

Script for TIR Monoclonal Antibody Disaster Reporting

Closed Captioning

Closed captioning for this presentation is available at the following link:
<https://tcc.1capapp.com/event/dshs/>

Title Slide

Monoclonal Antibody Disaster Reporting

Agenda

In this presentation we will discuss:

- What is the Texas Immunization Registry?
- Reporting requirements for Monoclonal Antibodies
- ImmTrac2 consents
- How to add Regeneron-IgG
- How to add Regeneron- COV
- How to add Bamlanivimab and Etesevimab
- Resources for Reporting Monoclonal Antibodies
- And we'll end with a Q and A session

What is the "Registry"?

The Texas Immunization Registry (ImmTrac2)

The Registry is secure and confidential. It safely consolidates and stores immunization records from multiple sources in one centralized system.

Organizations that are authorized for the Registry include health care providers, schools, and public health departments.

Reporting Requirements for Monoclonal Antibodies

Providers Must Report AIMs

A health care provider who administers an antiviral, immunization, or other medication, known as an AIM, used for the management or treatment of a publicly declared disaster will report this to the DSHS Texas Immunization Registry. I will be referring to Antivirals, Immunizations, or Medications as AIMs for the duration of this presentation.

The statute relating to the disaster reporting is Texas Administrative Code, Title 25 Chapter 100, Rule 100.7, which can be searched in a browser to read the full statute. I'll discuss the key points of this statute.

ImmTrac2 Consents

Disaster and Standard Consents

Disaster consents only affect disaster AIMs being reported. **Standard** minor or adult consents only affect **standard** (ACIP recommended) immunizations being reported. A client can have:

- No consents at all, or
- Only a disaster consent, or
- Only a standard minor or adult consent, or
- Both a disaster consent and a standard minor or adult consent

Disaster Consents

- Disaster AIMs must be reported regardless of ImmTrac2 consent status.
- BUT, If the client did sign a "Disaster Information Retention Consent", then the Registry can keep the disaster AIM for longer than 5 years after the end of the disaster.
- Otherwise, the client's disaster AIM is deleted 5 years after the end of the disaster.
- For more information about disaster consents, see the "Online Disaster Reporting" video on our User Training webpage at <https://www.dshs.texas.gov/immunize/immtrac/user-training/>.

How to Add Regeneron-IgG

Regeneron –IgG 1 Dosing

Individual CASIRIVIMAB AND IMDEVIMAB solutions must be ADMINISTERED TOGETHER but REPORTED SEPARATELY.

Casirivimab and Imdevimab may each be supplied as 1,332 mg per 11.1 mL (which is the equivalent of 120 mg per mL) single-dose vials, OR 300 mg per 2.5 mL (which is the equivalent of 120 mg per mL) single-dose vials.

In ImmTrac2, in the Client's Record, Click the Immunizations Button to go to the Client's Immunizations.

Click the "Add New Imms" button to add a new monoclonal antibody to the client's record.

Adding REGENERON-IgG 1

For reporting REGENERON-IgG 1, providers are required to report two records for the administration, one for Casirivimab and one for Imdevimab, at a dose of 1,332 mg per 11.1 mL each, as shown in the screenshot.

Regeneron-IgG 1 – Override Warning

Once you report one record for Casirivimab and one for Imdevimab, ImmTrac2 displays an override warning stating "You are attempting to enter potential duplicate immunization records". Select the "Save Selected" button at the bottom of the screen to save the AIM to the patient's record.

Casirivimab and Imdevimab monoclonal antibodies are now added to the client's record.

How to Add Regeneron-COV

Regeneron-COV Dosing

The authorized dosage is 600 mg of Casirivimab and 600 mg of Imdevimab administered by subcutaneous injection or together as a single intravenous infusion as soon as possible following exposure to SARS-COVID-2. For individuals in whom repeat dosing is determined to be appropriate for ongoing exposure to SARS-Covid-2 for longer than 4 weeks and who are not expected to mount an adequate immune response to complete SARS-COVID-2 vaccination, the initial dose is 600 mg of Casirivimab and 600 mg of Imdevimab by subcutaneous injection or intravenous infusion followed by subsequent repeat dosing of 300 mg of Casirivimab and 300 mg of Imdevimab by subcutaneous injection or intravenous infusion once every four weeks for the duration of ongoing exposure. **1 vial per carton contains both Casirivimab and Imdevimab with 600mg, 600mg per 10mL. 1 vial is one dose. It is administered intravenously and reported as one full dose.**

Adding Regeneron Dose Pack

For reporting REGEN-COV, select the option Regeneron Dose PK from the drop-down menu. Select Regeneron Dose Pack 39 as the trade name. Add the lot number. The manufacturer is REG-Regeneron Pharmaceuticals. It is administered intravenously and reported as one full dose. Select Save. This will save Regeneron COV in the client immunization record.

