



FAQ for Therapeutics Providers

Monoclonal Antibodies Overview

What are therapeutics?

From the CDC: Therapeutics are drugs to help treat and care for patients, who, in this case, are diagnosed with COVID-19 or exposed to COVID-19.

Early effective treatment of any disease can help avert progression to more serious illness, especially for patients at high risk of disease progression and severe illness, with the additional benefit of reducing the burden on healthcare systems. A number of novel therapeutics, e.g., monoclonal antibodies (mAbs) are available under EUA for early outpatient treatment. Trials to assess the potential effectiveness of these therapeutics in outpatients at high risk of disease progression are ongoing. Clinicians and patients who wish to consider their use, or the use of any other available investigational therapeutic, should review the [COVID-19 Treatment Guidelines](#) as well as the FDA EUA for the therapy. Health system administrators should be aware that a number of these agents are intended for outpatient intravenous infusion and be prepared to provide such care in a location and [manner in which patients with COVID-19 can be safely managed](#).

Read more from the CDC about therapeutics: [Information for Clinicians on Investigational Therapeutics for Patients with COVID-19](#)

How do monoclonal antibodies work?

From the Texas Department of Health and Human Services: The FDA has issued emergency use authorizations (EUAs) for a number of these monoclonal antibody treatments. These antibodies are made in a lab and can be given to a person with COVID-19 to quickly start fighting the SARS-CoV-2 virus (the virus that causes COVID-19).

Which monoclonal antibodies are available through Texas DSHS?

The mAbs currently available through VAOS are as follows:

- Bamlanivimab plus etesevimab
 - Manufacturer: Eli Lilly
- REGEN-COV (casirivimab/imdevimab).
 - Manufacturer: Regeneron
- Sotrovimab
 - Manufacturer: GlaxoSmithKline

Where can I find more information about each of the therapeutics available?

The following fact sheets offer more information about the therapeutics available:

- bam/ete Fact Sheets
 - Provider fact sheet: <https://www.fda.gov/media/145802/download>
 - Patient fact sheet: <https://www.fda.gov/media/145803/download>
 - Patient fact sheet (Spanish): <https://www.fda.gov/media/148713/download>
- REGEN-COV Fact Sheets
 - Provider fact sheet: <https://www.fda.gov/media/145611/download>
 - Patient fact sheet: <https://www.fda.gov/media/145612/download>



- Patient fact sheet (Spanish): <https://www.fda.gov/media/151404/download>
- FDA Frequently Asked Questions: <https://www.fda.gov/media/143894/download>
- REGEN-COV information from manufacturer: [Casirivimab and Imdevimab \(regeneron.com\)](https://www.regeneron.com)
- Sotrovimab
 - Provider fact sheet: <https://www.fda.gov/media/149534/download>
 - Patient fact sheet: <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

Provider System (VAOS) Access & Ordering

How can I submit an order?

You can submit your therapeutics order requests through the Vaccine Allocation & Ordering System (VAOS), the platform built for the distribution and management of vaccines and therapeutics. For more information about VAOS and using the platform to order therapeutics, see the [COVID-19 Therapeutics Enrollment Guide](#) for more information.

Who can submit an order for therapeutics?

To order therapeutics, you will need to be registered as a therapeutics provider with AmerisourceBergen, and you will need a VAOS account. For details on enrolling as a therapeutics provider and registering for these accounts, please see the [COVID-19 Therapeutics Enrollment Guide](#).

What is VAOS?

VAOS is an abbreviation for the Vaccine Allocation & Ordering System, the platform that is used to manage and order COVID-19 vaccines and therapeutics. To register for a VAOS account, please see the [COVID-19 Therapeutics Enrollment Guide](#).

How many VAOS users can each account have?

A facility can have two vaccine coordinators in VAOS (one primary and one backup coordinator) and another two therapeutics coordinators. Therapeutics coordinators will only be able to request COVID-19 therapeutics and won't have access to inventory management or vaccine requests.

How can I order therapeutics through VAOS?

If you are a vaccine coordinator in VAOS and have registered with AmerisourceBergen (ABC), you should currently be able to order therapeutics. You can review the COVID-19 Therapeutics Ordering Request job aid for step-by-step instructions on placing a COVID-19 therapeutics order request in VAOS: <https://www.dshs.texas.gov/immunize/covid19/COVID-19-Therapeutics-Job-Aid.pdf>.

