

COVID-19 Monoclonal Antibody (mAb) Therapeutics Provider Webinar

September 20, 2021

DISCLAIMER

The information presented today is based on current guidance and authorizations and MAY change.

September 20, 2021

Agenda Topics

- Opening Remarks - Imelda Garcia, MPH
- COVID-19 mAb Therapeutics
- COVID-19 mAb Therapeutics Ordering Process - Vaccine Allocation and Ordering System (VAOS)
- Shipping Timelines
- Federal & State Reporting Requirements
- Resources
- Live Q&A



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Opening Remarks

Imelda Garcia, MPH

Associate Commissioner | Laboratory & Infectious Disease Services Division

Background

- On September 13, 2021, federal US Health and Human Services (US HHS) notified states that, due to supply constraints, providers may no longer order COVID-19 monoclonal antibody (mAb) therapeutics direct from AmerisourceBergen Corporation (ABC).
- US HHS will provide weekly allocations to the states. The states will make allocations to their providers.
- This is specific for the following COVID-19 mAB therapeutics only:
 - **REGEN-COV™** (casirivimab/imdevimab; manufactured by Regeneron)
 - **bamlanivimab/etesevimab** (manufactured by Eli Lilly).
- Texas Department of State Health Services (DSHS) has worked to put a system in place for providers to make requests for COVID-19 mAb therapeutics.
- [Sotrovimab](#) (GlaxoSmithKline) can be purchased through [normal purchasing](#) routes from the distributor



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COVID-19 mAb Therapeutics Ordering

Vaccine Allocation and Ordering System (VAOS)

- Many Texas providers are already familiar with the Texas COVID-19 Vaccine Allocation and Ordering System (VAOS).
- DSHS has added a module in VAOS to allow providers to put in COVID-19 mAb therapeutics requests.
- Providers already registered in VAOS **and** are registered with ABC as a COVID-19 mAB therapeutics provider can place orders effective immediately.
- Providers already registered with ABC as a COVID-19 mAB therapeutics provider will receive access to VAOS on Friday, September 24th.
- Providers who do not have an mAb account with ABC must get one before being able to place orders.



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Federal Allocation of COVID-19 mAb Therapeutics

- US HHS has indicated that allocations to the states will decline in coming weeks due to supply limitations.
- DSHS understanding is that allocations to the state will be determined by the following factors:
 - State population
 - State COVID-19 cases and hospitalizations
 - **Provider adherence to reporting requirements**
 - Weekly Federal reporting to TeleTracking
 - Daily State reporting to TDEM Portal and
 - ImmTrac2
- The federal government has indicated that utilization and reporting will impact future Texas allocations.



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DSHS Allocation Strategy

- DSHS is working to implement a fair allocation strategy that ensures Texas is well positioned to receive its maximum allocation each week.
- DSHS will consider the following factors when evaluating provider requests:
 - Provider use and reporting
 - Geographic coverage
 - Rural and urban coverage
 - Proportionality to eligible population estimates
- Provider reporting will be a key and a deciding factor for whether a provider may receive mAb allocations.



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Week 1 Allocation

(Week of Sept 13th)

- Available COVID-19 mAb therapeutics for week 1 allocations are:
 - **BAM + ETE: 2,370 Patient Courses**
 - **REGEN-COV: 21,270 Patient Courses**
- Due to the high demand and limited supply of COVID-19 mAb therapeutics, not all requests will be fulfilled at this time.
- Providers that do not report will not receive allocations.



