

Texas HIV Medication Advisory Committee

DRAFT Meeting Minutes

July 31, 2020

1:30 p.m.

Location: Microsoft Teams Live Event

Member Name	Attended
Adjel, Margaret	No
Alozie, Ogechika Karl, M.D.	Yes
Heresi, Gloria, M.D.	Yes
Hillard, Lionel	Yes
Lazarte Susana, M.D.	Yes
Miertschin, Nancy, M.P.H.	Yes
Moore, Clyde "Ray"	Yes
Rodriguez-Escobar, Yolanda, Ph.D.	Yes
Rosas, Frank	Yes
Tennison, Demetra	No
Vanek, Natalie, M.D. (Chair)	Yes

Agenda Item 1: Call Meeting to Order, Welcome and Opening Remarks

Dr. Natalie Vanek, Chair, called the meeting to order at 1:35 pm and welcomed members, staff, presenters and public in attendance.

Agenda Item 2: Logistical Announcement and Roll Call

Ms. Sallie Allen, Project Manager, Advisory Committee Coordination Office, HHSC provided logistics announcement, called roll and asked members to introduce themselves, and determined a quorum was present.

Agenda Item 3: Review and approval of the January 24, 2020 meeting minutes

Ms. Allen requested a motion to approve the January 24, 2020 meeting minutes. Dr. Vanek requested the word "acting" be removed from the chair's name in agenda item #1.

Motion:

Dr. Yolanda Rodriguez-Escobar motioned to approve the January 24, 2020 meeting minutes with the noted correction. Dr. Vanek seconded the motion. Ms. Allen conducted a roll call vote, and the motion passed with no nays and one abstention.

Agenda Item 4: Commissioners and Legislative Update

Dr. Vanek introduced Ms. Imelda Garcia, and she provided the committee with an update.

Highlights of the discussion and committee member discussion included:

- The HIV Program has moved into the new Howard Lane location, with new phone numbers.
- Ms. Garcia described the Agency response to Coronavirus. The Agency is coordinating with the Texas Department of Emergency Management, governmental offices, hospital associations, and hospitals across the state to provide support. There is a dashboard for current information at: <https://dshs.texas.gov/coronavirus/additionaldata.aspx>. The Agency will be playing a lead role in a vaccine this Fall and early 2021.
- Ms. Miertschin asked if there is any data on how coronavirus is affecting people living with HIV and what is being done to support people living with HIV. Ms. Garcia stated that the State is still actively gathering epidemiology information through case studies and it is not ready for public release. The HIV program received additional federal funding to support Administrative Agencies and their providers to address COVID-19 restrictions. THMP has implemented an abbreviated Emergency application and is offering longer options for medication refills. THMP team members continue to come in to the office to keep processing applications.

Agenda Item 5: Budget Update

Dr. Vanek introduced Mr. Felipe Rocha, and he provided the committee with an update.

Highlights of the discussion and committee member discussion included:

- Budget data is from June 2020, and the information will look different at the end of the fiscal year in August. Ryan White rebates have decreased while medication dispenses have increased. New clients accessing the program due to Covid-19 were not anticipated expenses. The Program must focus on increasing revenue and be mindful of THMP resources.
- Dr. Lazarte asked if the expense of continuing 90-day fills is a limiting factor. Mr. Rocha replied that it is not, but we need more hands-on experience with maintaining 90-day medication refills.
- Dr. Vanek asked if it is a reasonable expectation that rebate funds can be recovered over the next few years. Mr. Rocha replied that THMP is discussing options that would require program changes. Revenue would gradually increase.

Agenda Item 6: THMP Update and COVID-19 Public Health Response

Dr. Vanek introduced Ms. Rachel Sanor, and she provided the committee with an update.