You can also view this provider webinar ([COVID-19 Monoclonal Antibody \(mAb\) Therapeutics Provider Webinar](#) from 9/20/21) or the webinar slides (<https://www.dshs.texas.gov/immunize/covid19/COVID-Therapeutics-Provider-Webinar-092021.pdf>) to learn more about how to order therapeutics in VAOS.

If you are not enrolled as a therapeutics provider with AmerisourceBergen, and/or do not have a VAOS account, please see the [COVID-19 Therapeutics Enrollment Guide](#).



How can I enroll as a therapeutics provider?

For details on enrolling as a therapeutics provider, please see the [COVID-19 Therapeutics Enrollment Guide](#).

Can more than two users per facility have access to VAOS?

Yes, providers will be allowed to request access for two additional people to be indicated as Therapeutics coordinators. Therapeutics coordinators will only be able to request COVID-19 therapeutics and won't have access to inventory management or vaccine requests. For more information about adding coordinators to your VAOS account, please see the detailed guide on enrolling for VAOS: [COVID-19 Therapeutics Enrollment Guide](#).

Can I order etesevimab (ete) alone if I already have bamlanivimab (bam) on hand?

You can email therapeutics@dshs.texas.gov, and DSHS can order etesevimab by itself to match your on-hand BAM.

Who will be my point of contact for additional ordering support?

Provider support can be reached at Therapeutics@dshs.Texas.gov or 833-832-7068, option 0.

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

If you are ordering REGEN-COV, then your order must be in multiples of 12 patient courses. If you are ordering bam/ete, then your order must be in multiples of 10 patient courses. If you are ordering Sotrovimab, then your order must be in multiples of 12 patient courses. For more information on ordering COVID-19 therapeutics, please see the [COVID-19 Therapeutics Job Aid](#).

How can I view my order status?

Once an order request has been confirmed by ABC, an email will be sent from noreply@ASDHealthcare.com to the point of contact of the facility.

Two days before your shipment is scheduled to be delivered, ABC will send another email including shipping information to the point of contact of your facility from c19therapies@amerisourcebergen.com. This email notification from ABC is only sent to the point of contact. To change the point of contact please email c19therapies@amerisourcebergen.com.

You can use your ABC account number to track your shipment by going to the following website:

AmerisourceBergen – Track My Shipment:

<https://asdorder.amerisourcebergen.com/btstoreui/trackmyshipment>

When should I place my order request? What is the expected wait time between placing my order request and receiving my shipment?

Providers may enter requests at any time. To be considered for the current week's shipments, place your orders by **5 PM on Thursday**. Currently, order requests placed in VAOS for therapeutics may take about a week until shipped. Shipments will only arrive on weekdays.



Whom should I contact if I am experiencing an SSO error or account lockout?

To receive access to your account or resolve your SSO error, contact Therapeutics@dshs.Texas.gov or 833-832-7068 (option 0).

How can I find other local infusion sites?

To locate other infusion sites nearby, please follow this link:

<https://tdem.maps.arcgis.com/apps/webappviewer/index.html?id=993e2c2079f8487cafcec74e00e8499>

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How much does it cost to order therapeutics?

Order requests for bam/ete (bamlanivimab/etesevimab), REGEN-COV (casirivimab/imdevimab), and Sotrovimab are at no cost. You can seek reimbursement for the administration of the vaccine. Questions on billing may be addressed with the DSHS webpage for Information for Hospitals & Healthcare Professionals, under "Billing and Coding":

<https://www.dshs.texas.gov/coronavirus/healthprof.aspx#thera>.

Therapeutics Reporting

Where do I need to report that I've administered therapeutics?

Every facility is required to report therapeutics administration to ImmTrac2 as well as other systems, depending on the type of facility and the therapeutic being reported.

As of November 23, 2021, non-hospitals no longer need to report therapeutics administration to TDEM.

Additional reporting requirements vary depending on the facility type and therapeutics the facility provides, as listed in the chart below:

	Molnupiravir and/or AZD7442	BAM/ETE, REGEN-COV, and/or 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](#)

Do TDEM records upload to TeleTracking?

DSHS uploads data reported to TDEM to HHS TeleTracking only for hospitals who are mandated to report per the [HHS per the CMS CoP](#). View the chart above to see whether your facility needs to report to TDEM or directly to HHS TeleTracking.

How can I register my hospital for the TDEM Reporting portal?

To register for TDEM, follow this link: <https://report.tdem.texas.gov> . If you have any issues, requests, or questions regarding TDEM, please send an email to vaccine@tdem.texas.gov .



