

Texas HIV Medication Advisory Committee Meeting Minutes

April 30, 2021, 1:30 p.m.

Location: Microsoft Teams Live Event

Member Name	Attended
Adjei, Margaret	Yes
Alozie, Ogechika Karl, M.D.	No
Heresi, Gloria, M.D.	Yes
Hillard, Lionel	Yes
Lazarte, Susana, M.D.	Yes
Miertschin, Nancy, M.P.H.	Yes
Rodriguez-Escobar, Yolanda, Ph.D.	Yes
Rosas, Frank (Vice-Chair)	Yes
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, Facilitator, 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 29, 2021, meeting minutes

Ms. Allen requested a motion to approve the January 29, 2021, meeting minutes.

Motion:

Dr. Yolanda Rodriguez-Escobar motioned to table the January 29, 2021, meeting minutes in order to research the numbers verbally presented for the ADAP participants. Mr. Lionel Hillard seconded the motion. Ms. Allen conducted a roll call vote, and the motion passed to table the January 29, 2021, meeting minutes.

Agenda Item 4: Department of State Health Services Updates (DSHS) - Manda Hall, M.D., Associate Commissioner of Community Health Improvement

Dr. Vanek introduced Dr. Manda Hall, Associate Commissioner of Community Health Improvement, DSHS, and she provided the committee with a legislative update. She also referenced the handout, *DSHS Organization Chart revisions*.

Highlights and committee member discussion included:

Dr. Manda Hall shared the current DSHS Organizational Chart for the section. Mr. Felipe Rocha is temporarily reporting to Dr. Hall. Ms. Imelda Garcia continues to be assigned to assist with the COVID vaccine response. Two vacancies currently exist in the HIV/STD/TB section: Director of HIV/STD/Prevention and Care and Manager for Program Informatics and Evaluation.

Dr. Hall provided a legislative session overview for the MAC members. Session is closing on May 31st. DSHS is currently tracking over 700 bills. 125 bills have been assigned to the Division and 27 bills have been identified as having potential impact on the HIV program. Program is focused on amendments and substitutions that will occur in committees for the House and the Senate Floor.

Program submitted an exceptional item funding request of \$103.4 million in General Revenue for coming Biennium to meet increasing THMP demands and restore HIV/STD/Care Services contracts. Senate has submitted a Rider (bill) of \$35 million dollars to be directed to the program (less than requested) for coming biennium to stabilize the program. The amount approved was lower than request due to the program's ability to secure supplemental funding from the Health Resource Services Administration (HRSA) and COVID Relief funds.

Discussion:

Frank Rosas inquired about the timeline for Ms. Garcia transitioning back to the division and how updates will be shared/provided given all the program changes that have occurred. Dr. Hall assured the committee that a transition plan will be shared with key staff and indicated that Ms. Garcia would return to the division in early summer.

Agenda Item 5: Laboratory and Infectious Diseases Section Updates – Felipe Rocha, MSSW Director TB/HIV/STD Section

Dr. Vanek introduced Mr. Felipe Rocha, MSSW Director TB/HIV/STD Section, DSHS, and he provided the committee with an update and referenced handout, *Monthly THMP Financial Report*.

Highlights and committee member discussion included:

Pharmacy inventory reporting discrepancies:

Mr. Rocha shared new information regarding the inventory reporting discrepancies. He reported that the internal pharmacy inventory reporting in FY2020 was incorrect and did not reflect approximately 25% of THMP's medication inventory already shipped. Subsequently, in 2021, the program believed they had more medication in inventory than what was on hand. Ultimately, the FY2021 budget did not account for the \$35 million dollars in medications that had already been shipped to clients.

The reporting discrepancies were a result of 1) errors in the pharmacy's product distribution report (PDR) query that reflects medications shipped in FY2020. This resulted in under reporting of medications that were already shipped, leading the program to believe there was more medication on-hand; 2) pharmacy experienced personnel losses and staff reassignments; 3) DSHS failed to consistently conduct and document routine stock on-hand inventory counts in FY2020; and 4) DSHS failed to revise the medication spend plan to account for temporary COVID-19 policy changes.

The error in the pharmacy's PDR, was a result of the pharmacy tracking system (ITEAMS) not correctly communicating with the shipping company's computer system. This resulted in some medications that had already been shipped to not be marked as "shipped" in the PDR. When this was discovered by pharmacy staff, they developed a work around to manually report ITEAMS inventory to IT staff who would then manually update shipping status in ITEAMS to reconcile the PDR in a weekly basis. In March 2020, pharmacy staff were reassigned to COVID-19 response activities which left little time for knowledge transfer of pharmacy processes. Additionally, when pharmacy staff were reassigned, weekly manual inventory reconciliation and monthly hand counts of inventory stopped which led to inaccurate ITEAMS inventory counts. This impacted the FY2021 spend plan projections since the number of medications shipped factors into the spend plan.

Mr. Rocha also reported that ITEAMS is currently undergoing a stabilization project until it will be phased out in 2022. ITEAMS replacement is underway and expected to be completed in August 2022.