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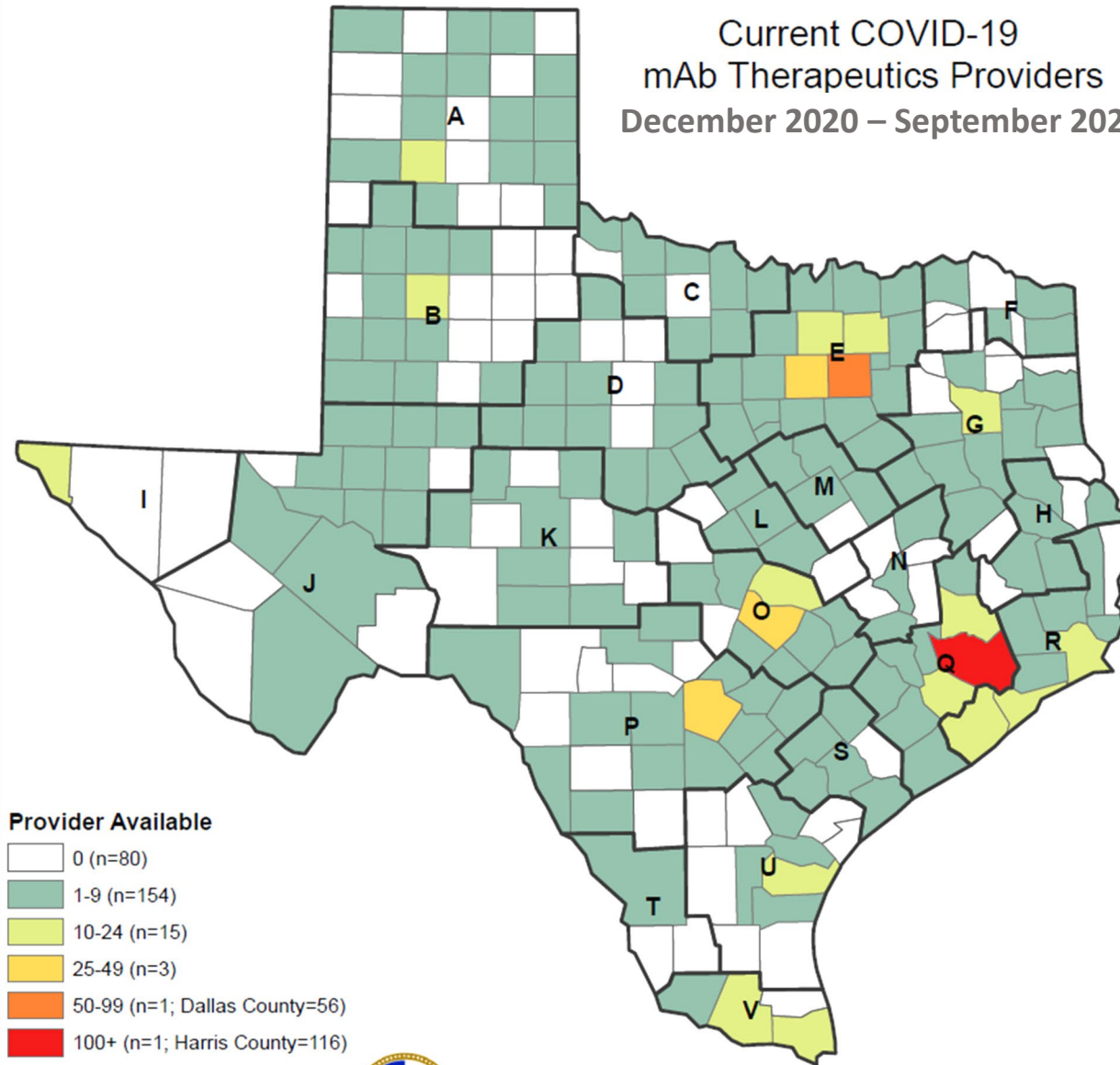
Weekly Allocation Cadence

- DSHS receives allocations every Tuesday.
- Providers could receive orders the same week or the following week.
- Providers will receive shipments on weekdays only.



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Current COVID-19 mAb Therapeutics Providers December 2020 – September 2021



Provider Available

- 0 (n=80)
- 1-9 (n=154)
- 10-24 (n=15)
- 25-49 (n=3)
- 50-99 (n=1; Dallas County=56)
- 100+ (n=1; Harris County=116)

Total Providers=888

(n=) means total number of counties



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People vaccinated includes first doses of
Pfizer/Moderna and single doses of Janssen.
Completely vaccinated includes second doses of
Pfizer/Moderna and single doses of Janssen.

COVID-19 Monoclonal Antibody (mAb) Therapeutics

Saroj Rai, PhD, MPH
Senior Scientific Advisor



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FDA Emergency Use Authorized COVID-19 Monoclonal Antibody Therapeutics Available Through State Ordering

