COVID-19 Therapeutics Product Guide

June 17, 2022

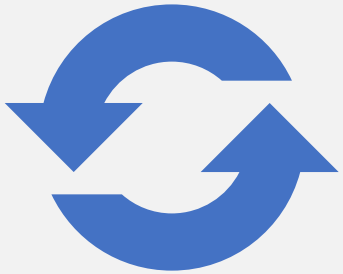
TEXAS Health and Human Services
Texas Department of State Health Services

Overview of this Product Guide

This guide provides an overview of the COVID-19 therapeutics products allocated by Texas DSHS.

Providers should refer to current clinical guidance and available resources to select the most appropriate therapeutic for their patients.

- Interim Clinical Considerations for COVID-19 Treatment in Outpatients (CDC)
- Therapeutic Management of Nonhospitalized Adults With COVID-19 (NIH)
- Side-by-Side Overview of COVID-19 Therapeutics (ASPR)
- COVID-19 Therapies (NIH)



Note: We receive new information and system changes frequently. Please review the DSHS therapeutics website for regular updates and subscribe to the weekly DSHS Therapeutics eDigest by emailing therapeutics@dshs.texas.gov.

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COVID-19 Therapeutics Products

COVID-19 Therapeutics products distributed by DSHS:

Therapeutic Name	Order in HPOP in Multiples of:	Manufacturer Contact Information	Fact Sheets
Paxlovid (ritonavir-boosted nirmatrelvir)	300 mg nirmatrelvir with 100 mg ritonavir: 20 patient courses 150 mg nirmatrelvir with 100 mg ritonavir (Renal Paxlovid): 5 patient courses	1-800-438-1985	- Healthcare Providers - Recipients and Caregivers
Bebtelovimab	5 patient courses	1-855-545-5921	- Healthcare Providers - Recipients and Caregivers
Lagevrio (molnupiravir)	24 patient courses	1-800-444-2080	- Healthcare Providers - Recipients and Caregivers
Evusheld (tixagevimab co-packaged with cilgavimab)	24 cartons (1 carton = 150 mg tixagevimab plus 150 mg cilgavimab)	1-800-236-9933	- Healthcare Providers - Recipients and Caregivers

Paxlovid

Description	Details
Manufacturer	Pfizer
Administration	Oral
Availability	Pharmacies enrolled to dispense Paxlovid can order in HPOP. Requests must be in multiples of 20 courses.
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

Bebtelovimab

Description	Details
Manufacturer	Eli Lilly and Company
Administration	Intravenous injection over 30 seconds followed by a monitoring period.
Availability	Providers enrolled to receive monoclonal antibodies can request in HPOP.
Reporting Requirements	Twice-weekly reporting (Mondays and Thursdays) in HPOP of number of courses administered and on-hand. Patient-level reporting to ImmTrac2 within 30 days of administering.
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/156152/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

Lagevrio

Description	Details
Manufacturer	Pfizer
Administration	Oral
Availability	Pharmacies enrolled to dispense Lagevrio can order in HPOP. Requests must be in multiples of 24 courses.
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

Evusheld

Description	Details
Manufacturer	AstraZeneca
Administration	Intramuscular Injection
Availability	Providers enrolled for 'Monoclonal Antibody Special' in HPOP can request Evusheld cartons 1 carton = 150 mg tixagevimab plus 150 mg cilgavimab.
Reporting Requirements	Report on-hand inventory and administration in HPOP on Mondays and Thursdays in HPOP. Evusheld is reported by number of cartons (150 mg tixagevimab/150 mg cilgavimab). Patient receiving 300 mg each of tixagevimab/cilgavimab would be reported as TWO units (cartons or courses) 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/
AstraZeneca Contact	1-800-236-9933

COVID-19 Therapeutics Products No Longer Authorized

The following products are no longer FDA authorized.

Therapeutic Name	Type/Form Details	Manufacturer	Manufacturer Contact Information	Fact Sheets
Bam/Ete	IV Infusion	Eli Lily	1-855-545-5921	- Healthcare Providers - Recipients and Caregivers
REGEN-COV	IV Infusion or subcutaneous injection	Regeneron	1-844-734-6643	- Healthcare Providers - Recipients and Caregivers
Sotrovimab	IV Infusion	GSK	1-866-475-2684	- Healthcare Providers - Recipients and Caregivers

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 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[illegible]

NO LONGER AUTHORIZED

NO LONGER AVAILABLE FOR ORDERING

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

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 to HHS Tracking
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
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

NO LONGER AUTHORIZED

NO LONGER AVAILABLE FOR ORDERING

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-Hospitals: Weekly reporting to HHS Teletracking of courses on-hand and administered All: Patient Intended to receive within 10 days of administration Must Be C
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 may seek reimbursement for the **medical evaluation** of the patient and the **administration** of the medication.

Pharmacies **may seek reimbursement from insurance** including Medicare and Medicaid for **dispensing fees** for the oral antivirals but may not pass the dispensing fee to the patient.

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
Fax: 1-888-876-2736
E-mail: medical.information@regeneron.com
Or call Regeneron Pharmaceuticals at 1-844-734-6643

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)

BAM/ETE, REGEN-COV, and Sotrovimab NO LONGER AUTHORIZED
NO LONGER AVAILABLE FOR ORDERING

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

Lagevrio - Merck
Fax: 215-616-5677
E-mail: dpoc.usa@msd.com

Reporting Requirements

Providers must report in HPOP twice per week on Mondays and Thursdays.

- HPOP reporting includes:
  - The count of patient courses **administered**/dispensed since last entry and
  - The count of patient courses currently **on hand**.
- Providers can find a help guide for HPOP here: Oracle HPoP Provider Portal - Get Started.

Note: Evusheld is reported by cartons (150 mg tixagevimab/150 mg cilgavimab).

Reporting of BAM/ETE, REGEN-COV, and Sotrovimab remains in the legacy reporting systems until moved into HPOP. Hospitals must report administration and courses on hand for sotrovimab into TDEM portal weekly. Non-hospitals must report to HHS TeleTracking weekly.

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

	Lagevrio, 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 COVID-19 Therapeutics Locator

Providers can use the US HHS COVID-19 Therapeutics locator to find locations with available Paxlovid, Renal Paxlovid, Evusheld, Lagevrio, and Bebtelovimab.

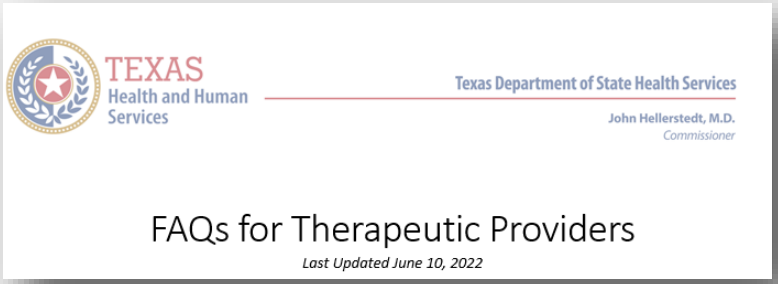
https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/

Reference Guides

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

[Therapeutics Webpage]

For therapeutics updates and resources.



[FAQ for Therapeutic Providers]

For therapeutics and HPOP questions.