVIDED SUPPLY TO BE REPORTED IN HPOP
- Evusheld (AstraZeneca)

What is a Partner or Central Partner?

Central Partner and Partner are the same entity. HPOP is designed around the concept of a Central Partner managing their Providers. A Partner is a:
- Jurisdiction (e.g., Texas, California, Guam, District of Columbia)
- Federal Retail Pharmacy Therapeutic Program (FRPTP) (e.g., CVS, Walgreens, Publix, Albertsons)
- Federal Entity (e.g., Department of Defense, Department of State, Indian Health Service)

DSHS is the Partner that will place orders on behalf of Texas providers and support the accounts of Texas providers that do not fall under another Partner.

What is a Provider?

A provider is the individual site-of-care (e.g., CVS store123, doctor's office, hospital) that receives therapeutic products. Providers are managed by the Partner. A provider may fall under more than one Partner in rare cases, such as FQHCs falling under both Texas DSHS and HRSA.

How do I create an account in HPOP?

DSHS must set up an account in HPOP. Providers cannot set up their own account. Once the account for the site and the associated Contact is created within HPOP, the contact will receive an activation email to begin the login process. Please contact Therapeutics@dshs.texas.gov to enroll.

How do I access my account in HPOP the first time?

You will receive an activation email to log onto the HHS HPOP Provider Portal. Each user must activate their account within 72 hours of the email being sent.
- Please click on the Activate Account button in the email when you receive it.
- The activation email will come from "VTrckSProvider Ordering Portal" https://vpop.cdc.gov/ or messaging_test@covpn.oraclecloud.com. Please whitelist these email addresses in email system, firewalls, etc. Check the spam/junk folder if you do not see it.
- Email therapeutics@dshs.texas.gov to have activation email resent if you miss the 72-hour window.
- Once you have activated your account, you may reset your password from the login page.
- Troubleshooting. Please make sure:
  - You are using this url to log in: https://vpop.cdc.gov/provider/signin/
  - You are using a supported browser (Microsoft Edge, Google Chrome, Mozilla Firefox, Safari).
  - Your browser does not have an extension for Internet Explorer compatibility
  - If you continue to experience access issues:
    - Consider switching browsers.
    - Clear/delete your cache and cookies.
- Contact CARS_HelpDesk@cdc.gov or (833) 748-1979 if you have issues with HPOP.

What do I do when I first log onto my account?

One user per site must complete these steps. These are required before the facility can place an order

1. On the Provider Detail tab:
    a. Add the license number and expiration date, if blank. This is the license that allows you to dispense medications. If you have a Texas pharmacy license at the address, use that. Otherwise, use the medical license of the authorizing provider.
2. On the Receiving Address/Hours tab:
    a. Click on Physical (with the pencil icon) to open the window.
    b. Verify/update your address
    c. Verify/Add the hours for **receiving shipments**
    d. Confirm/Add the email address and phone number that will be used by the distributor, AmerisourceBergen, for all communication.
    e. **Check the box** at the bottom of the page labeled, "Receiving Address & Hours Verified".

For more help for using the HHS HPOP system please refer to this Information Guide accessible from the ASPR website. Providers should contact CARS_HelpDesk@cdc.gov or (833) 748-1979 if they have any issues with logging in and completing the steps.

How do I edit my facility's address and hours?

Providers should set up their account the same day they receive it. During this process, they must verify their address, business hours, and license number and expiration date.

To edit a facility's address and hours, providers can navigate to the Receiving Address/Hours section of the provider portal.

How can I remove my facility from the US HHS Therapeutics Locator?

Please email therapeutics@dshs.texas.gov, and DSHS will set the account to Non-Public. Facilities are not able to make this change themselves.

Accessing HPOP

How can I access HPOP?

HPOP can be accessed online at: https://vpop.cdc.gov/provider/signin/.

Requests and Orders

How do I request therapeutics in HPOP?

Providers will place requests for therapeutics in HPOP.

- Click the Create Order button.
- Select the therapeutics to order. It may take up to ten seconds to move to the next window.
- Select the number of patient courses requested.
- Review and confirm request. You may add additional products at this step.

What is the status of my order?

Providers can **view the status** of an order in HPOP by clicking on the order line under the Therapeutics Orders tab. Once an order reaches a status of "Completed," "On-Hold," "Distributed," or "Transmitted" **there is nothing more a Provider needs to do.**

Submitted - Request placed by a provider in HPOP.

Processing – Request is being reviewed by Texas DSHS.

Completed – Texas DSHS has completed the review and the order is waiting for the distributor to do a check of the account before accepting the order.

On Hold – Order completed, but the provider details did not include an AmerisourceBergen (ASD) Account listed in HPOP. ASD reviews these orders and updates the ASD Account number in HPOP for the provider if necessary. After entering a valid ASD Account number, the order shows as Distributed or Transmitted.

Distributed - Order completed and combined for the distributor to pick up.

Transmitted -The distributor downloaded the order.