Monoclonal Antibody Indications and Routes of Administration		
Monoclonal Antibody	TREATMENT of Mild to Moderate COVID-19 Infection within 10 days of symptom onset in patient with high risk of progression to severe disease	POST-EXPOSURE PROPHYLAXIS for individuals who are not fully vaccinated or immunocompromised, with high risk of progression to severe disease
bamlanivimab and etesevimab ¹ (Eli Lilly) ^{***}	Dose: 700 mg bamlanivimab and 1400 mg etesevimab ^{***} Route: Intravenous administration Post-administration monitoring: 60 minutes	Dose: 700 mg bamlanivimab and 1400 mg etesevimab ^{***} Route: Intravenous administration Post-administration monitoring: 60 minutes
casirivimab and imdevimab ² (REGEN-COV)	Dose: casirivimab 600mg and imdevimab 600mg Route: Intravenous is preferred route, however subcutaneous injection may be utilized in situations where there would be a delay in intravenous administration Post-administration monitoring: 60 minutes	Dose: casirivimab 600mg and imdevimab 600mg Route: Intravenous or subcutaneous Post-administration monitoring: 60 minutes

^{***} Based on the most currently available data, bamlanivimab and etesevimab are now authorized in all U.S. states, territories, and jurisdictions (9/2/21)
[<https://www.fda.gov/media/151719/download>]

Refer to product Emergency Use Authorizations for detail on indications and administration

¹ Fact Sheet for Health Care Providers Emergency Use Authorization of Bamlanivimab and Etesevimab (<https://www.fda.gov/media/145802/download>)

² Fact Sheet for Health Care Providers Emergency Use Authorization of REGEN-COV™ (casirivimab and imdevimab) (<https://www.fda.gov/media/145611/download>)

Source: <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/USG-COVID19-Tx-Playbook.pdf>

Patient Eligibility

Bamlanivimab and Etesevimab (BAM/ETE) & Casirivimab and Imdevimab (REGEN-COV)

- For the **treatment** mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARSCoV-2 viral testing, and who are at high risk* for progression to severe COVID-19, including hospitalization or death.
- **Not authorized** for use in patients:
 - who are hospitalized due to COVID-19, OR
 - who require oxygen therapy due to COVID-19, OR
 - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.
- Adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for **post-exposure prophylaxis** of COVID-19 in individuals who are at high risk* for progression to severe COVID-19, including hospitalization or death, and are:
 - not fully vaccinated **or** who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications²) and
 - have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Center for Disease Control and Prevention (CDC)³ or
 - who are at high risk of exposure to an individual infected with SARS-CoV-2
 - not a substitute for vaccination against COVID-19
 - not authorized for pre-exposure prophylaxis

*People at high-risk: see EUAs and <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

REGEN-COV™ (casirivimab and imdevimab)

- Current authorized dose is 600 mg casirivimab and 600 mg imdevimab for treatment and post-exposure prophylaxis.
 - Note: this is a change from the previous dose of 1,200 mg casirivimab and 1,200 mg imdevimab.
- Due to multiple presentations, it is important to know the different presentations and how to prepare doses appropriately with each presentation ([Medication Error](#)).
- REGEN-COV is authorized for intravenous infusion. Subcutaneous injection is authorized as an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment.
- For post-exposure prophylaxis, either subcutaneous injection or intravenous infusion can be used.
- Lower dosage for repeat dosing post-exposure prophylaxis for ongoing exposure in settings like nursing homes and jails. Refer to the [Fact Sheet](#).

bamlanivimab and etesevimab (Eli Lilly)

- Current authorized dose is 700 mg bamlanivimab and 1,400 mg etesevimab for treatment and post-exposure prophylaxis.
- Must be administered together after dilution by intravenous (IV) infusion only.

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>)

COVID-19 Treatment Guidelines

- The [COVID-19 Treatment Guidelines Panel](#) recommends using anti-SARS-CoV-2 monoclonal antibodies for the treatment of mild to moderate COVID-19 and for post-exposure prophylaxis (PEP) of SARS-CoV-2 infection in individuals who are at high risk for progression to severe COVID-19, as outlined in the FDA Emergency Use Authorizations (EUAs). See [the individual EUAs](#) for details.
- Logistical constraints (e.g., limited space, not enough staff who can administer therapy) can make it difficult to administer these agents to all eligible patients. In situations where it is necessary to triage eligible patients, the Panel suggests:
 - Prioritizing the treatment of COVID-19 over PEP of SARS-CoV-2 infection.
 - Prioritizing the following groups over vaccinated individuals who are expected to have mounted an adequate immune response:
 - Unvaccinated or incompletely vaccinated individuals who are at high risk of progressing to severe COVID-19.
 - Vaccinated individuals who are not expected to mount an adequate immune response (e.g., immunocompromised individuals).
- **Providers should use their clinical judgment** when prioritizing treatment or PEP in a specific situation. When there are no logistical constraints for administering therapy, these considerations **should not** limit the provision of anti-SARS-CoV-2 monoclonal antibodies.

