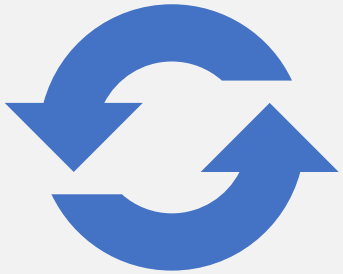
# COVID-19 Therapeutics Product Guide

March 15, 2022

# Overview of this Product Guide

The following guide provides an overview of the COVID-19 therapeutics products allocated by Texas DSHS, including their availability, request methods, reporting requirements, shipping timelines, and helpful resources.



Note: We receive new information and system changes frequently. Please review the DSHS therapeutics website for regular updates. You can also subscribe to DSHS' weekly Therapeutics eNewsletter by emailing therapeutics@dshs.Texas.gov.

# Table of Contents

# COVID-19 Therapeutics Products Distributed by DSHS

## Below you can find a list of the COVID-19 Therapeutics products distributed by DSHS:

| Therapeutic Name | Type/Form Details | Manufacturer | Manufacturer Contact Information | Fact Sheets | VAOS Ordering Request | Availability |
|---|---|---|---|---|---|---|
| Molnupiravir | Antiviral Pill | Merck | 1-800-444-2080 | - Healthcare Providers<br>- Recipients and Caregivers | No | Distributed to a predetermined list |
| Paxlovid | Antiviral Pill | Pfizer | 1-800-438-1985 | - Healthcare Providers<br>- Recipients and Caregivers | No | Distributed to a predetermined list |
| Evusheld | Intramuscular Injection | AstraZeneca | 1-800-236-9933 | - Healthcare Providers<br>- Recipients and Caregivers | No | Distributed to a predetermined list |
| Sotrovimab | IV Infusion | GSK | 1-866-475-2684 | - Healthcare Providers<br>- Recipients and Caregivers | Yes | Limited availability |
| Bebtelovimab | IV Injection | Eli Lilly | 1-855-545-5921 | - Healthcare Providers<br>- Recipients and Caregivers | No | Distributed to a predetermined list |

# COVID-19 Therapeutics Products No Longer Authorized

**The following products are no longer FDA authorized. Please review the most recent DSHS communication:**

| Therapeutic Name | Type/Form Details | Manufacturer | Manufacturer Contact Information | Fact Sheets | VAOS Ordering Request | Availability |
|---|---|---|---|---|---|---|
| Bam/Ete | IV Infusion | Eli Lily | 1-855-545-5921 | - Healthcare Providers<br>- Recipients and Caregivers | No (Ordering Paused) | Request Only |
| REGEN-COV | IV Infusion or subcutaneous injection | Regeneron | 1-844-734-6643 | - Healthcare Providers<br>- Recipients and Caregivers | No (Ordering Paused) | Request Only |

# Sotrovimab

| Description | Details |
|---|---|
| Manufacturer | GlaxoSmithKline (GSK) |
| Administration Type | Intravenous Infusion (IV) |
| Order Pack Sizes | 12 patient courses: Providers must request Sotrovimab in multiples of 12 courses. |
| Availability | Providers are currently able to request allocations of Sotrovimab in VAOS. For guidance on placing a request, see the Allocation Guide. |
| Reporting Requirements | For Hospitals: Weekly reporting to TDEM of courses on-hand and administered<br>For Non-Hospitals: Weekly reporting to HHS Teletracking of courses on-hand and administered<br>All: Patient-level data within 30 days of administration to ImmTrac2 |
| Summary Authorization Statement | https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#:~:text=22%2C%202021)%20(161KB)-,For%20the,-treatment%20of%20mild |

| Resource | Link/Contact |
|---|---|
| Provider Fact Sheet | https://www.fda.gov/media/149534/download |
| Patient Fact Sheet (English) | https://www.fda.gov/media/149533/download |
| Patient Fact Sheet (Spanish) | https://www.sotrovimab.com/content/dam/cf-pharma/hcp-sotrovimab-phase2/en_US/sotrovimab-eua-fact-sheet-for-patients-in-spanish.pdf |
| GSK Sotrovimab Site | https://www.sotrovimab.com/?cc=ps_WX47F4UZG81040671&mcm=300000&gclid=76b80e837c9f1fa7c4526fd8512974e1&gclsrc=3p.ds& |
| GSK COVID Contact Center | 1-866-475-2684 |