Discussion:

Several MAC members expressed concerns about:

- DSHS not discovering inventory discrepancies earlier
- pharmacy staff being reassigned since they had a very intimate knowledge of the shipping and inventory system process for THMP
- lack of transparency from DSHS about sharing information regarding inventory issues

Mr. Frank Rosas and Dr. Natalie Vanek requested that future MAC meetings include an update from pharmacy staff to the MAC about the status of inventory and purchasing.

THMP Financial report:

Mr. Rocha emphasized to the committee that the budget is a snapshot in time (April 20, 2021) and amounts reflected are always fluid. FY2021 budget is \$162,045,904;

total amount obligated (funds that can be spent between April and end of August) is \$85,545,422; expended amount is \$74,881,545; and remaining in the budget \$1,618,917. By comparison, in FY2020 THMP spent \$121,695,839.

DSHS estimates that THMP will be able to carryforward \$30 million dollars in COVID relief funds into FY2022. Also, for FY2022, (beginning September 2021) DSHS approximates that THMP will have a budget of \$95,950,340. This amount does not include the estimated carry forward COVID relief funds and does not include any exceptional item funds that may get approved. Both the carryforward funds and the exceptional item amount would be added to the budget year estimate of \$95,950,340 bringing the total estimated amount for FY2022 to \$126 million dollars.

Discussion:

Mr. Rosas inquired if the program uses financial analysts to forecast budget and what type of budget review is occurring at THMP. Mr. Rosas indicated that previous MAC meetings did not include budget reports which was concerning.

Mr. Rocha and Dr. Hall indicated the financial director in Dr. Hall's division and the financial analyst that was recently hired by the Section developed the budget for the April 30th MAC meeting. Dr. Hall shared that DSHS continues to have ongoing budgetary oversight meetings. DSHS has budget meetings once a month to review funding for various programs. Additionally, meetings are held by individual programs to review budgetary information. Likewise, leadership is involved in fiscal oversight and monitoring of the THMP budget. DSHS has also re-engaged with an actuary, Rudd and Wisdom, to provide future programmatic projections.

Mr. Rosas noted that his line of questioning regarding THMP finances is from the perspective of someone who is living with HIV and as a consumer and is not trying to dictate what DSHS needs to do.

Update on filling the Director position:

Mr. Rocha reported that the Director position has been vacant since March 19th. The position was posted perpetually on March 26th. DSHS has posted the position in both local and national social media outlets as well as strategic government websites (e.g., NASTAD,). To date, 83 applications have been received.

Per guidance of the Office of General Counsel and Human Resources, it is not recommended that external stakeholders participate in the interview process. However, stakeholders will be invited to provide input on the desired skill set and experience for the Director position. Persons interested in providing input can send Mr. Rocha an email.

Agenda Item 6: THMP Update

Dr. Vanek introduced Ms. Rachel Sanor, and she provided the committee with an update and referenced PowerPoint handout, *THMP Update*.

Highlights and committee member discussion included:

MAC Appointment Process:

There is a total of four positions to be filled on the MAC: 2 consumers and 2 physicians. Application review is currently underway. THMP anticipates that new MAC members will attend the July meeting.

THMP Enrollment as of April 3, 2021.

Clients served and prescriptions filled increased in December as many clients typically attempt to get prescriptions filled before the end of the year. Also, worth noting is that THMP ended the automatic eligibility extension at the end of December.

Data Demographics and Actuarial Projections:

THMP reported that overall enrollment is down this quarter. The previous quarter saw approximately 25,000 clients. This quarter the total enrolled is 22,596. SPAP and TIAP enrollment remained relatively unchanged. Ethnic and gender breakdown are similar as in the past, although somewhat lower this quarter overall.

The top 10 Medications are similar in order as last quarter. Total number of these medications ordered this quarter is 38,099 compared to last quarter of 41,000. There was a slight increase in orders of Biktarvy compared to last quarter. Other medications stayed relatively the same.

90-day supply medications have decreased significantly due to THMP discontinuing this feature as a cost containment measure for the program.

ADAP Projections:

THMP has secured Rudd and Wisdom actuarial firm to provide projections monthly (average annual cost per client and the projected number of clients that can be served) to help the program determine if the budget can adequately serve clients. Projections show that the total number of clients increased significantly from 2019 to 2020 mostly from COVID related impacts. Rudd and Wisdom is also projecting that client enrollment will continue to increase over the coming years but not at the rate seen in 2020. It was also noted that the automatic 60-day prescription fill, implemented by THMP as health and safety measure for clients, did increase overall program costs.

SPAP and TIAP Projections:

THMP has requested Rudd and Wisdom to provide projections on insurance purchasing, pharmaceutical rebates, and the effect of a standard deduction vs current spenddown model. Current projections by Rudd and Wisdom indicate a two percent growth in cost per member for SPAP and TIAP if the program makes no changes and continues the status quo.

Budget Mitigation Details:

The Texas Administrative Code (TAC) state rules for cost containment measures that DSHS may implement to ensure that expenditures do not exceed the program's budget. The cost containment measures in the TAC include:

- Initiate medical criteria to meet at minimum the most recent federal Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents;
- Discontinue using the formula for adjusting the applicant's gross annual income;
- Lower the financial eligibility criteria to a level not lower than 125% of federal poverty level; and
- Cease enrollment of new applicants.