Summary

As of 9/20/2021	FDA Authorized		Route of Administration	
	Treatment	Post-Exposure Prophylaxis	IV Infusion	Subcutaneous Injection
REGEN-COV (600 mg cas + 600 mg imd)	YES	YES	YES	YES
BAM/ETE (700 mg bam + 1,400 mg ete)	YES	YES	YES	NO

Provider Mandatory Reporting

Medication Errors & Serious Adverse Events

REGEN-COV™ (casirivimab and imdevimab)

- 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:

Regeneron Pharmaceuticals, Inc

Fax: 1-888-876-2736

E-mail: : medical.information@regeneron.com

Or call Regeneron Pharmaceuticals at 1-844-734-6643

bamlanivimab and etesevimab (Eli Lilly)

- 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:

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)



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COVID-19 mAb Therapeutics

Storage and Handling

casirivimab and imdevimab (REGEN-COV™)

- Store unopened casirivimab and imdevimab vials in a refrigerator at **2°C to 8°C (36°F to 46°F)** in the original carton to protect from light.
- **DO NOT FREEZE, SHAKE, OR EXPOSE TO DIRECT LIGHT.**
- Solution in vial requires dilution prior to intravenous administration.
- The prepared infusion solution is intended to be used immediately.
- If immediate administration is not possible, store diluted casirivimab and imdevimab infusion solution:
 - In the refrigerator at 2°C to 8°C (36°F to 46°F) for no more than **36 hours** or
 - At room temperature up to 25°C (77°F) for no more than **4 hours**
 - If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 30 minutes prior to administration
- The prepared syringes should be administered immediately.
- If immediate administration is not possible, store the prepared casirivimab and imdevimab syringes:
 - In the refrigerator at 2°C to 8°C (36°F to 46°F) for no more than **4 hours** or
 - At room temperature up to 25°C (77°F) for no more than **4 total hours**
 - If refrigerated, allow the syringes to equilibrate to room temperature for approximately 20 minutes prior to administration

bamlanivimab and etesevimab (Eli Lilly)

- Store unopened vials under refrigerated temperatures at **2°C to 8°C (36°F to 46°F)** in the original carton to protect from light.
- **DO NOT FREEZE, SHAKE, OR EXPOSE TO DIRECT LIGHT.**
- Solution in vial requires dilution prior to administration.
- The prepared infusion solution is intended to be used immediately.
- If immediate administration is not possible, store diluted infusion solution:
 - In the refrigerator at 2°C to 8°C (36°F to 46°F) for up to **24 hours** or
 - At room temperature (20°C to 25°C [68°F to 77°F]) for up to **7 hours, including infusion time**
 - If refrigerated, allow the infusion solution to equilibrate to room temperature prior to administration



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Provider and Patient EUA Fact Sheets

- Each product under EUA also has an FDA fact sheet for providers and one for patients and caregivers.
- **bamlanivimab and etesevimab**
 - Provider fact sheet: <https://www.fda.gov/media/145802/download>
 - Patient fact sheet: <https://www.fda.gov/media/145803/download>
 - Patient fact sheet (Spanish): <http://pi.lilly.com/eua/span/bam-and-ete-eua-factsheet-patient-span.pdf>
- **casirivimab and imdevimab (REGEN-COV)**
 - 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.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-patient-spanish.pdf>



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Manufacturers' Contact Information



Regeneron Medical Information Contact

1-800-743-6643

www.REGENCOV.com



Eli Lilly Medical Information Contact

1-800-545-5921

www.LillyAntibody.com

Audience Poll

Have you ever ordered COVID-19 monoclonal antibody therapeutics before?

