Disclaimer

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

February 11, 2022
Discussion Topics

- 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
Provider Best Practice Sharing

UTSW & APH

Sonia Bartolome, MD, FCCP
Professor, Pulmonary and Critical Care Medicine
Associate Chief Quality Officer, Health System Affairs

Desmar Walkes, MD
Medical Director / Health Authority
Austin / Travis County

UT Southwestern
Medical Center
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

Monoclonal Antibodies for PEP
- Casirivimab + Imdevimab (RGen)
- Bamlanivimab + Etesevimab (Lilly)**

Oral Antivirals
- Paxlovid (Pfizer)
- Molnupiravi (Merck)

Monoclonal Antibodies for treatment
- Sotrovimab (GSK/Vir)
- Bamlanivimab + Etesevimab (Lilly)
- Casirivimab + Imdevimab (RGen)**

**Not expected to be active against omicron variant.

• 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)

## Summary of Texas COVID-19 Therapeutics Allocation

<table>
<thead>
<tr>
<th></th>
<th>Monulpiravir*</th>
<th>Paxlovid*</th>
<th>Sotrovimab</th>
<th>Evusheld</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>December 2021</strong></td>
<td>19,800</td>
<td>4,240</td>
<td>4,974</td>
<td>7,872</td>
</tr>
<tr>
<td><strong>January 2022</strong></td>
<td>52,740</td>
<td>13,100</td>
<td>18,372</td>
<td>27,312</td>
</tr>
<tr>
<td><strong>February 2022</strong></td>
<td>26,328</td>
<td>6,540</td>
<td>4,416</td>
<td>3,912</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>98,868</td>
<td>23,880</td>
<td>27,762</td>
<td>39,096</td>
</tr>
</tbody>
</table>

*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-19-therapeutics-locator-dhhs
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 administered as two separate consecutive intramuscular injections.

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 **pre-exposure prophylaxis (prevention)** of COVID-19 in certain adults and pediatric individuals (12 years of age and older and weighing at least 40kg / 88lbs).
- It is **only** authorized for those individuals:
  - who are **not** 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 moderate to severe immune compromise 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)

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

- 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/mm$^3$, 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)

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Fact Sheet for Health Care Providers Emergency Use Authorization for Evusheld (tixagevimab c - packaged with cilgavimab (https://www.fda.gov/media/154701/download)
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 is not a substitute for vaccination 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

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

Fact Sheet for Health Care Providers Emergency Use Authorization for Evusheld (tixagevimab c - packaged with cilgavimab (https://www.fda.gov/media/154701/download)
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>
<thead>
<tr>
<th>Table 6</th>
<th>Incidence of Symptomatic COVID-19 in Adults (PROVENT)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EVUSHIELD†</td>
</tr>
<tr>
<td></td>
<td>N*</td>
</tr>
<tr>
<td>EVUSHIELD†</td>
<td>3,441</td>
</tr>
<tr>
<td>Placebo</td>
<td>1,731</td>
</tr>
</tbody>
</table>

N = number of subjects in analysis; CI = Confidence Interval
* subjects were censored after receiving the vaccine or being unblinded to consider the vaccine, whichever occurred earlier
† EVUSHIELD dose (150 mg tixagevimab and 150 mg cilgavimab)

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

<table>
<thead>
<tr>
<th>Event</th>
<th>EVUSHELD N= 3,461</th>
<th>Placebo N= 1,736</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>6%</td>
<td>5%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Cough</td>
<td>3%</td>
<td>3%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Category</th>
<th>EVUSHELD N= 3,461</th>
<th>Placebo N= 1,736</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects with any cardiac SAE*</td>
<td>22 (0.6%)</td>
<td>3 (0.2%)</td>
</tr>
<tr>
<td>SAEs related to coronary artery disease or myocardial ischemia†</td>
<td>10 (0.3%)</td>
<td>2 (0.1%)</td>
</tr>
<tr>
<td>Myocardial infarctions‡</td>
<td>8 (0.2%)</td>
<td>1 (0.1%)</td>
</tr>
<tr>
<td>SAEs related to cardiac failure‡</td>
<td>6 (0.2%)</td>
<td>1 (0.1%)</td>
</tr>
<tr>
<td>SAEs related to an arrhythmia‡</td>
<td>4 (0.1%)</td>
<td>1 (0.1%)</td>
</tr>
<tr>
<td>Other (cardiomegaly, cardiomyopathy, and cardio-respiratory arrest)</td>
<td>3 (0.1%)</td>
<td>0</td>
</tr>
</tbody>
</table>

*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 term 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.