Shipped - Order has been shipped by the distributor. Tracking information should be available. If a shipment is incorrect or missing, please contact C19Therapies@AmerisourceBergen.com.

Cancelled - A Texas DSHS user canceled the order.

Note: A created order request **does NOT guarantee** that an order will be distributed to the Provider. **It must first be reviewed and approved by Texas DSHS**.

Is there a minimum number of patient courses required to place an allocation request and/or do allocation requests need to be placed in specific increments?

Yes. Each therapeutic is shipped in certain pack sizes and therefore has a specific number of courses that requests must be placed in multiples of. HPOP will require that you order by the pack size for each product.

Contacts

What is a Contact?

A contact is a user that has access to their site(s) within HPOP. They are responsible for verifying that the site information is correct and for required reporting.

How can I view my organization's contacts?

The contacts section shows all the Provider contacts that exist for the Provider. If a provider selects a name, they will be presented with specific information about that user. Every provider needs at least one contact to be designated as the "Primary Contact" to receive products. To edit/view a user, select their name.

Can I add users to my site on HPOP?

Any user for your facility may add additional HPOP users. To create a new contact, click the +. For the "Email" field, enter the user's email. If the user already exists, the next screen will have contact

information prepopulated otherwise the provider will have to fill it out. For the "Primary Contact" field, every Provider will need at least one contact tagged as a primary contact to receive product. After the contact is created, an email will be sent to the contact to activate their account.

How do I edit my provider details?

Navigate to the Provider Details section of the provider portal. This section lists information such as the federal/state pins associated with the provider. To edit provider details, select the Provider Details tab. Select the button with the pen icon to edit the information. Only certain fields are editable by the provider.

Inventory and Reporting

What am I required to report into HPOP?

Providers are required to report twice each week on Mondays and Thursdays
- The number of therapeutics administered/dispensed since their last entry and
- The number of therapeutics courses on-hand

Providers must report Lagevrio and Paxlovid in HPOP. To centralize reporting, facilities will also report unauthorized therapeutics sotrovimab, bam/ete, and REGEN-COV, Evusheld, and USG provided Bebtelovimab in HPOP. Reporting is NOT cumulative; please enter only the courses distributed since the previous entry for that product even if the number is zero. A site does not need to report zeros for products that they do not have in their inventory.

If more training is needed in HPOP reporting, please contact hpop-therapeutics@hhs.gov.

Where do I report the therapeutics I have administered?

Under Courses Administered and Courses Available, for each Therapeutic type a provider has administered/dispensed, providers select the space in the row and enter the total number administered then select **"Save Therapeutic Courses".** After selecting Save, the provider will see a brief pop up saying the saving operation completed successfully. NOTE: After clicking "Save Therapeutic Courses" the columns will still show the data the provider input. These values will remain until the system executes a batch job overnight and saves the data to the History column.

ImmTrac2

Am I required to report to ImmTrac2?

No. As of October, 2022 all reporting was centralized to HPOP. Reporting of all USG supply remains mandatory until all doses delivered are accounted for as administered, wasted (unusable due to damage or expiration), or transferred to another facility. For more information, please visit COVID-19 Guidance for Hospital Reporting and FAQs for Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting (hhs.gov)

How can I transfer my inventory?

Providers can transfer their inventory to another enrolled therapeutic provider. The receiving facility must be active in HPOP and eligible for the same class of therapeutics of the product that is being transferred (i.e. antiviral medication can only be transferred to a site that may order oral antivirals). If

you do not see the site to which you plan to transfer products, please email therapeutics@dshs.texas.gov so that we can enroll that facility. All transfers must follow applicable state and federal laws regarding medication dispensing.

Using this "Transfer" section will not automatically ship product to the provider; this is a mechanism to account for the transfer. Providers must arrange to physically move the medications to the new facility. Select the Add Transfer button and fill out the required information.

Providers may refer patients to facilities who have therapeutics available on hand by visiting the Texas COVID-19 Therapeutics Availability webpage: Therapeutics Locator

Therapeutics Use & Availability

Where can providers find guidelines on therapeutics implementation or administration?

Therapeutics providers can access the Federal Response to COVID-19: Therapeutics Clinical Implementation Guide for outpatient administration of therapeutics for healthcare providers by visiting this webpage: Outpatient Administration Guide for Healthcare Providers This document reviews authorizations, indications, preparation, administration, response to adverse events, site preparation, patient pathways to therapeutics administration, and additional resources.

What are the guidelines for therapeutics storage?

Providers can find information on therapeutics storage by accessing the provider fact sheets for each product here: COVID-19 Therapeutics – Product Information (texas.gov).

What should a provider do with expired therapeutics?

Before removing products from refrigeration, contact the manufacture to confirm expiration dates. Expiration dates may be extended from the expiration date printed on the vial or box.