A. Yes

B. No

COVID-19 mAb Therapeutics

Ordering through VAOS

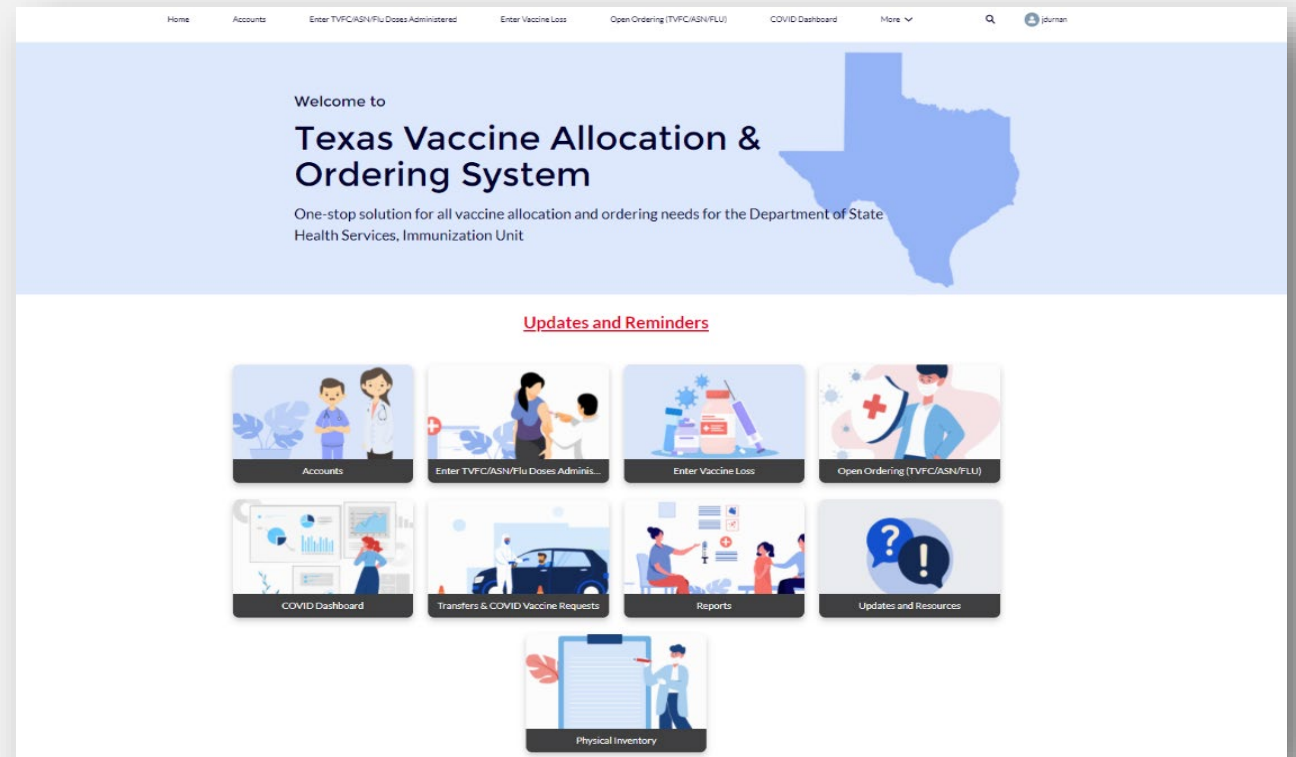


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Vaccine Allocation and Ordering System (VAOS)

Eligible Texas
Therapeutic providers
will utilize the VAOS
system to place their
therapeutic orders.



Who Can Order Therapeutics?

Providers who have **already registered with AmerisourceBergen** and who have **existing accounts in the Vaccine Allocation & Ordering System (VAOS)** may place order requests in VAOS.

How to get access to VAOS

Current Therapeutics providers not enrolled in VAOS

Current Therapeutics providers who are registered with AmerisourceBergen but who do not have VAOS accounts will be added to VAOS Friday, September 24 and will receive an invite to a “new VAOS user” webinar hosted next week.