Highlights of the discussion and committee member discussion included:

- Ms. Sanor reported that the THMP Data Manager position is vacant. Data services staff have been covering regular duties in addition to Covid-19 data support.
- The ADAP Data Report (ADR) was submitted to the Health Resources and Services Administration (HRSA) who funds THMP through Ryan White. The 2019 ADR Report showed improved data quality over the 2018 report. Data quality is expected to improve further as a new computer system is implemented.
- The THMP Covid-19 public health response included
 - An emergency application in place through 08/31/2020
 - Not requiring copies of eligibility documents
 - Extension of eligibility for recertification
 - 60-day prescriptions provided for most medications
 - Medication delivery encouraged
 - 90-day prescriptions encouraged for approved medications
- Dr. Lazarte requested clarification on the 90-day prescriptions. Ms. Sanor explained that the prescription and the Medical Certification Form (MCF) should both designate a 90-day prescription and be signed by a physician. THMP will develop a one-page information sheet to help providers better understand the MCF.
- Dr. Heresi asked if THMP has seen a change in how clients are requesting medications. Ms. Sanor replied that there has not been a significant increase in 90-day prescriptions. THMP is sending 60-day fills proactively and encouraging clients to move to mail-order delivery. The Governance and Data and Formulary subcommittees are developing strategies to increase uptake of 90-day prescriptions. THMP made a rule change before COVID-19 to allow 90-day prescriptions.
- Dr. Vanek asked how long eligibility has been extended. Ms. Sanor answered that eligibility has been extended through August 31st but we anticipate that it will be extended through December 31st.

Agenda Item 7: Presentation: Dynavax Technologies – HEPLISAV B

Dr. Vanek introduced Mr. Brian Faulconer and Ms. Natalie Taylor, Dynavax Technologies representatives. They provided overview of Heplisav-B medication,

and referenced powerpoint handout, *Consideration for Incorporating Heplisav-B into Texas HIV Medication Program*.

Agenda Item 8: Presentation: Viiv Healthcare - Fostemsavir

Dr. Vanek introduced Ms. Aimee Metzner, Viiv Healthcare representative. She provided overview of Fostemsavir, and referenced powerpoint handout, *RUKOBIA (Fostemsavir)*.

Agenda 9: Formulary Sub-committee report

Dr. Vanek provided highlights of the Formulary subcommittee discussion and committee member discussion included:

- 90-day prescription utilization. Currently, Biktarvy is the most dispensed medication for 90-day fills, though uptake is still low. The subcommittee is discussing strategies to increase uptake of 90-day prescriptions
- COVID-19 public health response
- Temixys was added to the THMP formulary because it already contains medication on the formulary and does not require a vote by the MAC.
- Heplisav B – The subcommittee discussed and noted that the addition of a vaccine would break precedent of the formulary. The Adult Safety Network could potentially cover vaccine. The sub-committee expressed reservations due to the cost of vaccine and impact on budget, vaccine not currently approved for pregnant women, no pricing information available. Advantages noted - requires two injections vs three. Discussion was tabled.
- Emergency Preparedness plans
- Addressed supply chain shortages with Mycobutin, Azithromycin, Nevirapine XR. Issues have been resolved.
- Reviewed Top 10 Non-HIV Medications – utilization is growing
- Revisited supply chain issues with Azithromycin, Mepron as Fall approaches to develop work arounds if shortages are experienced.
- Voted on Heplisav B – voted not to recommend vaccine to the formulary
- Reviewed Fostemsavir – new category/class of medication, per DSHS guidelines must be added to formulary within 90 days. Does not have agreed upon task force pricing. Sub-committee voted to recommend to the MAC pending task force approval pricing.

Agenda Item 10: MAC to vote on addition of two medications to the THMP formulary – HEPLISAV B and Fostemsavir

Dr. Vanek led the discussion regarding the medications HEPLISAV B and Fostemsavir and asked for a motion to add them to the THMP formulary.

