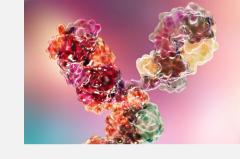


Disclaimer

The information presented today is based on FDA's recent guidance and MAY change.

February 11, 2022





- Welcome and Opening Remarks
- Evusheld for Pre-Exposure Prophylaxis
- Provider Best Practices
 UT Southwestern Medical Center & Austin Public Health
- Q&A (UTSW, APH & AstraZeneca Medical Team)
- Evusheld Ordering & Reporting Requirements
- Q&A
- Closing Remarks
- Resources



Texas Department of State Health Services

Provider Best Practice Sharing

UTSW & APH

Sonia Bartolome, MD, FCCP

Professor, Pulmonary and Critical Care Medicine Associate Chief Quality Officer, Health System Affairs

UTSouthwestern

Medical Center

Desmar Walkes, MD

Medical Director / Health Authority Austin / Travis County



Guest Panelists AstraZeneca

Lisa I. Glasser, MD
US Medical Affairs Head
Vaccines-Infectious Diseases
AstraZeneca Pharmaceutical, LP

Marcella Chock, PharmD, PAHM Senior Medical Science Liaison US Vaccines-Infectious Diseases AstraZeneca Pharmaceutical, LP

Welcome and Opening Remarks

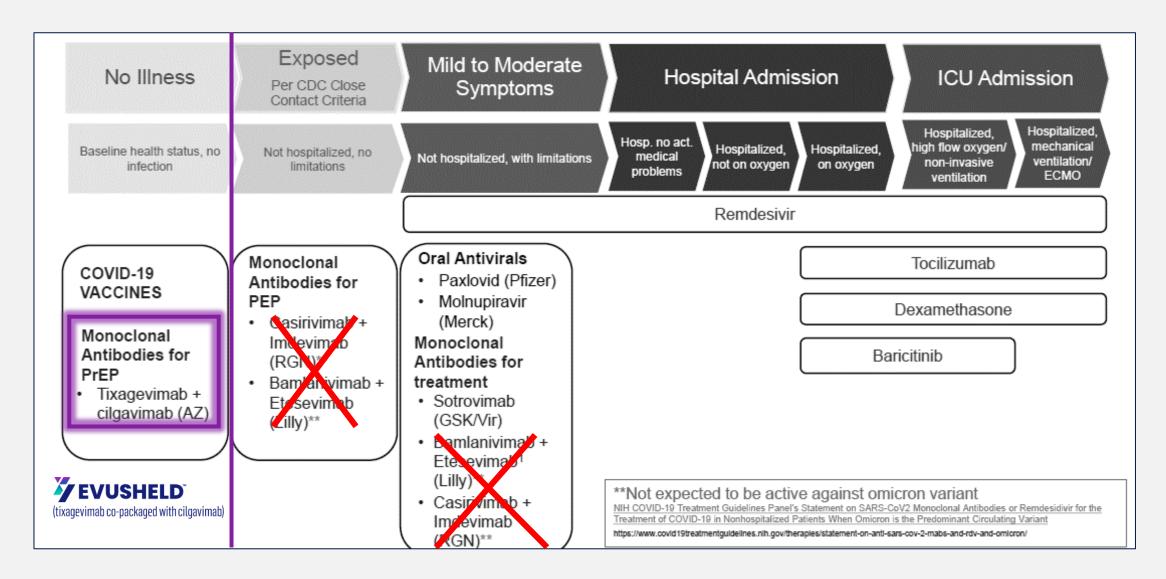
February 11, 2022

Manda Hall, M.D.

Associate Commissioner | Community Health Improvement

Texas Department of State Health Services

Summary of COVID -19 Preventative Agents & Therapeutics





- Key learning from this study of hospitalized adults is compared with receipt of 2 mRNA COVID-19 vaccine doses, receipt of a third dose increased vaccine effectiveness against hospitalization among adults without and with immunocompromising conditions, from 82% to 97% and from 69% to 88%, respectively.*
- Additionally, in the most recent CDC's Advisory Committee on Immunization Practices meeting on February 4th, 2021, there was discussion to reduce the booster dose (4th dose) interval of a mRNA COVID-19 vaccine to 3 months from previously 5 months interval for people with immunocompromising conditions or people who take immunosuppressive medications/therapies.**

^{*}Effectiveness of a Third Dose of Pfizer-BioNTech and Moderna Vaccines in Preventing COVID-19 Hospitalization Among Immunocompetent and Immunocompromised Adults — United States, August—December 2021 | MMWR (cdc.gov)