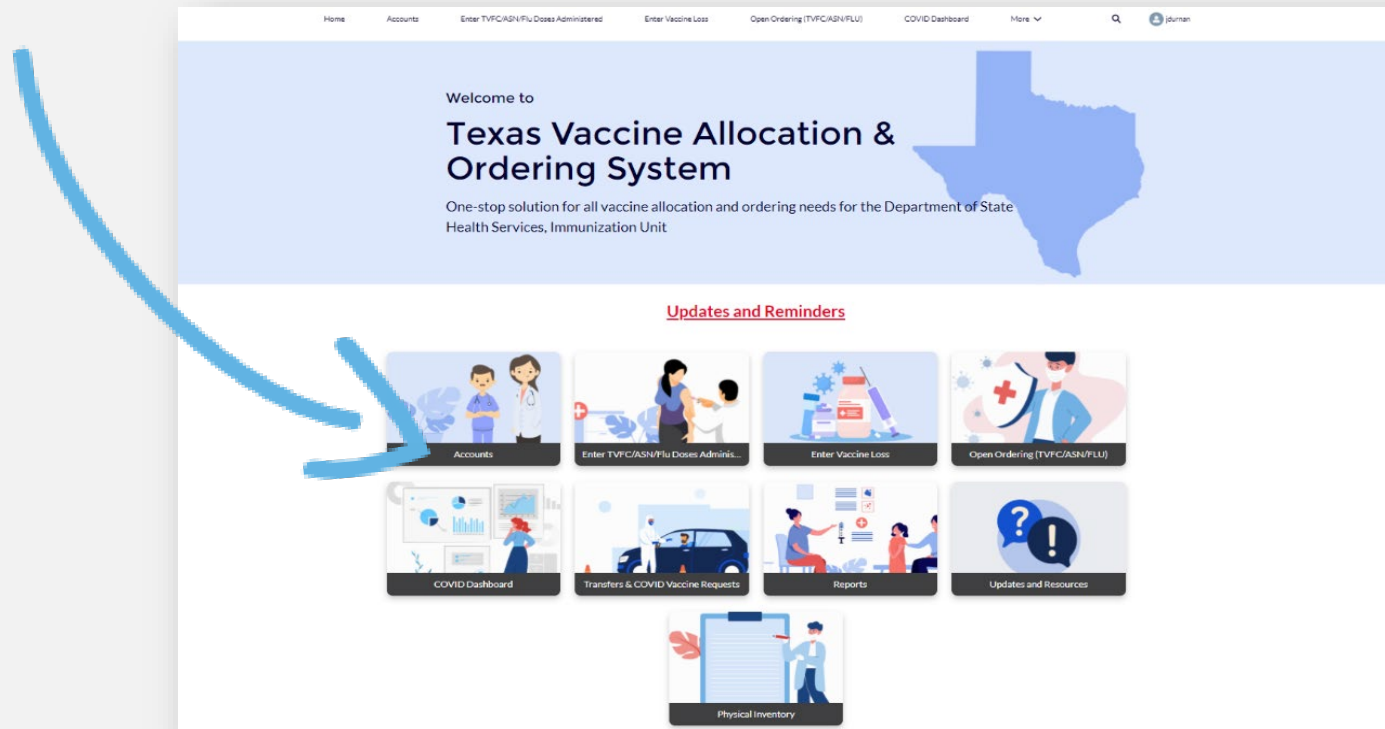
How to get started

Providers who want to become Therapeutics providers

Providers who want to become therapeutics provider can register by emailing therapeutics@dshs.Texas.gov. They will help you start an AmerisourceBergen account.

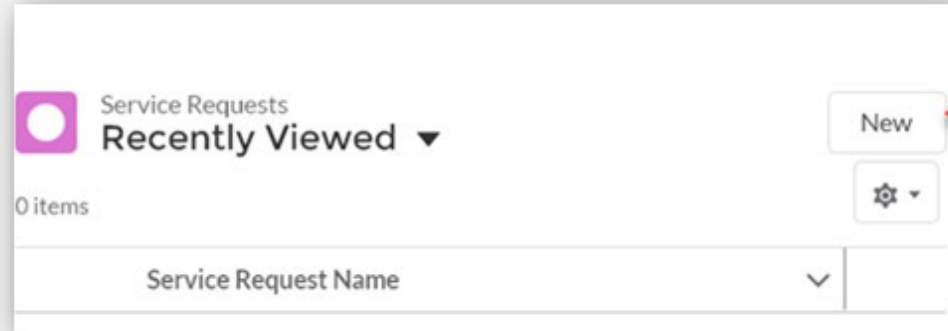
Navigate to the VAOS Provider Portal

1. Log into VAOS at <https://texasvaccines.dshs.texas.gov/> and
2. Navigate to the **Transfers & COVID Vaccine Requests** tab.