Please see the table below for the required information for registering providers:

Facility Name	
Immtrac2 Provider Org ID*	
Facility License Number or CCN	
Facility Type	
Contact Phone	
Contact Email	
Street	

* Enter 0 if you do not yet have your ImmTrac2 Provider Org ID

How can I register for TeleTracking?

Email hhs-protect@teletracking.com to create your account.

How do you enroll in Immtrac2?

You can register for Immtrac2 using this link: <https://immtrac.dshs.texas.gov/TXPRD/portalHeader.do>.

Contact ImmTrac2@dshs.texas.gov for general ImmTrac2 application support.

How often do I have to report to ImmTrac2?

Providers are required to report to ImmTrac2 daily.

Therapeutics Use & Availability

Where can I find guidelines on monoclonal implementation or administration?

You can access the Federal Response to COVID-19: Monoclonal Antibody Clinical Implementation Guide for outpatient administration of mAbs for healthcare providers by visiting this webpage:

<https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/USG-COVID19-Tx-Playbook.pdf>. This document reviews authorizations, indications, preparation, administration, response to adverse events, site preparation, patient pathways to monoclonal administration, and additional resources.

Where can I find information on bam/ete use or resumption?

Please visit the following webpage to review the current Resumption in Use and Distribution of bam/ete in the United States: <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab-etesevimab/Pages/resume-distribution-bamlanivimabetesevimab-all-states-2sept2021.aspx>. You can check for updates under “bamlanivimab and etesevimab (Lilly)” here:

<https://www.dshs.texas.gov/coronavirus/healthprof.aspx#thera>.

What are the guidelines for therapeutics storage?

You can find information on therapeutics storage by accessing the following fact sheets:



- Fact Sheet for Health Care Providers Emergency Use Authorization of Bamlanivimab and Etesevimab: <https://www.fda.gov/media/145802/download>
- Fact Sheet for Health Care Providers Emergency Use Authorization of REGEN-COV™ (casirivimab and imdevimab): <https://www.fda.gov/media/145611/download>
- Fact Sheet for Health Care Providers Emergency Use Authorization of Sotrovimab: <https://www.fda.gov/media/149534/download>

How will I know when my therapeutics have expired?

You can find expiration information by visiting the manufacturer websites listed below or by contacting the manufacturer directly:

- REGEN-COV: Visit <https://www.regencov.com/hcp/resources/faq> If you have questions about the products' expiration date, you may contact Regeneron Medical Information at 1-844-734-6643.
- BAM/ETE: Visit <https://www.covid19.lilly.com/bam-ete> or contact the Lilly COVID Hotline at 1-855-545-5921.
 - The shelf-life of bamlanivimab has been extended from 12 to 18 months. For specific lot information, see <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab/Pages/20Aug21-announcement.aspx>.
 - The shelf-life of etesevimab has been extended from 12 to 18 months For specific lot information, see <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab-etesevimab/Pages/extension.aspx>.
- Sotrovimab: Visit https://www.sotrovimab.com/?cc=ps_WX47F4UZG81040671&mcm=300000&gclid=76b80e837c9f1fa7c4526fd8512974e1&gclsrc=3p.ds& You can also contact the GSK COVID Contact Center at 1-866-475-2684.

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

Due to the high demand and short supply of therapeutics across the nation, federal US HHS announced a transition in how therapeutics are distributed throughout the country. Previously, sites could directly order products from the distributor. Late September 13, US HHS notified Texas that therapeutics will now be distributed through the states.

HHS also notified DSHS that the national supply has considerably decreased, and states should expect lower amounts of therapeutics available for shipment. The federal government is working to acquire increased supply given the heavy demand. You may see the national and state allocation amounts at <https://www.phe.gov/emergency/events/COVID19/therapeutics/distribution/Pages/data-tables.aspx>.

DSHS will be allocating Regeneron, Bamlanivimab and Etesevimab, and Sotrovimab for the state of Texas and will seek to allocate as proportionally as possible. The quantity available to distribute is expected to be disproportionately less than the quantity needed.



Can I receive therapeutics transfers from other facilities?

You may contact facilities who may be able to transfer therapeutic supply to your facility. You do not need DSHS approval to transfer monoclonal antibodies (mAbs). Please record any transfers you may have received into your facility and transferred out of your facility in the TDEM portal.

Requesting transfers of therapeutics is not a current feature in VAOS.

