Transcript for
TIR Monoclonal Antibody Disaster Reporting

Given on October 15, 2021

Welcome to monoclonal antibody disaster reporting. In this we'll discuss about reporting requirements for monoclonal antibodies, ImmTrac2 consents, how to add Regeneron IgG. How to add Regeneron-COV, how to add Imdevimab and Etesevimab, and we'll end with a question and answer session.

What is the Registry?

The Texas Immunization Registry, known as ImmTrac2. The registry is secure and confidential. It safely consolidates and stores immunization records from multiple sources into one centralized system. Organizations that are authorized 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 and treatment of a publicly declared disaster will report this to the DSHS Texas Immunization Registry. I'll be referring to antivirals, immunizations, or medications as AIMs for the duration of this presentation. The statute related to the disaster reporting is Texas Administrative Code Title 25, Chapter 100, Rule 100.7, which can be searched in a browser. 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 a disaster AIM for longer than five years after the end of

the disaster. Otherwise, the client's disaster AIM is deleted five years after the end of the disaster. For more information about disaster consents see the online disaster reporting video on our User Training web page that you can get to by using the link at the bottom of this screen.

How to add Regeneron IgG.

Regeneron IgG dosing. Individual Casirivimab and Imdevimab solutions must be administered together but reported separately. Casirivimab and Imdevimab may each be supplied as 1,332 milligrams for 11.1 milliliters, which is the equivalent of 120 milligrams per milliliter single dose vials or 300 milligrams per 2.5 milliliters, which is the equivalent of 120 milligrams per milliliters 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 antibody to the client's record.

Adding Regeneron IgG1. For reporting Regeneron, IgG1 providers are required to report two records for the administration, one for Casirivimab, and one for Imdevimab at a dose of 1,332 milligrams per 11.1 milliliters each, as shown in the screenshot.

Regeneron IgG1 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 dozing. The authorized dosage is 600 milligrams of Casirivimab and 600 milligrams of Imdevimab administered by subcutaneous injection or together as a single 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 four weeks and

who are not expected to mount an adequate immune response to complete SARS-COVID-2 vaccination, the initial dose is 600 milligrams of Casirivimab and 600 milligrams of Imdevimab by subcutaneous injection or intravenous infusion followed by a subsequent repeat dosing of 300 milligrams of Casirivimab, and 300 milligrams of Imdevimab by subcutaneous injection or intravenous infusion once every four weeks for the duration of ongoing exposure. **One vial per carton contains both Casirivimab and Imdevimab with 600 milligrams and 600 milligrams, or 10 milliliters. One 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 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 Bamlamivimab and Etesevimab. Bamlamivimab and Etesevimab combined treatment for post-exposure prophylaxis: Dosing is one vial of Bamlamivimab and two vials of Etesevimab.

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

Adding Bamlamivimab and Etesevimab if Pulling Etesevimab from ONE lot number. The Etesevimab dose will be two. For reporting the combined treatment of Bamlamivimab and Etesevimab, providers are required to report two records for the administration, one full dose for Bamlamivimab 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 two, and 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 "okay" 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 "Okay" was chosen on the previous slide, here you can add a DIR consent by clicking Option One and clicking "Disaster Information Retention Consent Form" and then clicking "Update Client".

The client's immunization record is updated with one dose of Bamlamivimab and two doses of Etesevimab of the same lot. The two doses of Etesevimab were, again, from the same lot and the dose equals two.

Adding Bamlamivimab 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.

An override warning. Once you report one dose of Bamlamivimab 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 Bamlamivimab 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 and 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 labeled "Disaster Information Retention Consent Form". Finally, click the "Update Client" button.

The client's immunization record is now updated with one dose of Bamlamivimab and two doses of Imdevimab from two different lots.

Resources for reporting monoclonal antibodies. I'll 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 the 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. The 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 clinical considerations for 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 a.m. to 5:00 p.m., Monday through Friday.

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

Now I'll open the floor up with a question and answer session.

>> We don't currently have any questions. Oh, here we go. Can DSHS comment on whether or not the -- are reportable AIMs to ImmTrac under Title 25, Chapter 100, Rule 100.7?

>> I can answer that, Kelly. Any medication that is given for COVID reasons is reportable under the AIMs Title 25, Chapter 100, Rule 100.7. It doesn't matter what treatment it is, what medication it is, if it was used for a disaster, it needs to be reported.

>> What is disaster consent?

>> I can answer that. It's actually a disaster information retention consent. All disaster AIMs, including the monoclonal antibodies have to be reported to the Texas Immunization Registry. Regardless of whether a person has a consent or not, if they don't have a consent, they are classified as a disaster-unconsented client, but if we don't have a disaster consent from a disaster client, then we can only keep that disaster record for up to five years, and at the end of five years after the end of the disaster, we have to delete that record. However, if we have a disaster consent, then we can keep that disaster record for the client for longer than five years after the end of the disaster. And the consent forms can be found on our Forms and Publications website. If you go to a browser, if you just type in "Immunize Texas" and then click on "ImmTrac 2 Immunization Registry" and then click on the "Forms and Publications", you can scroll down and see the publications and all the consent forms that we have, the disaster consent, consent for minors, consent for adults, so forth in addition to our publications.

>> Also, go ahead and add that you have the link for our forms and document website.

>> Is it still required to report Remdesivir?

>> I believe so.

>> Go ahead, please, thank you.

>> Yes, as was mentioned previously anything that is used for COVID treatment has to be reported to the Registry, and as such, if used for the COVID treatment, needs to be reported.

>> Will this webinar be archived to be reviewed later?

>> Yes, it will. The reporting and the transcript and the PowerPoint slides will be displayed probably on our User Training website, and, in fact, in ImmTrac2 there's even a tab that you can click on to go directly to the User Training website. That's where we have recorded webinars, and it will have everything we have on this. The PowerPoint slides, the MP4 recording, and the transcription with the captions and so forth.