Motion 1 – HEPLISAV B

Mr. Lionel Hillard motioned to disapprove the addition of the medication HEPLISAV-B to the THMP formulary. Dr. Susana Lazarte seconded the motion. Ms. Allen conducted a roll call vote, and the motion carried unanimously to disapprove the addition of the HEPLISAV B medication to the THMP formulary.

Motion 2 – Fostemsavir

Dr. Gloria Heresi motioned to approve the addition of the medication Fostemsavir to the THMP formulary contingent on pricing. Mr. Lionel Hillard seconded the motion. Ms. Allen conducted a roll call vote, and the motion carried unanimously to approve the addition of the Fostemsavir medication to the THMP formulary.

Agenda Item 11: Sub-Committee Reports (Governance/Data and Eligibility)

Ms. Miertschin provided highlights of the Governance and Data subcommittee discussion and committee member discussion included:

- Expressed appreciation for support of meetings
- Reviewed member attendance/sub-committee membership
- Established goals for sub-committee
 - Reviewing baseline eligibility data for Texas
 - Alignment of all Ryan White eligibility documentation
 - Developing one-page info graphic to educate providers on eligibility
 - Identify organizations that are experiencing challenges with application submission
- Consumer representation on MAC
- Reviewed MAC application process and member recruitment
 - For recruitment want to include advertisement to medical directors of HIV Clinics and DSHS HIV Clinical Panel
- Reviewed program data presented at the MAC
 - THMP program update
 - COVID-19 impact
- Hurricane Preparedness
- In the process of removing a member who has not been attending MAC meetings. Per MAC policies, THMP is routing documentation to HHSC Commissioner for approval.

-
- Reviewed budget information and provided feedback to THMP program on presentation format to the MAC.
 - Program data – requested to see analysis over time of viral suppression for ADAP clients and Texas in general.
 - No action items noted.

Mr. Rosas provided highlights of the Eligibility subcommittee discussion and committee member discussion included:

- Discussed Federal Poverty Levels (FPL) guidelines which are not standardized between EMA and TGAs in the state. Would like to have uniform FPL guidelines.
- Discussed ADAP clients enrolling in RAPID start
- Reviewed status of HRAR
 - Still on track – no impact from COVID-19
- Lionel Hillard invited to participate on Eligibility sub-committee – Lionel accepted invitation

Agenda Item 12: Public Comment

No public comment was offered.

Agenda Item 13: MAC to vote on Summer and Fall meeting dates of 2021

Dr. Vanek led the discussion regarding the meeting dates for Summer and Fall 2021. The January 29, 2021 meeting date was approved at January 24, 2020.

Dr. Vanek requested a motion for: April 30, 2021, July 30, 2021 and November 5, 2021.

Motion:

Mr. Frank Rosas motioned to approve April 30, 2021. Mr. Lionel Hillard seconded the motion; Mr. Frank Rosas motioned to approve July 30, 2021. Dr. Susana Lazarte seconded the motion; Dr. Natalie Vanek motioned to approve November 5, 2021. Mr. Ray Moore seconded the motion.

Ms. Allen conducted a roll call vote to approve April 30th, July 30th and November 5th, 2021 for the Texas HIV MAC 2021 meeting dates, and the motion carried unanimously with no nays or abstentions.

Agenda Item 14: Action Items and agenda topics for next scheduled meeting, October 16, 2020

Dr. Vanek led the discussion on the action items and agenda topics for next scheduled meeting, October 16, 2020.

There were no additional action items or agenda topics to be discussed.

Agenda Item 15: Adjournment

Dr. Vanek thanked the members and the public and adjourned the meeting at 4:20pm.

To view and listen to the archived video of the July 31, 2020 Texas HIV Medication Advisory Committee meeting in its' entirety, click on the link below.

<https://texashhsc.swagit.com/play/07312020-714>

[NOTE: The watermark for DRAFT should be left on the document until the committee has voted to approve/accept the minutes as the official record of the meeting. Once the Committee/Council has approved the minutes, remove the DRAFT watermark and rename the document to say, "Approved" with the date.]