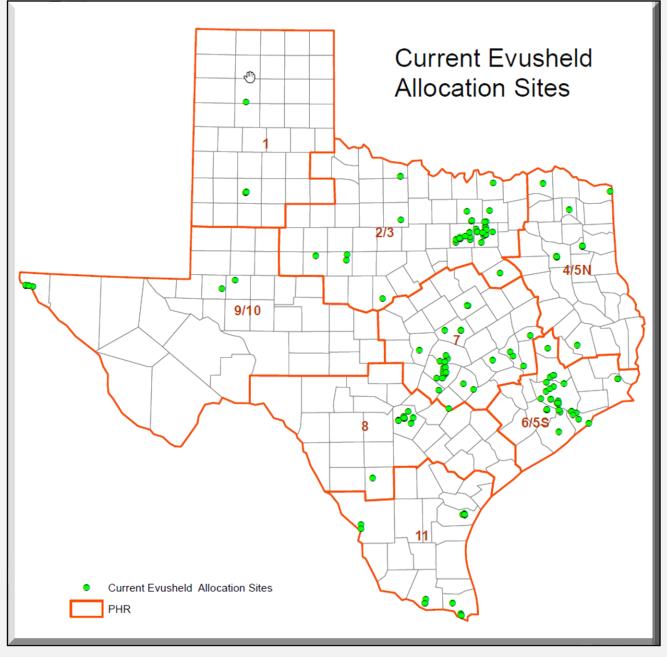
^{**} https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/08-COVID-Hall-508.pdf

Summary of Texas COVID -19 Therapeutics Allocation

Monthly Available Doses (Patient Courses) for Allocation

Texas	Monulpiravir*	Paxlovid*	Sotrovimab	Evusheld
December 2021	19,800	4,240	4,974	7,872
January 2022	52,740	13,100	18,372	27,312
February 2022	26,328	6,540	4,416	3,912
Total	98,868	23,880	27,762	39,096

^{*}Excludes HRSA, ICE, and Indian Health Service reporting



- The map shows the current locations of Evusheld allocation in Texas.
- Specific providers and their contacts can be found here: covid-19therapeutics-locatordhhs

Evusheld Emergency Use Authorization for Pre-Exposure Prophylaxis

Saroj Rai, PhD, MPH

Senior Scientific Advisor | Office of the Chief State Epidemiologist

Texas Department of State Health Services

Evusheld for Pre-Exposure Prophylaxis

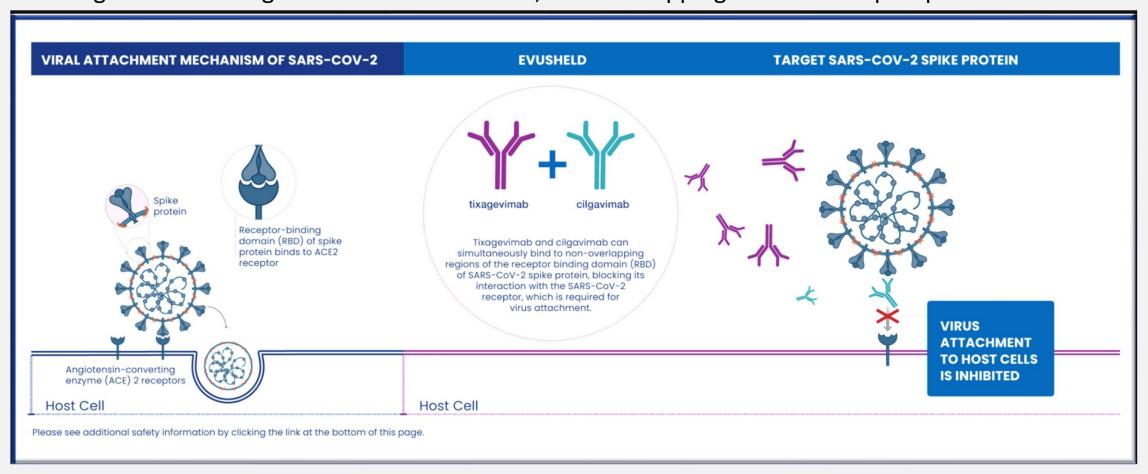
Evusheld (tixagevimab and cilgavimab) for Pre-Exposure Prophylaxis

- Evusheld is a combination of two long-acting monoclonal antibodies (tixagevimab and cilgavimab) that are specifically directed against the spike protein of SARS-CoV-2, designed to block the virus' attachment and entry into human cells.
- Evusheld (tixagevimab) injection; (cilgavimab) injection, co-packaged for intramuscular use.
- The dosage of Evusheld for emergency use is 150 mg of tixagevimab and 150 mg of cilgavimab <u>administered as two</u> <u>separate consecutive intramuscular injections</u>.



Evusheld (tixagevimab and cilgavimab) for Pre-Exposure Prophylaxis Mechanism of Action

• Tixagevimab and cilgavimab bind to different, non-overlapping sites on the spike protein of the virus.