# Bebtelovimab

| Description | Details |
|---|---|
| Manufacturer | Eli Lilly and Company |
| Administration Type | Intravenous Infusion (IV) |
| Availability | As of March 9, 2022: Bebtelovimab is not available for order directly in VAOS. The ordering process is being developed, and it will be available to order requests in the next several weeks. In the meantime, if you would like to be considered for an allocation, please place a request for Sotrovimab and select “Willing to accept another product” on the request form. |
| Reporting Requirements | Daily reporting to HPOP of number of courses dispensed and on-hand.<br>Patient-level reporting to ImmTrac2 within 30 days of dispensing. |
| Summary Authorization Statement | https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#:~:text=Bebtelovimab%20is%20authorized,or%20clinically%20appropriate. |

| Resource | Link/Contact |
|---|---|
| Provider Fact Sheet | https://www.fda.gov/media/156151/download |
| FDA FAQ | https://www.fda.gov/media/156154/download |
| Bebtelovimab Webpage | https://www.covid19.lilly.com/bebtelovimab |
| Lilly COVID Hotline | 1-855-545-5979 |

# Molnupiravir

| Description | Details |
|---|---|
| Manufacturer | Pfizer |
| Administration Type | Oral |
| Availability | Pharmacies enrolled to dispense molnupirvair can email therapeutics@dshs.Texas.gov to request courses in the next coming allocation. Requests must be in multiples of 10 courses. |
| Reporting Requirements | Daily reporting to HPOP of number of courses dispensed and on-hand<br>Patient-level reporting to ImmTrac within 30 days of dispensing |
| Summary Authorization Statement | https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#:~:text=Molnupiravir%20is%20authorized,or%20clinically%20appropriate |

| Resource | Link/Contact |
|---|---|
| Provider Fact Sheet | https://www.fda.gov/media/155054/download |
| FDA FAQ | https://www.fda.gov/media/155056/download |
| Molnupiravir Site | https://www.molnupiravir-us.com/hcp/ |
| Merck Contact | 1-800-444-2080 |

# Paxlovid

| Description | Details |
|---|---|
| Manufacturer | Pfizer |
| Administration Type | Pills |
| Availability | Pharmacies enrolled to dispense Paxlovid can email therapeutics@dshs.Texas.gov to request courses in the next coming allocation. Requests must be in multiples of 12 courses. |
| Reporting Requirements | Daily reporting to HPOP of number of courses dispensed and on-hand<br>Patient-level reporting to ImmTrac within 30 days of dispensing |
| Summary Authorization Statement | https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#:~:text=Paxlovid%20is%20authorized,hospitalization%20or%20death |

| Resource | Link/Contact |
|---|---|
| Provider Fact Sheet | https://www.fda.gov/media/155050/download |
| FDA FAQ | https://www.fda.gov/media/155052/download |
| Pfizer Medical Information | www.pfizermedicalinformation.com |
| Paxlovid Health Care Provider Site | https://www.covid19oralrx-hcp.com/ |
| Pfizer Medical | 1-800-438-1985 |

# Evusheld

| Description | Details |
|---|---|
| Manufacturer | AstraZeneca |
| Administration Type | Intramuscular Injection |
| Availability | Providers enrolled to provide Evusheld can email therapeutics@dshs.Texas.gov to request courses. |
| Reporting Requirements | Daily reporting to HPOP of courses on-hand and administered<br>Patient-level reporting to ImmTrac within 30 days of administration |
| Summary Authorization Statement | https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#:~:text=For%20emergency%20use,vaccine%20component(s). |

| Resource | Link/Contact |
|---|---|
| Provider Fact Sheet | https://www.fda.gov/media/154701/download |
| FDA FAQ | https://www.fda.gov/media/154703/download |
| Evusheld Webpage | https://www.evusheld.com/splash.html |
| Astrazeneca Contact | 1-800-236-9933 |

# Bamlanivimab plus Etesevimab

| Description | Details |
|---|---|
| Manufacturer | Eli Lilly |
| Administration Type | Intravenous Infusion (IV) |
| Availability | Bam/Ete is paused for allocation requests in VAOS. For more information, please view the most recent DSHS communication |
| Reporting Requirements | For Hospitals: Weekly reporting to TDEM of courses on-hand and administered<br>For Non-Hospitals: Weekly reporting to HHS Teletracking of courses on-hand and administered<br>All Patients Data within 30 days of Administration to HHS |
| Summary Authorization Statement: | https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#:~:text=bamlanivimab/etesevimab%20(ASPR)-,Bamlanivimab,-and%20etesevimab%20administered |