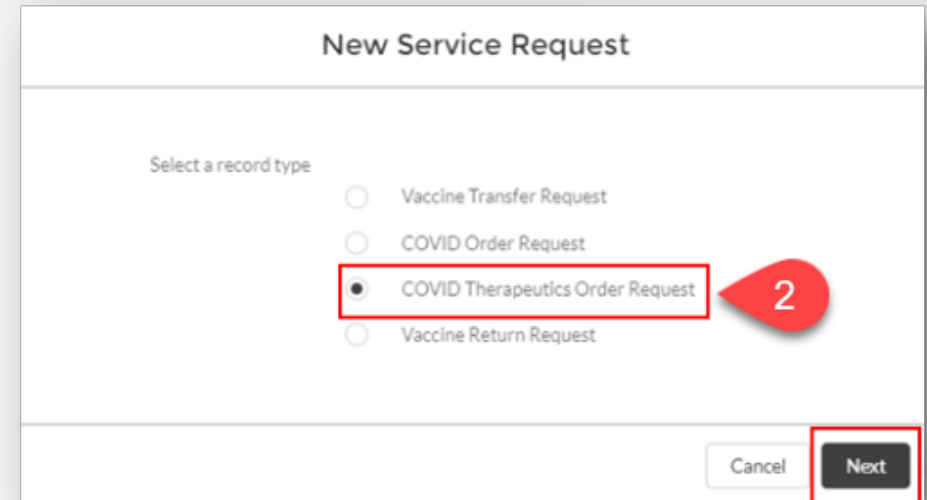
Create New COVID Therapeutics Order Request

1. From the service request form select **New**.



The screenshot shows a web interface for 'Service Requests'. At the top, there's a header with a purple square icon, the text 'Service Requests', and a dropdown menu labeled 'Recently Viewed'. Below this, it says '0 items'. On the right side, there is a 'New' button and a settings gear icon. A red callout bubble with the number '1' points to the 'New' button. At the bottom, there is a search bar labeled 'Service Request Name' with a dropdown arrow.

2. From the **New Service Request** pop up box. Select **COVID Therapeutics Order Request**.



The screenshot shows a 'New Service Request' pop-up box. It has a title bar 'New Service Request'. Inside, there is a section 'Select a record type' with four radio button options: 'Vaccine Transfer Request', 'COVID Order Request', 'COVID Therapeutics Order Request' (which is selected and highlighted with a red box and callout 2), and 'Vaccine Return Request'. At the bottom right, there are two buttons: 'Cancel' and 'Next' (which is highlighted with a red box and callout 3).

3. Select **Next**.

Enter Ordering Information

Fill out all required fields in the “*New Service Request*” form.

Field Title	Meaning
Current quantity	Enter the number of courses you currently have on hand
Courses requested	Enter the number of courses you would like to order
AmerisourceBergen Account Number	Input your AmerisourceBergen account information <i>(It's required to order therapeutics)</i>
Intended Method of Admin	Choose your method of administration
Intended use of the therapeutics product	Choose the intended use of the product
Contact Information	Fill out primary and secondary contact information
AmerisourceBergen Shipping Address	Input the shipping address that is in your AmerisourceBergen account

New Service Request: COVID Therapeutics Order Request

COVID Therapeutics Order Request

* Facility

Search Accounts...

* Current quantity: bamlanivimab ⓘ

* Current quantity: bam/ete ⓘ

* Current quantity: REGEN-COV ⓘ

* Intended method of admin for therapeutic

--None--

* Primary Contact Name

* Primary Contact Email

* Primary Contact Phone Number

AmerisourceBergen Shipping Address ⓘ

Salesforce Sans

12

* Amerisource Bergen Account Number ⓘ

* Patient Courses Requested: bam/ete ⓘ

* Patient c

5

* Patient Courses Requested: REGEN-COV ⓘ

* Intended use of therapeutics product

--None--

Willing to accept another product ⓘ

☐

* Secondary Contact Name

* Secondary Contact Email

* Secondary Contact Phone Number

Cancel

Save & New

Save

Audience Poll

Are you a VAOS coordinator or backup coordinator?

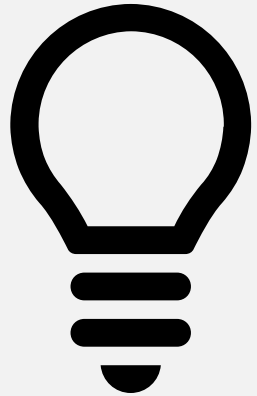
A. Yes

B. No

Live Demo – Placing a Therapeutics order in VAOS

Therapeutic Order Form

Important Notes



1. The shipping address you list in the therapeutic order request form **MUST** be the same as your AmerisourceBergen shipping address.
2. Don't forget to check the "*willing to accept another product*" box, if you are willing to accept either product in the event your original choice is unavailable.

Inventory Management Reminder



Currently, there will be no inventory management for therapeutics in VAOS.

What does that mean?