>> If we have trouble getting registered for ImmTrac 2 despite repeated requests, can we get help? No one seems to answer at ImmTrac2.gov.

>> That inbox is monitored every day, and we are up-to-date on that inbox. It should end up in our Registration/Renewal inbox.

>> If we are reporting to TDEM, do we need to report to ImmTrac, or does ImmTrac get its data from TDEM?

>> TDEM doesn't report to us at all.

>> So, yes, you would need to report to ImmTrac.

>> Can you confirm which entity we need to report to?

>> Kind of a general question. Can you all be more specific on what you are talking about. It needs to be reported to ImmTrac if dealing with COVID-19. If there are other people asking to report to them, I'm not sure what the answer is for them.

>> You have to report to both TDEM and ImmTrac2.

>> May I ask why you would want to keep the consent for longer than five years?

>> It's a lifetime registry. Basically, from birth to death we keep anything that people consent for. That's why we keep -- as long as they consent to being in the registry, they'll be kept for a lifetime. If they're only disaster consented, then it's only for five years by law.

>> What was the contact information for questions on monoclonal antibody reporting?

>> You can send your questions to ImmTrac2@DSHS.Texas.gov. We have a COVID-2 team at the Registry that answers all the questions related to monoclonal antibody reporting. We are up-to-date with all the emails, so if your question has not been answered, please put "Attention COVID-2" on that, and we'll be glad to answer your questions.

>> Has reporting on ImmTrac always been a requirement, or is this a new process? Do we need to go back and enter our infusions from previous weeks?

>> If it was given for COVID-related treatment, then yes, they need to be reported. Anything that is COVID related that is disaster-related needs to be reported to the Registry. And if they have given monoclonal antibodies for

treatment of as prophylaxis post-exposure, then, yes, they need to be reported, that needs to be reported.

>> Is there a plan to allow users to upload this data into ImmTrac, like we do with the vaccines?

>> If you are referring to manually entering the immunizations through ImmTrac, you are able to do that, and there's actually a way for organizations to report through data exchange, but if you are saying-- if you mean, like, a mass amount, like through a CSV file, that option is not available.

>> Why is ImmTrac or TDEM or both?

>> Could you repeat that question, please?

>> Why is it ImmTrac or TDEM or both?

>> It has to be reported to both TDEM and ImmTrac2 both.

>> I think referring back to the previous question where we didn't have enough information, what was the context, can you clarify who we must report to? I think it's referring to, and the follow-up was TDEM federal entities or registry.

>> Can you repeat the question?

>> Sure. I believe earlier the next question refers to this. Can you clarify who or which entity we must report to and the follow-up for more information, TDEM, federal entities, or registry.

>> Your first question, it has to be reported to both, the reporting has to be done to both ImmTrac and TDEM. ImmTrac is the Registry where we're getting all the data that we are submitting for the therapeutics. Did I answer that question? Do you need more clarification?

>> We're going to move on to the next. Where do we find the RXA thing that's for sending the EMR's interface?

>> So, the segment is a segment, also in a message. This is something that she'll definitely need to work to be able to specifically use in regards to the segment when it comes to reporting the immunization. You would definitely need to work with the EHR vendor to be able to report any of those immunizations through data exchange and specifically, reporting those immunizations for that

segment.

>> We will be posting more information on specifically about data exchange and monoclonal antibody reporting also.

>> For our facility, vaccines are able to be reported through an ADT that sends data daily. Is there a way to automate the reporting since they aren't vaccines? The manual process is very inefficient for large organizations.

>> The registry does not support the ADT message trigger, so what we use for immunizations is -- you would definitely need to work with your EHR vendor to see if you are able to report or cause the trigger, because we do not use the ADT because ADT is usually for admit, discharge, and transfer, whereas the VX is specifically for vaccine or immunization reporting. That's something that you would definitely need to work with your EHR vendor to get to be able to send over to the registry.

>> How often must it be reported?

>> I'm assuming they're asking how often the immunization must be reported, but they must be reported as you are reporting them. Actually, administer them. They need to be reported to the registry.

>> For reporting the vaccinations, the disaster COVID-19 vaccinations, those should be reported to the Registry within 24 hours. For monoclonal antibodies, it's a good idea to report them within two or three days for the main reason -- well, for several reasons, but one of them being that if you don't report the administration promptly, then that could affect the distribution to you later on.

>> I'm assuming this is just a general question and not just COVID, but we follow the CDC specs as well, but you can definitely check on our Forms and Documents website where we have our implementation guide and our implementation guide does list a few segments. There are a few segments that Texas requires that the CDC may not require. To answer your question, though, definitely check out our Forms and Documents website. That information will be on there.

>> We received an email stating we did not need to be reporting to ImmTrac at this time. That was on 9/30. Did something change?

>> I would say could you please forward that email over to the Registry

because I'm not sure why it would be stated. Maybe, in regards to something else, but please forward that email over to the ImmTracMU@DSHS.Texas.gov email, and in the subject line just attach or state "Webinar Question". That way we get to look at the email to see what was stated in that email.

>> So, in TDEM we don't have to report daily?

>> I don't know what the TDEM requirements are for reporting. We were saying earlier, if it's a COVID vaccination, then for the vaccination, that needs to be reported daily. For the monoclonal antibodies, it's a good idea to report it within two or three days, but I don't know what the requirements are for the TDEM reporting.

>> That's all the questions I have right now.

>> Okay. Well, we will be posting all of this, the transcript and slides and the video, all of it, onto our User Training webpage later on. Thank you very much for joining us, and I hope this is -- we hope this has been helpful, and informational to you. Have a great day.