The Regeneron Dose Pack is Now Added.

How to Add Bamlanivimab and Etesevimab

Bamlanivimab and Etesevimab Combined Treatment for Post-Exposure Prophylaxis: Dosing is one vial of Bamlanivimab plus two vials of Etesevimab

The dosage in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) is 700 mg of Bamlanivimab and 1,400 mg of Etesevimab administered together as soon as possible following exposure to SARS-COVID-2. Bamlanivimab and Etesevimab are supplied in individual single-dose vials but are administered together using a single infusion bag. Use one vial of Bamlanivimab and two vials of Etesevimab.

Adding Bamlanivimab and Etesevimab if Pulling Etesevimab from ONE Lot Number. The Etesevimab Dose = 2.

For reporting the combined treatment of Bamlanivimab and Etesevimab, providers are required to report two records for the administration, one full dose for Bamlanivimab and set the dose to two for Etesevimab, as shown in the screenshot on the slide. The manufacturer is Eli Lilly and Company.

Note: The dose is 2 in the bottom right corner indicating TWO Doses, NOT the Second in a Sequence.

Last Warning for Consent or No Consent

When you click to add the disaster AIM you will see this message pop-up. Click "OK" if you received consent for this client and want to enter it. If the client elected to not consent their participation in the Registry, click "Cancel".

If "OK" was Chosen on the Previous Slide, Here You Can Add a DIR Consent by clicking Option 1 and clicking Disaster Information Retention Consent Form, and then clicking "Update Client".

The Client's Immunization Record is Updated with One Dose of Bamlanivimab and Two Doses of Etesevimab, of the Same Lot.

The two doses of Etesevimab were from the same lot and the dose = 2.

Adding Bamlanivimab and Etesevimab if Pulling Etesevimab from TWO Different Lots. Etesevimab is on two lines with a full dose on each line and the doses have different lot numbers.

Adding Bamlanivimab and Etesevimab - Override Warning

Once you report one dose of Bamlanivimab and two doses of Etesevimab from different lots, ImmTrac2 displays an override warning. Click the "Selected" boxes and then click the "Save Selected" button at the bottom of the screen to save the

Monoclonal Antibodies to the patient's record.

A "Validation Errors" Message is Displayed. Click "OK".

This message is currently displayed but will be removed later. The Bamlanivimab dose has already been recorded and to continue to record the Etesevimab doses you must click OK.

On the Third Row (Which is Blank), Click the "Remove" Box on the Left Side of that Row, then Click Save.**Another "Duplicate Immunization" Warning is Displayed.**

Again click the two "Selected" boxes on the right, and then click the "Save Selected" button at the bottom of the screen to continue.

If the Client Signed a DIR Consent, Add the DIR Consent Now.

Click the "OK" box to add a disaster-related consent if the client signed one. Otherwise, click the "Cancel" button to save the monoclonal antibody to the client's record without a disaster-related consent.

If "OK" was Chosen on the Previous Slide, You Can Add a DIR Consent Now.

To add a disaster related consent, click the Option 1 button and then click the button labelled "Disaster Information Retention Consent Form". Finally, click the "Update Client" button.

The Client's Immunization Record is Now Updated with One Dose of Bamlanivimab and Two Doses of Etesevimab from Two Different Lots.**Resources for Reporting Monoclonal Antibodies**

I will now mention some resources that may be beneficial to providers.

Resources for COVID-19 Reporting.

Data exchange specifications for monoclonal antibody reporting will soon be available. Information for COVID-19 vaccination providers is given on this first link, and a video on how to report disaster immunizations to ImmTrac2 is given on the second link.

Resources for Clinicians – Monoclonal Antibody Treatment Part 1.

This first link discusses Monoclonal Antibody Eligibility - Treatment and Post Exposure Prophylaxis. The next link is a Monoclonal Antibody Checklist for subcutaneous and intravenous administration.

Resources for Clinicians – Monoclonal Antibody Treatment Part 2.

The first link gives subcutaneous injection instructions for REGEN-COV.

The second link discusses treatment and post-exposure prophylaxis of REGEN-COV.

Resources for Clinicians – Monoclonal Antibody Treatment Part 3.

This link provides interim clinical considerations for use of COVID-19 vaccines currently approved in the United States.

Resources for Clinicians – Monoclonal Antibody Treatment Part 4.

This link gives step-by-step instructions for placing a COVID-19 therapeutic order in VAOS. The COVID-19 Support Line is 833-832-7068, option zero, from 8:00 am to 5:00 pm, Monday through Friday.

Thank You!

Thank you, from the Texas Immunization Registry. This concludes our presentation.

Questions?

I will now open the floor for the Question and Answer session.

AFTER Q&A if time runs out.

We have reached the top of the hour and our time is up. Any questions that were not answered will be addressed via email correspondence. Thanks for attending the webinar. Bye!