Evusheld (tixagevimab and cilgavimab) for Pre-Exposure Prophylaxis Emergency Authorized Use

- **Evusheld** (tixagevimab and cilgavimab) is indicated for <u>pre-exposure prophylaxis</u> (<u>prevention</u>) of COVID-19 in <u>certain</u> adults and pediatric individuals (<u>12 years of age and older and weighing at least 40kg / 88lbs</u>).
- It is only authorized for those individuals:
 - who are <u>not</u> currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 AND
 - who have <u>moderate to severe immune compromise</u> due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination **OR**
 - for whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and /or COVID-19 vaccine component(s)

Medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination include but are not limited to¹:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm³,
 history of an AIDS-defining illness without immune reconstitution, or clinical manifestations
 of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents)

Evusheld (tixagevimab and cilgavimab) for Pre-Exposure Prophylaxis Limitation of Authorized Use

- Evusheld is not authorized for use in individuals:
 - For treatment of COVID-19, or
 - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2
- Pre-exposure prophylaxis with EVUSHELD <u>is not a substitute for vaccination</u> in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination
- Evusheld may only be prescribed by a healthcare provider licensed under State law to
 prescribe drugs for an individually identified patient and who has the education and training
 to make the clinical assessment necessary for appropriate use of Evusheld

Evusheld (tixagevimab and cilgavimab) for Pre-Exposure Prophylaxis COVID-19 Vaccination and Evusheld

• In individuals who have received a COVID-19 vaccine, Evusheld should be administered at least two weeks after vaccination

Evusheld (tixagevimab and cilgavimab) for Pre-Exposure Prophylaxis Efficacy Data from a Clinical Trial (PROVENT)

- PROVENT is an ongoing Phase III, randomized (2:1), double-blind, placebo-controlled clinical trial studying Evusheld for the pre-exposure prophylaxis of COVID-19 in adults ≥18 years of age.
- All subjects were either ≥60 years of age, had a pre-specified co-morbidity (obesity, congestive heart failure, chronic obstructive pulmonary disease, chronic kidney disease, chronic liver disease, immunocompromised state, or previous history of severe or serious adverse event after receiving any approved vaccine), or were at increased risk of SARS-CoV-2 infection due to their living situation or occupation.

Table 6 Incidence of Symptomatic COVID-19 in Adults (PROVENT)				
	N*	Number of events, n (%)	Relative Risk Reduction, % (95% CI)	
EVUSHELD†	3,441	8 (0.2%)	77% (46, 90)	
Placebo	1,731	17 (1.0%)	7770 (40, 90)	

N = number of subjects in analysis; CI = Confidence Interval

Fact Sheet for Health Care Providers Emergency Use Authorization for Evusheld (tixagevimab c - packaged with cilgavimab (https://www.fda.gov/media/154701/download)

^{*} subjects were censored after receiving the vaccine or being unblinded to consider the vaccine, whichever occurred earlier

[†] EVUSHELD dose (150 mg tixagevimab and 150 mg cilgavimab)

Evusheld (tixagevimab and cilgavimab) for Pre-Exposure Prophylaxis

Safety Data from Two Clinical Trials

Table 2 Adverse Events (All Grades) Regardless of Causality Occurring in at Least 3% of Subjects Receiving EVUSHELD or Placebo in Primary Safety Analysis

	EVUSHELD N= 3,461	Placebo N= 1,736
Headache	6%	5%
Fatigue	4%	3%
Cough	3%	3%

At the additional data cut-off (median follow-up 6.5 months), the overall adverse event profile for subjects who received EVUSHELD remained similar to events displayed in Table 2.

Table 3 Cardiac SAEs Regardless of Causality in PROVENT with Onset Prior to Day 183
Using the Median 6-Month Data Cut-off Date

	EVUSHELD N= 3,461	Placebo N= 1,736
Subjects with any cardiac SAE*	22 (0.6%)	3 (0.2%)
SAEs related to coronary artery disease or myocardial ischemia [†]	10 (0.3%)	2 (0.1%)
Myocardial infarctions [‡]	8 (0.2%)	1 (0.1%)
SAEs related to cardiac failure ^{§α}	6 (0.2%)	1 (0.1%)
SAEs related to an arrhythmia [¶]	4 (0.1%)	1 (0.1%)
Other (cardiomegaly, cardiomyopathy, and cardio-respiratory arrest)	3 (0.1%)	0

^{*}One EVUSHELD recipient and one placebo recipient had two cardiac SAEs each.

[†] Includes the preferred terms angina pectoris, coronary artery disease, arteriosclerosis, troponin increased, acute myocardial infarction, and myocardial infarction.

[‡] Includes the preferred terms acute myocardial infarction, myocardial infarction, and troponin increased (with a discharge diagnosis of myocardial infarction).

[§] Includes the preferred terms cardiac failure congestive, acute left ventricular failure, cardiac failure, and cardiac failure acute.

[¶]Includes the preferred terms atrial fibrillation, arrhythmia, paroxysmal atrioventricular block, and heart rate irregular.

Evusheld (tixagevimab and cilgavimab) for Pre-Exposure Prophylaxis Warning and Precautions

- **Hypersensitivity Including Anaphylaxis:** Serious hypersensitivity reactions, including anaphylaxis, have been observed with IgG1 monoclonal antibodies like EVUSHELD. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals after injections and observe for at least 1 hour.
- Clinically Significant Bleeding Disorders: As with any other intramuscular injection, EVUSHELD should be given with caution to individuals with thrombocytopenia or any coagulation disorder.
- Cardiovascular Events: A higher proportion of subjects who received EVUSHELD versus placebo reported myocardial infarction and cardiac failure serious adverse events. All of the subjects with events had cardiac risk factors and/or a prior history of cardiovascular disease, and there was no clear temporal pattern. A causal relationship between EVUSHELD and these events has not been established. Consider the risks and benefits prior to initiating EVUSHELD in individuals at high risk for cardiovascular events and advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event.