- ***NO*** reporting waste features in VAOS for therapeutics
- You ***CANNOT*** view shipment and inventory records for therapeutics

Shipping Timelines



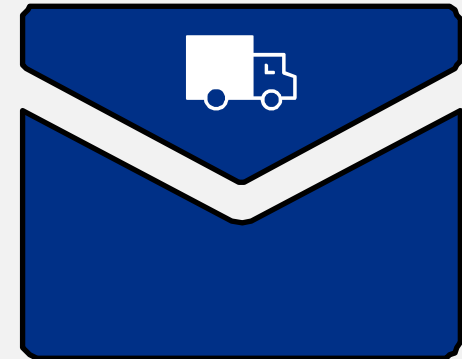
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Shipment Notification Email

Providers will receive an email regarding their therapeutics shipment from AmerisourceBergen c19therapies@amerisourcebergen.com.

At this time, VAOS will not reflect any approval or shipment information regarding therapeutics allocation requests or orders.



Therapeutic Ordering Timeline

Remember! Providers may enter requests at any time.

Mondays

DSHS will pull provider requests at end of day to begin the allocation process. Providers cannot update or edit requests after 5pm CST.



Tuesdays

The states will receive their allocated amounts for the following week.



Wednesdays

US HHS will take its snapshot of provider mAb use, which will feed into Texas's future allocations from HHS.



Tuesday - Fridays

The state must enter all orders for the state.



The Same or the Following Week

Allocation shipments will be received.

Providers will receive an email from ABC when their order request is shipped.



Remember! Shipments will arrive throughout the week. Shipments will only arrive on weekdays.

COVID-19 mAb Therapeutics

Federal & State Reporting Requirements



Federal Reporting Requirements




- Administration of all COVID-19 monoclonal antibody therapeutics must be reported **weekly on Wednesdays to HHS TeleTracking.**

HHS TeleTracking: <https://teletracking.protect.hhs.gov/>

- Hospitals that are required to report daily data to [HHS per the CMS CoP](#) do not need to report directly in TeleTracking.

Adherence to the Federal reporting requirements is critical and will impact all future Texas allocations.




State Reporting Requirements



- Administration of all COVID-19 monoclonal antibody therapeutics must be reported **daily** to:
 1. Texas Division of Emergency Management (TDEM) Portal
 2. ImmTrac2

Adherence to the Texas reporting requirements is critical and will impact future allocations.



Resources



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Resources

For questions about ordering therapeutics:



Email therapeutics@dshs.texas.gov



Call the Provider Support Center at 833-832-7068 and press 0 to speak to a representative about ordering therapeutics

HHS/ASPR Office Sessions

- Office Call Sessions on Distribution and Administration of COVID-19 Therapeutics
 - This session is an open forum for state and territorial health officers, health care providers and professionals at administration sites to ask HHS/ASPR your questions on administration of therapies.
 - Tuesdays and Thursdays (1:00 – 2:00PM CT)
- Email therapeutics@dshs.Texas.gov for meeting link.



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Helpful Links

Federal Monoclonal Antibody Site	https://www.phe.gov/mAbs
PHE COVID-19 Toolkit	https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/toolkit.aspx
CMS Hospital Without Walls	https://www.cms.gov/newsroom/press-releases/cms-announces-comprehensive-strategy-enhance-hospital-capacity-amid-covid-19-surge
CMS Monoclonal Antibody Reimbursement	
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
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

COVID-19 Monoclonal Antibody Eligibility Checklist: Treatment and PEP	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
EMS Template Protocol	https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/EMS-Template-Protocol-for-COVID19-mAbs-Administration.aspx
Guides on Vaccination after mAb administration	https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Step-by-Step Ordering Instructions

Review the COVID-19 Therapeutics Ordering Request job aid for step-by-step instructions on placing a COVID-19 therapeutic order in VAOS.

<https://www.dshs.texas.gov/immunize/covid19/COVID-19-Therapeutics-Job-Aid.pdf>



Live Q&A

Final Notes



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Have Questions or Need Help?

Contact COVID-19
Support at **833-832-
7068, option "0"** from
8:00AM-5:00PM
Monday –Friday.



Look for Our Follow-Up Email!

Monitor your inbox for a follow-up email communication that contains a **link to access today's webinar materials**.

The email also contains **helpful links and resources**.

The follow-up email will come from GovDelivery



DISCLAIMER

The information presented today is based on current authorization and guidance and MAY change.

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