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

<https://tdem.maps.arcgis.com/apps/webappviewer/index.html?id=993e2c2079f8487cafcec74e00e84991>

Are ancillary kits included with COVID-19 therapeutic orders?

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 I change my shipping address for my AmerisourceBergen account?

If you want to change your shipping address on file, you must contact AmerisourceBergen at c19therapies@amerisourcebergen.com

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

There are restrictions in the type of patient course you can order depending on treatment type and administration type. Help text bubbles located beside each field in the therapeutics order request window may be helpful when determining how much of each type of patient course you wish to request.

If you have no conflicting restrictions and continue to experience issues when ordering, please reach out to Therapeutics@dshs.Texas.gov or 833-832-7068, option 0.

What should I do if I received the wrong shipment?

To resolve a wrong shipment, contact our provider support at Therapeutics@dshs.Texas.gov or 833-832-7068, option 0.



Additional Support

I am a new provider. Where can I find more information?

Every other Friday, HHS hosts a mAb 201 webinar designed for sites that are new to monoclonal antibodies. Email COVID19Therapeutics@HHS.gov for more information on webinar dates and registration links.

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

The Office of the Assistant Secretary for Preparedness and Response hosts national office hours where providers can ask their therapeutics-related questions.

National Office Call Sessions: HHS / ASPR Allocation, Distribution, Administration of COVID-19 Therapeutics. Tuesdays and Thursdays 1:00-1:30 PM Central Time.

Link: <https://hhsasproea.zoomgov.com/j/1604329034?pwd=dGRwZTBETTJzWFliQW83TXZSOFVNQT09>

Meeting ID: 160 432 9034

Passcode: 897674

My question isn't listed here. Who can I contact for support?

Contact provider support at Therapeutics@dshs.texas.gov or 833-832-7068, option 0.

Helpful Links

For the General Public

- Texas Department of State Health Service COVID-19 Therapeutics Information: <https://dshs.texas.gov/coronavirus/therapeutics/>
- Combat Covid Monoclonal Antibodies for High-Risk Covid-19 Positive Patients: <https://combatcovid.hhs.gov/i-have-covid-19-now/monoclonal-antibodies-high-risk-covid-19-positive-patients>
- Federal Monoclonal Antibody Site: <https://www.phe.gov/mAbs>
- National Allocations of Monoclonal Antibody Therapeutics to States and Territories: <https://www.phe.gov/emergency/events/COVID19/therapeutics/distribution/Pages/data-tables.aspx>
- CDC COVID Data Tracker: <https://covid.cdc.gov/covid-data-tracker/>
- Clinical Trial Information for Patients not Eligible for EUA
 - Lilly Clinical Trials: <https://trials.lillytrialguide.com/en-US/>
 - Regeneron Clinical Trials: <https://www.regeneron.com/covid19>

Helpful Resources for Clinicians

- Texas Department of State Health Services Resources for Therapeutics: [Information for Hospitals & Healthcare Professionals \(texas.gov\)](#)
- PHE COVID-19 Toolkit: <https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/toolkit.aspx>
- CMS Monoclonal Antibody Reimbursement: <https://www.cms.gov/files/document/covid-infographic-coverage-monoclonal-antibody-products-treat-covid-19.pdf>
- Monoclonal Antibody COVID-19 Infusion: Monoclonal Antibody Products to Treat COVID-19: <https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion>
- COVID-19 Monoclonal Antibody Eligibility Checklist: Treatment and Post-exposure Prophylaxis: <https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/mAb-eligibility-treatment-and-post-exposure-prophylaxis.aspx>
- COVID-19 Monoclonal Antibody Checklist for Subcutaneous and Intravenous Administration: <https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/covid19-mAb-checklist-subcutaneous-intravenous-administration.aspx>



- Subcutaneous Injection Instructions: <https://www.phe.gov/emergency/events/COVID19/therapeutics/Documents/REGEN-COV-SubQ-FactSheet-July2021-508.pdf>
- National Infusion Center Association (NICA) COVID-19 Resource Center: <https://infusioncenter.org/healthcare-providers-monoclonal-antibody-therapies/>
- EMS Template Protocol: <https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/EMS-Template-Protocol-for-COVID19-mAbs-Administration.aspx>
- CMS Hospital Without Walls: <https://www.cms.gov/newsroom/press-releases/cms-announces-comprehensive-strategy-enhance-hospital-capacity-amid-covid-19-surge>
- Guides on Vaccination after mAb administration: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>