Evusheld (tixagevimab and cilgavimab) for Pre-Exposure Prophylaxis Preparation, Dose, & Administration

- Dose: tixagevimab 150mg and cilgavimab 150mg
- Administration:
 - Administer the two components sequentially
 - Withdraw 1.5mL of tixagevimab and 1.5mL of cilgavimab solution into TWO separate syringes
 - Administer the intramuscular (IM) injections at different injection sites, preferably one in each of the gluteal muscles, one after the other. The vastus lateralis is acceptable if gluteal injection is contraindicated
 - The solutions for injection do not contain a preservative. Discard unused portion in accordance with local requirements
 - As with any other IM injection, administer with caution to patients with thrombocytopenia or any coagulation disorder
- **Observation:** 60 minutes post-administration

- **Storage:** Refrigerate unopened vials at 2-8°C/36-46°F
 - The prepared syringes should be administered immediately.
 - If immediate administration is not possible, and the prepared tixagevimab and cilgavimab syringes need to be stored.
 - The total time from vial puncture to administration must not exceed 4 hours:
 - in a refrigerator at 2°C to 8°C (36°F to 46°F), or
 - at room temperature up to 25°C (77°F)



Evusheld (tixagevimab and cilgavimab) for Pre-Exposure Prophylaxis Required Reporting of Adverse Events and Medication Errors

Submit adverse event and medication error reports, using Form 3500, to FDA MedWatch using one of the following methods:

- Complete and submit the report online: www.fda.gov/medwatch/report.htm
 - Complete and submit a postage-paid FDA Form 3500 (https://www.fda.gov/media/76299/download) and return by:
 - o Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or
 - Fax to 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 AstraZeneca:

Fax 1-866-742-7984

and to report adverse events please:

- Visit https://contactazmedical.astrazeneca.com, or
- Call AstraZeneca at 1-800-236-9933.

The prescribing healthcare provider and/or the provider's designee is/are to provide mandatory responses to requests from FDA for information about adverse events and medication errors associated with EVUSHELD.

Provider Best Practices

Sonia Bartolome, MD, FCCP

Professor, Pulmonary and Critical Care Medicine Associate Chief Quality Officer Health System Affairs



Operationalizing the Administration of Evusheld™ – The UTSW Experience

Operational Strategy

Education

- Medical Staff Communication
- Targeted Communication Toward Clinics

Order

- Standing Medical Orders
- Released to Clinics in Order of Risk
- Nurse calls patient, reviews reason for recommendation, physician available for questions, FDA patient fact sheet given to the patient electronically



Administration

- Epic Order Triggers Scheduling into Appointment Times
- Space Previously Utilized for Vaccines
- Patient Given a Hard Copy of the "Fact Sheet for Patients, Parents and Caregivers"
- Space for 1 hour observation

Evusheld™ Allocation



Phased Allocation by Risk



Group of clinical specialists, ethicists, equity experts met to create an allocation strategy



Epic Order and SMO released to clinics based on this phased allocation



Specific communication sent to clinics

Emails to clinic directors and managers, meetings, huddles

Phased Allocation Example

Phase 1 (highest risk)

- Lung transplant recipient (any time frame)
- Kidney or heart transplant recipient within the last 12 months
- Liver transplant recipient within the last 6 months
- Receipt of the following immunosuppressive medication within the past 12 months (including for solid organ transplant)
 - o Anti-thymocyte globulin (ATG)
 - o Alemtuzumab
- Allogeneic stem cell transplant, within 12 months of transplant
- Autologous stem cell transplant, within six months of transplant
- Allogeneic stem cell transplant at any time since transplant with GVHD of any grade or stage requiring systemic immunosuppression
- Receipt of anti-CD19 or anti-BCMA (CAR)-T-cell immunotherapy, within six months of treatment
- Primary T-cell immunodeficiency, including severe combined immunodeficiency



EvuSheld

Monoclonal Antibody Clinic Operations and Procedures for a Regional COVID Therapeutic Collaborative Texas Department of State Health Services' Therapeutics Provider Webinar – focused on EVUSHELD

2.11.22

DESMAR WALKES MD

MEDICAL DIRECTOR / HEALTH AUTHORITY

AUSTIN/TRAVIS COUNTY





Topics

- . Creation of Collaborative in Austin Travis County
- Rationale and Guidance Documents Used
- . System Model Created
- . Pros and Cons
- . Available Resources



TIER	RISK GROUP
1	•Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); <i>or</i> •Unvaccinated individuals at the highest risk of severe disease (≥75 years or anyone aged ≥65 years w/ risk factors)
2	•Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥65 years or anyone aged <65 years with clinical risk factors)
2	•Vaccinated individuals at high risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with clinical risk factors)

/

•Vaccinated individuals at risk of severe disease (anyone aged ≥65 years or anyone aged <65 with clinical risk factors)