**NO LONGER AUTHORIZED**

**NO LONGER AVAILABLE FOR ORDERING**

| Resource | Link/Contact |
|---|---|
| Provider Fact Sheet | https://www.fda.gov/media/145802/download |
| Patient Fact Sheet (English) | https://www.fda.gov/media/145803/download |
| Patient Fact Sheet (Spanish) | https://www.fda.gov/media/148713/download |
| Eli Lilly Bam/Ete Site | https://www.covid19.lilly.com/bam-ete |
| Lilly COVID Hotline | 1-855-545-5921 |

# REGEN-COV

| Description | Details |
|---|---|
| Manufacturer | Regeneron |
| Administration Type | Intravenous Infusion (IV) or subcutaneous injection (SQ) |
| Availability | Bam/ete is paused for allocation requests in VAOS. For more information, please view the most recent DSHS communication |
| Reporting Requirements | For Hospitals: Weekly reporting to TDEM of courses on-hand and administered<br>For Non-Hospitals: Weekly reporting to HHS Teletracking of courses on-hand and administered<br>All: Patient-level data within 3 days of administration to [illegible] |
| Summary Authorization Statement: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#:~:text=Casirivimab%20and%20imdevimab%20to,including%20hospitalization%20or%20death. | |

**NO LONGER AUTHORIZED**

**NO LONGER AVAILABLE FOR ORDERING**

| Resource | Link/Contact |
|---|---|
| Provider Fact Sheet | https://www.fda.gov/media/145802/download |
| Patient Fact Sheet (English) | https://www.fda.gov/media/145803/download |
| Patient Fact Sheet (Spanish) | https://www.fda.gov/media/148713/download |
| FAQ | https://www.regencov.com/hcp/resources/faq |
| Regeneron Medical Information | 1-844-734-6643 |

# No Cost to Therapeutics Providers

US HHS has purchased these therapeutics and they are provided to facilities at no cost. Providers may not charge for the medication itself. Providers can seek reimbursement for the administration or dispensing of the therapeutics.

# Provider Mandatory Reporting
# *Medication Errors & Serious Adverse Events*

- Submit adverse event reports to FDA MedWatch using one of the following methods:
  - Complete and submit the report online: www.fda.gov/medwatch/report.htm, or
  - Complete and submit a postage-paid FDA Form 3500 (https://www.fda.gov/media/76299/download) and return by:
    - Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or
    - Fax (1-800-FDA-0178), or
  - Call 1-800-FDA-1088 to request a reporting form.
- In addition, please provide a copy of all FDA MedWatch forms to the appropriate therapeutic manufacturer:

## Therapeutics Manufacturer's Contact Information

**Bam/Ete - Eli Lilly and Company, Global Patient Safety**
Fax: 1-317-277-0853
E-mail: mailindata_gsmtindy@lilly.com
Or call Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921)

**Regen-COV – Regeneron Pharmaceuticals**
Or call Regeneron Pharmaceuticals at 1-844-734-6643

**BAM/ETE AND REGEN-COV NO LONGER AUTHORIZED**
**NO LONGER AVAILABLE FOR ORDERING**

**Sotrovimab – GlaxoSmithKline, Global Safety**
Fax: 919-287-2902
Email: WW.GSKaereportingUS@gsk.com
Or call GSK COVID contact center at 1-866-GSK-COVID (866-475-2684)

**Lilly - Bebtelovimab**
Call: 1-855-545-5979
Website: https://www.covid19.lilly.com/bebtelovimab/hcp

**Paxlovid - Pfizer Safety**
Fax: 1-800-438-1985
Website: https://www.pfizersafetyreporting.com/#/en
Or call Pfizer Safety at 1-866-635-8337

**Evusheld - AstraZeneca**
Fax: 1-866-742-7984
Website: https://contactazmedical.astrazeneca.com
Or call AstraZeneca safety at 1-800-236-9933

**Molnupiravir - Merck**
Fax: 215-616-5677
E-mail: dpoc.usa@msd.com
For voluntary pregnancy reporting: 1-877-888-4231 or pregnancyreporting.msd.com (Requires agreement from patient and provider)

# Reporting Requirements

Providers must report the amount **administered**/dispensed since last entry (which should be the day before) and current **on hand** amounts for each product for Paxlovid, molnupiravir, Evusheld, and bebtelovimab to **HPOP daily**. Providers can find a help guide for HPOP here: Oracle HPoP Provider Portal - Get Started.