- Paxlovid: Providers can visit www.pfizermedicalinformation.com or https://www.covid19oralrx-hcp.com/. Providers may contact Pfizer medical at 1-800-438-1985 with questions. See https://www.covid19oralrx-hcp.com/files/hcp-letter-update-for-expiry-date_04Apr2022-003.pdf
- LAGEVRIO: Providers can visit https://www.molnupiravir-us.com/hcp/. Providers may contact Merck at 1-800-444-2080 with questions.
- REGEN-COV (NO LONGER AUTHORIZED): https://www.regencov.com/hcp/resources/faq. Providers may contact Regeneron Medical Information at 1-844-734-6643 with expiration date questions about the products' expiration date.
- BAM/ETE (NO LONGER AUTHORIZED): Providers can visit https://www.covid19.lilly.com/bam-ete or contact the Lilly COVID Hotline at 1-855-545-5921.
    - The shelf-life of both bamlanivimab and etesevimab has been extended from 12 to 18 months. For specific lot information, see https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-20May2022.aspx and https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-12May2022.aspx .
- Sotrovimab (NO LONGER AUTHORIZED): Providers can visit https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-12May2022.aspxProviders can also contact the GSK COVID Contact Center at 1-866-475-2684 with questions.

- Evusheld (NO LONGER AUTHORIZED): Providers can visit https://www.evusheld.com. Therapeutics providers may contact AstraZeneca at 1-800-236-9933 with questions.
- Bebtelovimab(NO LONGER AUTHORIZED): Providers can visit https://www.covid19.lilly.com/bebtelovimab or contact the Lilly COVID Hotline at 1-855-545-5921.

What should a provider do with products that are no longer authorized for use in their area?

Products that no longer are authorized for use in the area should be properly maintained at the facility so that they can be used if/when authorization is returned for use against future variants. Some of the products that are currently not authorized could potentially be useful again in the future.

What is the current availability of therapeutics at the national level? How does that impact the availability of therapeutics in Texas?

There is no shortage of COVIID-19 therapeutics. Clinicians should review the NIH guidelines to determine the best course of treatment for their patients.

DSHS will continue to allocate therapeutics for the state of Texas for as long as U.S. HHS requires allocation.

Are ancillary kits included with COVID-19 therapeutic shipments?

Ancillary kits are not included in shipments of COVID-19 therapeutic products or supplied by DSHS. Providers will need to order ancillary supplies directly from their medical supply company.

Troubleshooting

How can providers change their shipping addresses?

Enrolled providers can update their shipping address in HPOP.

What should I do if I receive an error message when attempting to place a therapeutics allocation request?

Be sure not to use Internet Explorer to access HPOP. If you encounter errors with HPOP, please email cars_helpdesk@cdc.gov or call (833) 748-1979.

What should I do if I received the wrong shipment?

Contact the distributor, AmerisourceBergen, for missing or incorrect shipments at C19Therapies@AmerisourceBergen.com.

Resources

Who can I contact for support?

- If you need the activation email resent, please email therapeutics@dshs.texas.gov
- For issues logging into HPOP, please email cars_helpdesk@cdc.gov or call (833) 748-1979.
- For password resets, please use the "I forgot my password..." link on the sign-in screen.
- Access HPOP user documents from the Help button in the menu bar in HPOP

⑦ Help ∨
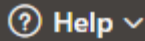
- For commercially purchased bebtelovimab, please contact
  asdaccountsetup@amerisourcebergen.com

Who will be my point of contact for additional allocation request support?

Provider support can be reached at Therapeutics@dshs.Texas.gov

How can providers or the public find facilities with therapeutics?

See the US HHS Therapeutics Locator at: https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/.
The link lists all public Therapeutic facilities in HPOP that have received an order of therapeutic) within
the last two months and/or have reported availability of therapeutic vaccine inventory within the last
two weeks. This locator is only for USG-supplied therapeutics and also shows outpatient Veklury
(remdesivir) provider sites which have opted to appear on the locator tool. Please note, outpatient
Veklury (remdesivir) is commercially available and not currently distributed by the U.S. Government.
This data may not be complete and Veklury (remdesivir) may have associated costs for patients related
to the medication. Please see "How do I find COVID-19 Therapeutics and Test to Treat Locator Tools"
section for more information.

Where can providers find more information and ask other questions about therapeutics?

The Office of the Assistant Secretary for Preparedness and Response hosts bi-weekly national office
hours plus additional clinical information sessions where providers can ask their therapeutics-related
questions. Please email COVID-19.Therapeutics@hhs.gov to request invitations and schedules.

Helpful Links

- Texas Department of State Health Service COVID-19 Therapeutics Information:
  https://dshs.texas.gov/coronavirus/therapeutics/
- COVID-19 Therapeutics | HHS/ASPR
- COVID-19 Therapeutics Locator: https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/
- National Allocations of Therapeutics to States and Territories: State/Territory-Coordinated
  Distribution of COVID-19 Therapeutics (hhs.gov)
- CDC COVID Data Tracker: https://covid.cdc.gov/covid-data-tracker/