COVID-19 Therapeutics Product Guide

January 26, 2022

Overview of this Product Guide

The following guide provides an overview of the COVID-19 therapeutic 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.

One of the most effective ways to stay up-to-date with current COVID-19 therapeutics news is by subscribing to DSHS' weekly Therapeutics eNewsletter. Email therapeutics@dshs.Texas.gov to be added to the eNewsletter mailing list.

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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 - Recipients and Caregivers	No	Distributed to a predetermined list
Paxlovid	Antiviral Pill	Pfizer	1-800-438-1985	- Healthcare Providers - Recipients and Caregivers	No	Distributed to a predetermined list
Evusheld	Intramuscular Injection	AstraZeneca	1-800-236-9933	- Healthcare Providers - Recipients and Caregivers	No	Distributed to a predetermined list
Sotrovimab	IV Infusion	GSK	1-866-475-2684	- Healthcare Providers - Recipients and Caregivers	Yes	Limited availability

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 - Recipients and Caregivers	No (Ordering Paused)	Request Only
REGENCOV	IV Infusion or subcutaneous injection	Regeneron	1-844-734-6643	- Healthcare Providers - Recipients and Caregivers	No (Ordering Paused)	Request Only

Sotrovimab

Description	Details
Manufacturer	GlaxoSmithKline (GSK)
Administration Type	Intravenous Infusion (IV)
Availability	Providers are currently able to request allocations of Sotrovimab in VAOS. However, as of January 11, 2022, demand for Sotrovimab far exceeds its supply throughout the state. For guidance on placing a request, see the Allocation Guide.
Reporting Requirements	For Hospitals: Weekly reporting to TDEM of courses on-hand and administered For Non-Hospitals: Weekly reporting to HHS Teletracking of courses on-hand and administered 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

Molnupiravir

Description	Details
Manufacturer	Pfizer
Administration Type	Oral
Availability	Distributed by DSHS to a predetermined list of providers
Reporting Requirements	Daily reporting to HPOP of number of courses dispensed and on-hand 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	Distributed by DSHS to a predetermined list of providers
Reporting Requirements	Daily reporting to HPOP of number of courses dispensed and on-hand 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	Distributed by DSHS to a predetermined list of providers
Reporting Requirements	Daily reporting to HPOP of courses on-hand and administered 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 For Non-Hospitals: Weekly reporting to HHS Teletracking of courses on-hand and administered All Patient-level data within 3 Days of administration in VAOS
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 For Non-Hospital: Weekly Reporting to HHS Tele-tracking of courses on-hand and administered All Patient-level data within 30 days of administration or immediately
Summary Authorization Statement: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#:~:text=as%20well%20as%20bamlanivimab%20and%20etesevimab%20to%20include%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 but 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_g[illegible]
Or call Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921)

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Regen-COV – Regeneron Pharmaceuticals
Fax: 1-888-876-2736
E-mail: medical.inform[illegible]
Or call Regeneron Pharmaceuticals at 1-844-734-6643

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

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)

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

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

All providers are required to report to ImmTrac2. Paxlovid, Molnupiravir, Evusheld, and Sotrovimab **administration** and **on-hand amounts** need to be reported to ImmTrac2 **daily**. **Additional reporting** requirements vary by product and institution type.

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

Hospitals are also required to report both administration and courses on hand for **Sotrovimab** into **Teltracking daily**.

	Molnupiravir, Paxlovid, 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.

How to Request Therapeutics

Paxlovid, Evusheld, and Molnupiravir are currently only available to a predetermined list of providers, as DSHS begins to roll out the ordering and allocation system for these new drugs.

The therapeutics bam/ete and REGEN-COV are **no longer authorized for use** and no longer available for requests in VAOS. For more information, please review this DSHS communication.