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

• 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
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
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)
  - Anti-thymocyte globulin (ATG)
  - 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
<table>
<thead>
<tr>
<th>TIER</th>
<th>RISK GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>• 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); or • Unvaccinated individuals at the highest risk of severe disease (≥75 years or anyone aged ≥65 years with risk factors)</td>
</tr>
<tr>
<td>2</td>
<td>• Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥65 years or anyone aged &lt;65 years with clinical risk factors)</td>
</tr>
</tbody>
</table>
| 3    | • Vaccinated individuals at high risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years 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. |
| 4    | • 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. |
COVID-19 Risk Framework

**Age**
- <30
- 30-49
- 50-69
- ≥70

**Comorbidity**
- None
- 1
- 2
- 3+

**Vaccination Status**
- Full vaccination plus boosting
- Full vaccination
- Partial vaccination
- Unvaccinated

**Immunosuppression**
- None
- Steroids
- Lymphodepletion (e.g., Rituximab)
- Solid organ transplant
- TNF-α
- Anti-metabolites (e.g., mycophenolate)
- AIDS
- Active heme malignancy/BMT

Consider exposure risks and societal/structural risk factors
### CTC Evusheld Patients Medical Diagnoses

<table>
<thead>
<tr>
<th>Condition</th>
<th>Referrals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking current or former</td>
<td>2%</td>
</tr>
<tr>
<td>Stroke or cerebrovascular disease</td>
<td>2%</td>
</tr>
<tr>
<td>Chronic liver disease</td>
<td>6%</td>
</tr>
<tr>
<td>Asthma</td>
<td>3%</td>
</tr>
<tr>
<td>None</td>
<td>5%</td>
</tr>
<tr>
<td>Dementia</td>
<td>8%</td>
</tr>
<tr>
<td>Immunosuppression</td>
<td>9%</td>
</tr>
<tr>
<td>Chronic pulmonary disease</td>
<td>20%</td>
</tr>
<tr>
<td>Obesity</td>
<td>12%</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>14%</td>
</tr>
<tr>
<td>Other</td>
<td>1%</td>
</tr>
<tr>
<td>Unknown</td>
<td>10%</td>
</tr>
<tr>
<td>Cardiac disease</td>
<td>22%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>28%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>45%</td>
</tr>
</tbody>
</table>

### Distribution of Medical Conditions within Evusheld Patient Referrals

- None: 7%
- Active treatment for solid tumor and...: 11%
- Receipt of solid-organ transplant and taking...: 21%
- Moderate or severe primary immunodeficiency...: 4%
- Advanced or untreated HIV infection (people...: 2%
- Active treatment with high-dose corticosteroids...: 35%
- 2+ conditions: 18%
- Receipt of chimeric antigen receptor (CAR)-T...: 1%
Covid-19 Therapeutics Collaborative (CTC)

CTC

- Hospitals
- Provider Groups / Solo
- Congregant Providers
  - LTCF/Jails/Shelters
- FQHC
# EvuSheld Pros vs Cons

<table>
<thead>
<tr>
<th><strong>PROS</strong></th>
<th><strong>CONS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>No special storage requirements</td>
<td>One-hour observation</td>
</tr>
<tr>
<td>No dilution needed</td>
<td>Fridge space may require additional space if large volumes</td>
</tr>
<tr>
<td>Can use standard IM injection process</td>
<td>If large volumes address observation space needs</td>
</tr>
<tr>
<td>Does not require infusion</td>
<td></td>
</tr>
<tr>
<td>Quick and easy to pull and give</td>
<td></td>
</tr>
</tbody>
</table>
Pt. arrives having already received the EUA explanation/risks/benefits with their medical provider.

Pt. is checked in/registered/screened for illness (+1 Staff). Given Patient info sheet and opportunity to ask questions given. Takes 5-10 minutes.

Clinical staff pull the two 1.5 ml shots of EvuSheld meds and administers shots individually (gluteal) in private setting (+1 Staff). Takes 5-10 minutes.

Pt. is taken to observation area where they are monitored for 60 minutes (+1 staff). Largest space commitment and sitting time.

Pt is given a good to go time, checking out when time is reached. Screened for reactions. Given follow-up information with ordering provider if needed.