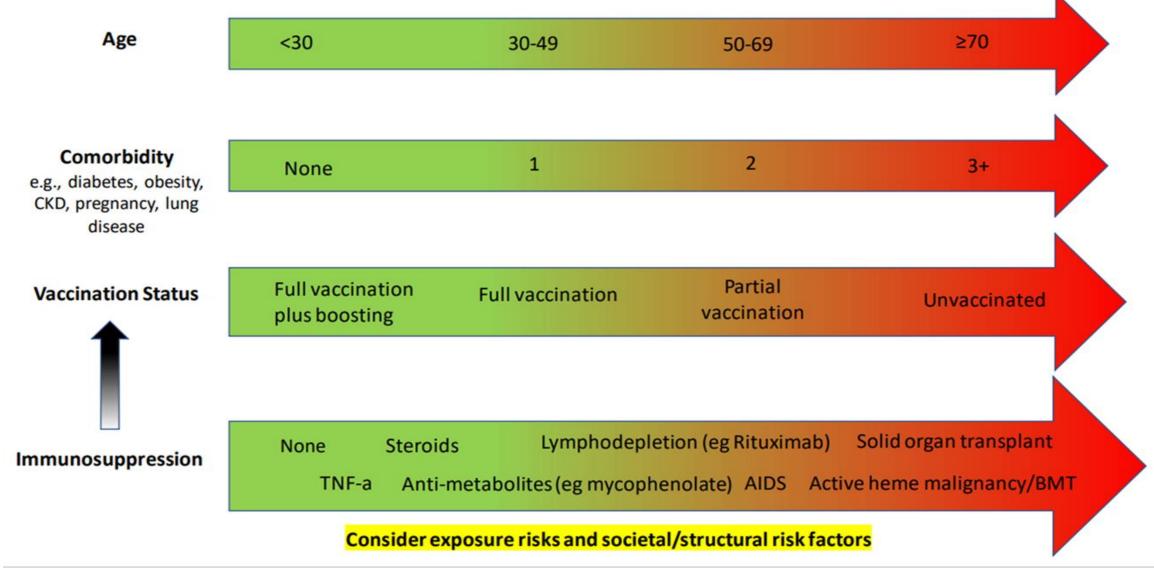
Note: Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment.

Note: Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for

severe disease; patients in this situation within this tier should be prioritized for treatment.

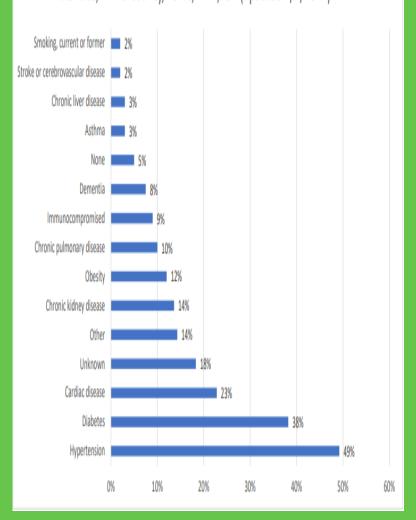


COVID-19 Risk Framework



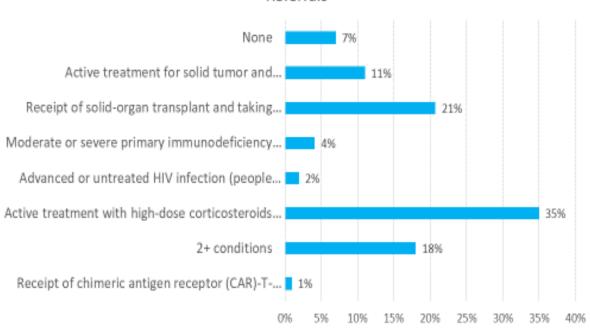


Comorbidities reported among confirmed COVID-19 case fatalities, Travis County, Texas, n= 1,282 (updated 2/7/2022)