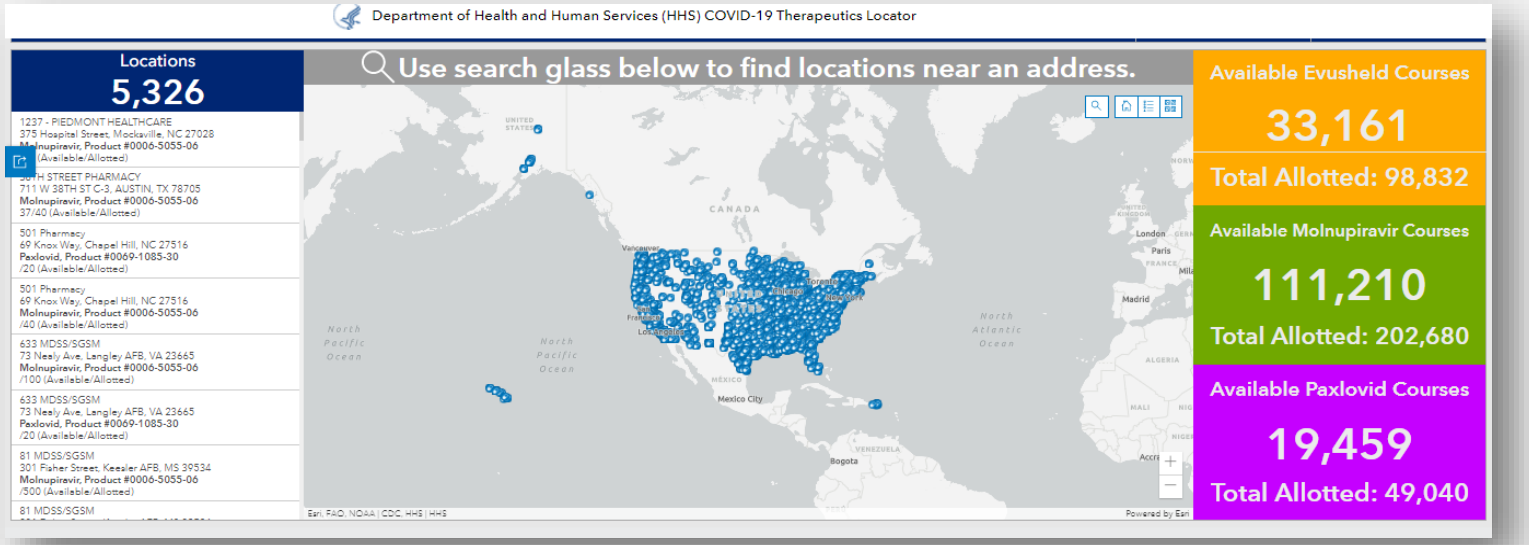
Providers can request allocations of Sotrovimab through VAOS. However, supply is currently low relative to demand.

Providers may contact therapeutics@dshs.Texas.gov or call (833) 832-7069, Option 0 if they have any questions.

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, and Evusheld.



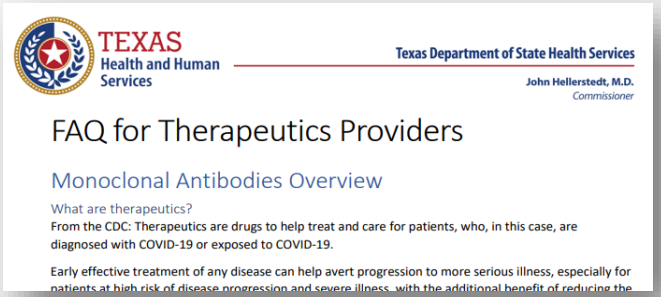
https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/

Reference Guides

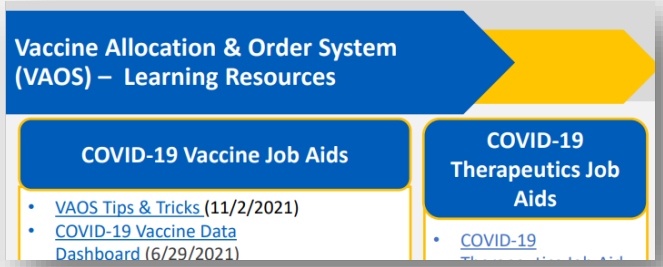
Providers may refer to the following resources for more specific guidance:

[Therapeutics Webpage]
For most therapeutics updates and resources.

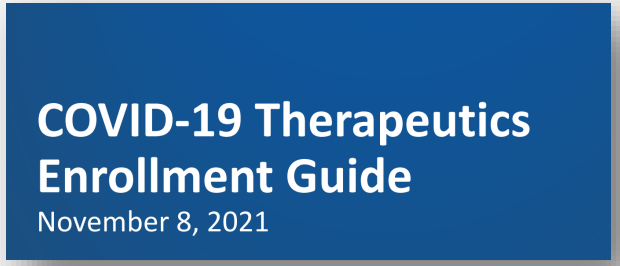
[Therapeutics Allocation Request Guide]
For a walkthrough of how to place an allocation request for therapeutics in VAOS.



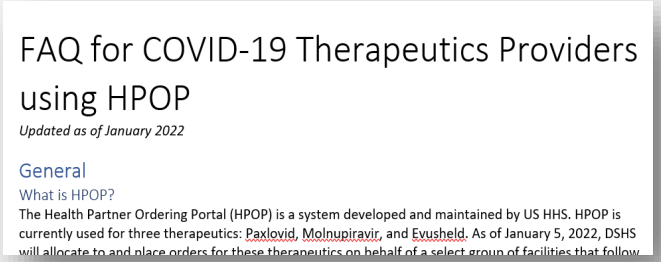
[Therapeutics FAQ]
For more detailed answers to common questions.



[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.