**Reporting of sotrovimab remains in the old reporting systems. Hospitals** must report administration and courses on hand for **sotrovimab** into **TDEM portal daily**. Non-hospitals must report to HHS TeleTracking.

**All providers are required to report administration of COVID-19 therapeutics to ImmTrac2 within 30 days of administration.**

| | Molnupiravir, Paxlovid, Bebtelovimab, and/or Evusheld | Sotrovimab |
|---|---|---|
| **Hospital *** | HPOP, ImmTrac2 | TDEM, ImmTrac2 |
| **Non-Hospital** | HPOP, ImmTrac2 | Teletracking, ImmTrac2 |

* A facility is considered a "Hospital" for DSHS reporting purposes if they are mandated to report per the HHS per the CMS CoP.

**Reporting is required. Adherence to reporting requirements is crucial, as it affects the allocations the state receives.**

# Provider Tools

# HHS New COVID-19 Therapeutics Locator

Providers can use the New US HHS COVID-19 Therapeutics locator to find locations with available Paxlovid, Molnupiravir, Evusheld, Bebtelovimb, and Sotrovimab.

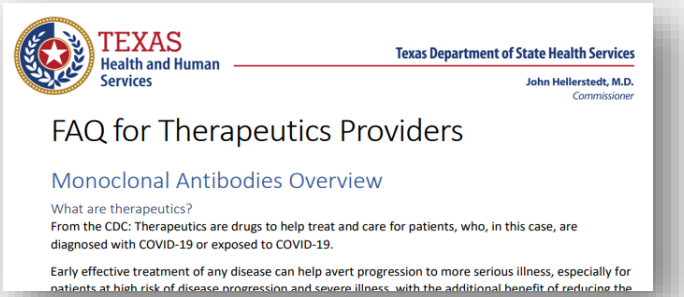

https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/

# Reference Guides

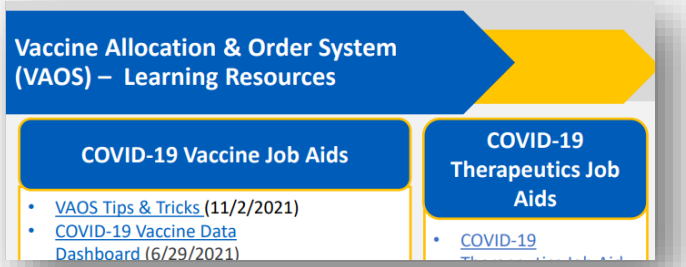
Providers may refer to the following resources for more specific guidance:


[Therapeutics Webpage]
For most therapeutics updates and resources.

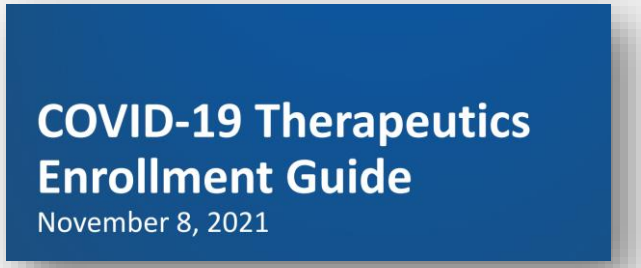

[Therapeutics Allocation Request Guide]
For a walkthrough of how to place an allocation request for therapeutics in VAOS.



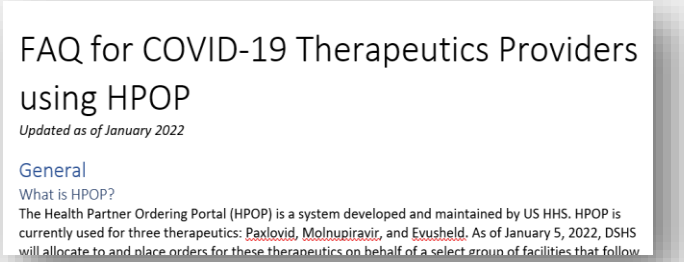

[Therapeutics FAQ]
For more detailed answers to common questions.




[VAOS Catalog]
For a list of guides on specific VAOS actions.




[Therapeutics Enrollment Guide]
For how to enroll as a therapeutics provider.




[HPOP FAQ]
For answers specific to HPOP.