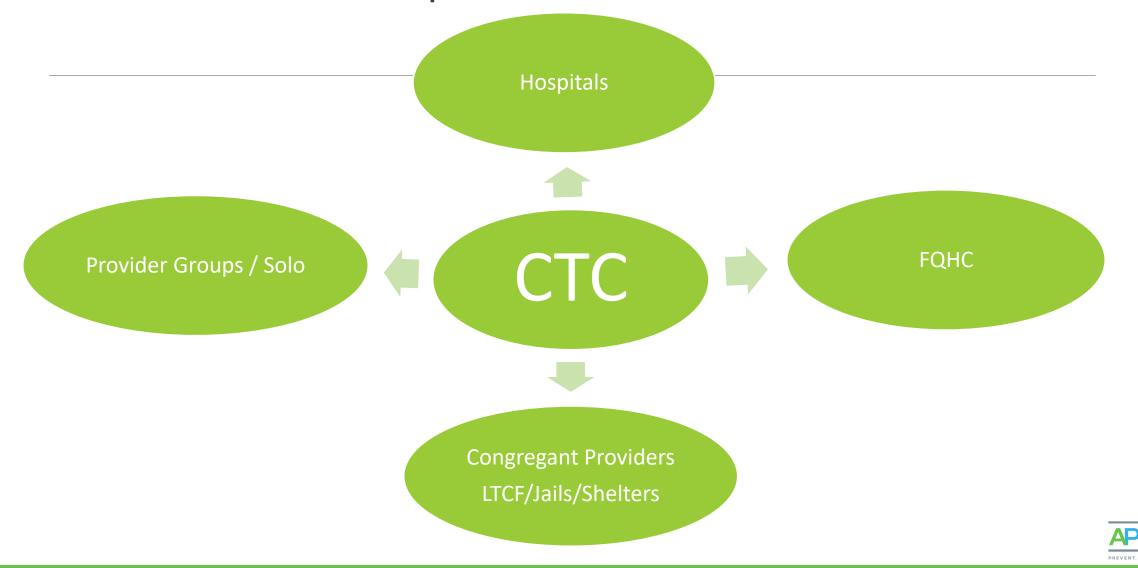


CTC Evusheld Patients Medical Diagnoses





Covid-19 Therapeutics Collaborative (стс)



EvuSheld Pros vs Cons

PROS

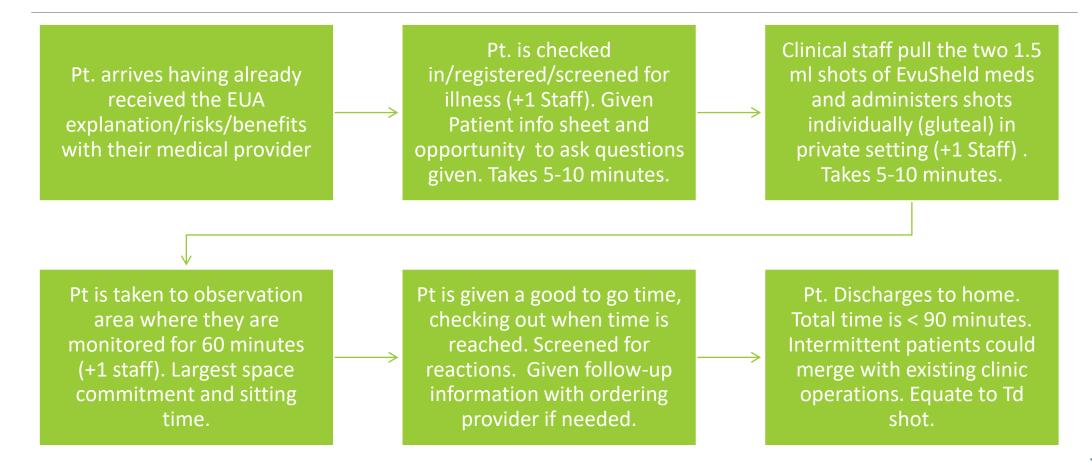
- No special storage requirements
- No dilution needed
- Can use standard IM injection process
- Does not require infusion
- •Quick and easy to pull and give

CONS

- One-hour observation
- Fridge space may require additional space if large volumes
- If large volumes address observation space needs

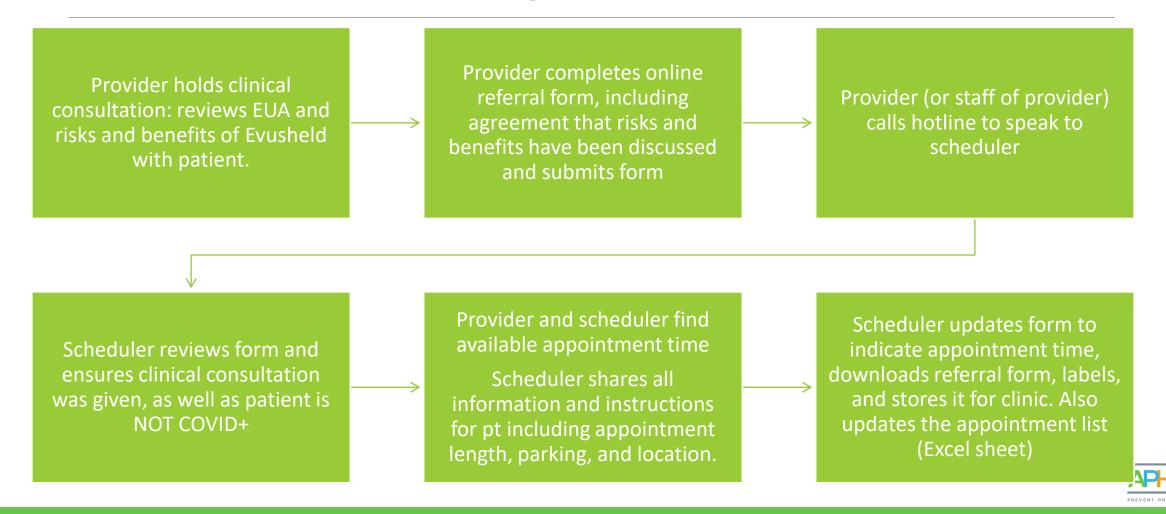


EvuSheld Continuous Clinic Process Flow





Evusheld Scheduling Process



Evusheld Analytics

Total Referrals: 314

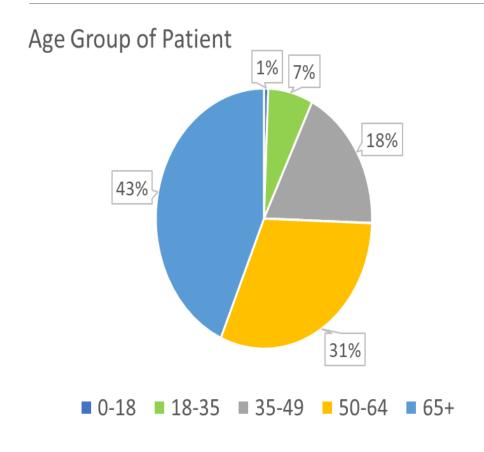
Total Treatments Given: 237 as of February 9th