Pt. Discharges to home. Total time is < 90 minutes. Intermittent patients could merge with existing clinic operations. Equate to Td shot.
Evusheld Scheduling Process

1. Provider holds clinical consultation: reviews EUA and risks and benefits of Evusheld with patient.
2. Provider completes online referral form, including agreement that risks and benefits have been discussed and submits form.
3. Provider (or staff of provider) calls hotline to speak to scheduler.
4. Scheduler reviews form and ensures clinical consultation was given, as well as patient is NOT COVID+.
5. Provider and scheduler find available appointment time.
6. Scheduler shares all information and instructions for pt including appointment length, parking, and location.
7. Scheduler updates form to indicate appointment time, downloads referral form, labels, and stores it for clinic. Also updates the appointment list (Excel sheet).
Evusheld Analytics

Total Referrals: 314

Total Treatments Given: 237 as of February 9th

<table>
<thead>
<tr>
<th>County</th>
<th>Patient Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bastrop</td>
<td>11</td>
</tr>
<tr>
<td>Bell</td>
<td>1</td>
</tr>
<tr>
<td>Bexar</td>
<td>1</td>
</tr>
<tr>
<td>Brazos</td>
<td>2</td>
</tr>
<tr>
<td>Caldwell</td>
<td>2</td>
</tr>
<tr>
<td>Comal</td>
<td>7</td>
</tr>
<tr>
<td>Dallas</td>
<td>4</td>
</tr>
<tr>
<td>DeWitt</td>
<td>1</td>
</tr>
<tr>
<td>Fort Bend</td>
<td>1</td>
</tr>
<tr>
<td>Harris</td>
<td>1</td>
</tr>
<tr>
<td>Hays</td>
<td>16</td>
</tr>
<tr>
<td>Hood</td>
<td>1</td>
</tr>
<tr>
<td>Kendall</td>
<td>1</td>
</tr>
<tr>
<td>Lampasas</td>
<td>1</td>
</tr>
<tr>
<td>Live Oak</td>
<td>1</td>
</tr>
<tr>
<td>Llano</td>
<td>1</td>
</tr>
<tr>
<td>Mason</td>
<td>1</td>
</tr>
<tr>
<td>McLennan</td>
<td>2</td>
</tr>
<tr>
<td>Milam</td>
<td>1</td>
</tr>
<tr>
<td>Nueces</td>
<td>1</td>
</tr>
<tr>
<td>Travis</td>
<td>204</td>
</tr>
<tr>
<td>Williamson</td>
<td>50</td>
</tr>
</tbody>
</table>
CTC Evusheld Analytics

Age Group of Patient

- 0-18: 31%
- 18-35: 18%
- 35-49: 43%
- 50-64: 7%
- 65+: 1%

Gender of Patient

- Female: 60%
- Male: 40%
- Prefer not to Answer: 0%
CTC Evusheld Analytics
# Thanks to CTC Members

<table>
<thead>
<tr>
<th>Name</th>
<th>Profession/Role</th>
<th>Organization/Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director Adrienne Sturrup APH</td>
<td>Dr. Amy Young OB Gyn UT Dell Medical</td>
<td>Dr. Samson Jesudass Ascension</td>
</tr>
<tr>
<td>Dr. Jason Reichenberg Ascension</td>
<td>Dr. Parker Hudson Infectious Disease UT Dell Medical</td>
<td>Dr. Rajesh Shetty Pulmonology Critical Care</td>
</tr>
<tr>
<td>Dr. Ken Mitchell HCA</td>
<td>Dr. Bill Rice HCA</td>
<td>Dr. Mary Beth Cishek Cardiology Ascension</td>
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<td>Dr. Nick Yagoda Community Cares</td>
<td>Dr. Robin Watson BSW</td>
<td>Dr. Jason Martin Internal Medicine Ascension</td>
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<td>Dr. Scott Clitheroe Internal Medicine TCMS</td>
<td>Marshall Cothran TCMS</td>
<td>Belinda Clare TCMS</td>
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<tr>
<td>Jason Fournier Community Cares FQHC</td>
<td>Mike Geeslin Central Health</td>
<td>Dr Alan Schalscha Central Health</td>
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<td>Dr. Manish Naik Austin Regional Clinic</td>
<td>Dr. Butler Lonestar Circle of Care FQHC</td>
<td>Dr. Liam Fry Internal Medicine</td>
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<tr>
<td>Dr. Louis Appel Peoples Community Clinic FQHC</td>
<td>Toby Hatton RN Ascension</td>
<td>Dr. Mike Stefanowicz Community Cares</td>
</tr>
<tr>
<td>Ashley Hawes MPH APH</td>
<td>Dr. Anas Daghestani Austin Regional Clinic</td>
<td>Dr. Nancy Foster Internal Medicine</td>
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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

⚠️ Therapeutic Address needs verification
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 therapeutics@dshs.texas.gov before you transfer to a site for the first time.
- Account for transfer within HPOP
- Receiving site must report

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 **ImmTrac2**

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
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
- IDSA Clinician Call (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
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: AZUSIDMSL.com
Thank you
Disclaimer

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

February 11, 2022