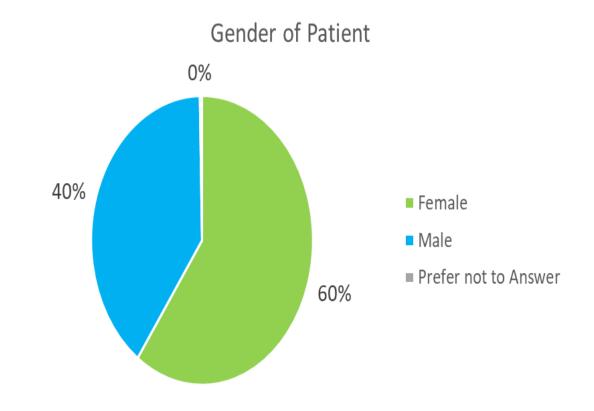
County	Patient Count
Bastrop	11
Bell	1
Bexar	1
Brazos	2 2
Caldwell	2
Comal	7
Dallas	4
DeWitt	1
Fort Bend	1
Harris	1
Hays	16

County	Patient Count
Hood	1
Kendall	1
Lampasas	1
Live Oak	1
Llano	1
Mason	1
McLennan	2
Milam	1
Nueces	1
Travis	204
Williamson	50



CTC Evusheld Analytics

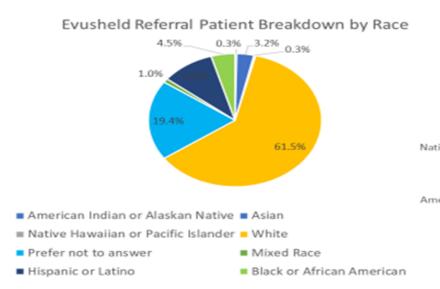


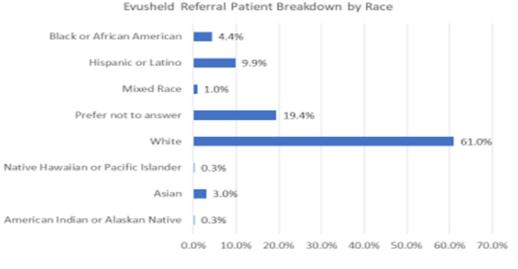




CTC Evusheld Analytics

Racial Breakdown







Thanks to CTC Members

Director Adrienne Sturrup APH

Dr. Jason Reichenberg Ascension

Dr. Ken Mitchell HCA

Dr. Nick Yagoda Community Cares

Dr. Scott Clitheroe Internal Medicine TCMS

Jason Fournier Community Cares FQHC

Dr. Manish Naik Austin Regional Clinic

Dr. Louis Appel Peoples Community Clinic FQHC

Ashley Hawes MPH APH

Dr. Amy Young OB Gyn UT Dell Medical

Dr. Parker Hudson Infectious Disease UT Dell Medical

Dr. Bill Rice HCA

Dr. Robin Watson BSW

Marshall Cothran TCMS

Mike Geeslin Central Health

Dr. Butler Lonestar Circle of Care FQHC

Toby Hatton RN Ascension

Dr. Anas Daghestani Austin Regional Clinic

Dr. Samson Jesudass Ascension

Dr. Rajesh Shetty Pulmonology Critical Care

Dr. Mary Beth Cishek Cardiology Ascension

Dr. Jason Martin Internal Medicine Ascension

Belinda Clare TCMS

Dr Alan Schalscha Central Health

Dr. Liam Fry Internal Medicine

Dr. Mike Stefanowicz Community Cares

Dr. Nancy Foster Internal Medicine





Thank you

Panel Q&A

Evusheld Ordering and Reporting Requirements

Ellen Willmore, MPH
Texas Department of State Health Services

Enrolling as a site for Evusheld

- Required: Texas pharmacy license OR Medical license of an authorizing provider (MD, DO, NP, Pharmacist) to complete account for distributor (AmerisourceBergen) to receive Evusheld
- Sites must have the facilities and resources needed to safely administer Evusheld to qualified patients
- Prescribers must determine the eligibility of a patient to receive Evusheld



Enrolling as a site for Evusheld

- Complete enrollment form and email to DSHS therapeutics
 - Texas pharmacy license OR Medical license of an authorizing provider (MD, DO, NP, Pharmacist)
 - Contact information for two users for HPOP (Health Partner Order Portal) Provider Portal
- DSHS will enter site into HPOP
- Each USER must activate their account from an email within 72 hours
- One user per site must VERIFY SITE ACCOUNT



Texas Department of State Health Services



Requesting Evusheld

You will not order in HPOP

After you receive the first shipment – to obtain additional Evusheld for your facility, email therapeutics@dshs.texas.gov with the number of courses of Evusheld requested.

- Requested quantities must be in multiples of 24. Any other quantity will be rounded UP.
- Please include the full name of the facility and State PIN from HPOP (e.g., TXA123456)
- Emailed requests received by COB on Wednesdays will be ordered that same week. Requests received after Wednesdays may not be ordered until the following week.
- At this time, DSHS receives Evusheld allocations each week

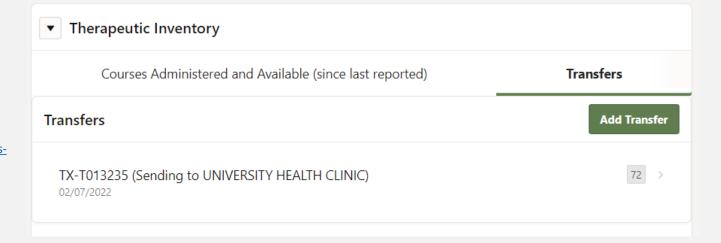


Transferring Evusheld

- You may only transfer to a location that is enrolled as an Evusheld provider.
- Please email <u>therapeutics@dshs.texas.gov</u> before you transfer to a site for the first time.
- Account for transfer within HPOP
- Receiving site must report

HPOP Help:

https://docs.oracle.com/en/industries/healthsciences/vpop-provider/vpopu/transfer-therapeuticsprovider.html



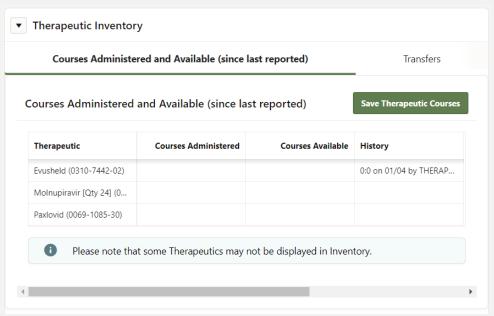


Reporting

- DAILY reporting in HPOP is required for Evusheld
 - Administered courses since your last entry
 - On-hand courses at that time
- No need to enter zeros for products not in inventory
- Patient/dose level reporting to <u>ImmTrac2</u>

HPOP Help: https://docs.oracle.com/en/industries/health-sciences/vpop-provider/vpopu/track-courses-stock.html

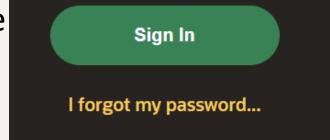




HPOP Resources

- HPOP Log in: https://vpop.cdc.gov/provider/signin/
- Quick Start Guide (available in Help menu)
- Oracle Resource Guide (available in Help menu)
- Health Partner Ordering Portal (HPOP) FAQs
- Login/system issues
 - CARS HelpDesk@cdc.gov or (833) 748-1979
- User able to reset password on sign-in page





Q&A

Closing Remarks

Manda Hall, MD

Associate Commissioner | Community Health Improvement
Texas Department of State Health Services

Resources



DSHS Resources

- For all questions, please contact therapeutics@dshs.Texas.gov
- DSHS Information for COVID-19 Therapeutics Providers



Resources

- NIH Treatment Guidelines for Prevention of COVID-19 Infection
- IDSA/CDC COVID-19 Clinician Resource Page
- <u>IDSA Clinician Call</u> (2/7/2022) discussion by panelists on addressing barriers to delivery/access of COVID-19 therapeutics including Evusheld
- Specialty Society Information on Evusheld
 - National Comprehensive Cancer Network
 - American Society of Transplantation
 - American College of Rheumatology
 - National Multiple Sclerosis Society
- covid-19-therapeutics-locator-dhhs



Resources

- DSHS Information for COVID-19 Therapeutics Providers
- U.S. HHS COVID-19 Public Therapeutic Locator
- Federal Response to COVID-19: Therapeutics Clinical Implementation Guide
- National Calls hosted by HHS/ASPR
 - Office Call Sessions: HHS/ASPR Distribution and Administration of COVID 19 Therapeutics
 - Tuesdays (1:00 2:00PM CT)
 - Federal COVID 19 Response: COVID 19 Therapeutics Clinical Webinar
 - Alternating Fridays (11:00 12:00PM CT); next meeting Feb. 18
 - Medical Professionals COVID 19 Roundtable
 - Alternating Fridays (11:00 12:00PM CT); next meeting Feb. 25
 - Email COVID19Therapeutics@hhs.gov for Zoom invitations



Texas Department of State Health Services



Medical Information Contact Information

Website: Welcome to AstraZeneca Medical

Telephone: 1-800-236-9933

Medical Team

Dr. Marcella Chock, PharmD, PAHM

Senior Medical Science Liaison

Mobile: 1+(808) 294-2799

marcella.chock@astrazeneca.com

Virtual Appointments: <u>AZUSIDMSL.com</u>

Thank you

Disclaimer

The information presented today is based on FDA's recent guidance and MAY change.

February 11, 2022