It was noted that THMP is not expected to implement a waitlist, but the final decision will be dependent on approval of request for exceptional items.

Discussion:

Mr. Rosas inquired about future elections of chair and co-chair and new appointees. When would this happen? Ms. Sallie Allen stated that the MAC would need to refer to the bylaws for guidance on elections.

Dr. Vanek inquired about discontinuation of the spenddown. Ms. Sanor stated that the spenddown will be in place at least until the end of June. THMP is currently analyzing a replacement of the spenddown with the option of a standard deduction.

Additionally, Ms. Sanor indicated that implementation of cost containment measures is determined by THMP based on cost effectiveness and not necessarily in any order. Ms. Sanor also clarified that THMP does not currently have a waitlist. Exceptions to a potential waitlist would include people determined to be medically fragile.

Dr. Vanek inquired about the length of time that it currently takes for applications to be processed and approved. Ms. Sanor stated that THMP is currently running 4 weeks behind on new applications. The standard processing time is 14 calendar days.

Mr. Lionel Hillard inquired about how the program handled restoring eligibility for clients that were denied due to the spenddown being discontinued at the end of December. Ms. Sanor stated that the program ran reports on clients who were denied or rejected as a result of the discontinuation of the spenddown. THMP sent these clients letters stating that they would review these applications again and make a final determination. THMP mailed letters to applicants informing them of their application status.

Mr. Rosas and Mr. Hillard inquired about advance notice provided to clients and agencies about any upcoming changes to THMP processes. Ms. Sanor reported that DSHS is still in discussion regarding what time frame makes sense. Once a timeline is determined, DSHS will communicate with stakeholders.

Agenda Item 7: Presentation: Cabotegravir-Rilpivirine

Dr. Vanek introduced Ms. Aimee Metzner, PharmD, AAIVP, Viiv Healthcare, and she provided the committee with an overview and referenced PowerPoint handout, *CABENUVA (cabotegravir long-acting plus rilpivirine long-acting)*

Highlights and committee member discussion included:

Ms. Metzner reported both the DHHS and IAS-USA studies have strongly recommended Cabenuva for virally suppressed patients as a priority innovation. Reported advantages of Cabenuva by DHHS include reduced pill fatigue, reduced stigma, and improvement in quality life.

The once-monthly, intramuscular injection regimen can replace the current ARV regimen in those who are virologically suppressed with no history of treatment failure and with no known or suspected resistance to either Cabenuva or Rilpivirine. FDA approval was based on two global phase 3 clinical trials: Antiretroviral Therapy as Long-Acting Suppression (ATLAS) and First Long-Acting HIV Injectable Regimen (FLAIR). The most common adverse side effects reported were mild injection site reactions. Other noted side effects included: pyrexia, fatigue, and headache.

Oral lead in dosing will consist of one daily tablet of Cabotegravir and one daily tablet of Rilpivirine for one month to assess patient tolerability. The 30-day oral lead in dose will be provided at no cost to patient or payor. On the last day of the oral lead in dose, the following intramuscular injections will be administered separately by a health care provider: one injection dose of Cabenuva and one injection dose of Rilpivirine. Treatment thereafter will be separate doses of Cabenuva and Rilpivirine monthly. Medication is packaged as a dosing kit.

It was also noted that before beginning this regimen, significant consideration should be given by clients and their treating medical professional as this medication requires monthly dosing adherence.

Discussion:

Mr. Hillard inquired about a client who may miss their injectable dose. How would that be addressed? Ms. Metzner stated that it depends on the length of time since the client's last dose.

Ms. Yolanda Escobar-Rodriguez inquired about the possibility of administering the medication through a "pen" like diabetic medication that is self-administered. Ms. Metzner indicated that Viiv has only looked at the gluteal injection site at this time. As such, self-administration has not been assessed at this time.

Dr. Vanek inquired about the cold chain-shipping of medication to providers. Ms. Metzner stated the medication does have to maintain cold chain integrity from wholesaler distributor, to pharmacy, and to the prescriber.

Formulary sub-committee - Dr. Natalie Vanek, Chair – provided:

The Formulary sub-committee met Feb. 9th, March 2nd, April 6th and April 20th.

Items discussed included:

February:

Discussed revision of the THMP formulary, reviewed the most expensive medications and prioritized HIV medications, and keep medications typically utilized in rural areas, and remove medications that are not HIV related that could bring the most cost savings to the program

- Reviewed removal of 90-day supply of medications – HIV medications would only be available in 30-day supply - Top 10 Non-HIV medications would stay as 90-day supply
- Discussed removal of Hepatitis C medications (due to discontinuation of the pilot program as a cost saving measure)
- Sub-committee also reviewed medications used to treat side effects of HIV medications that are expensive - due to low utilization the sub-committee agreed to recommend removing Egrifta and Mytesi
- Sub-committee agreed to review Hepatitis B medication Vemlidy
- Discussed the Top 10 medications (non-HIV medications) which are the least expensive category of all medications on the formulary; these have the least utilization and all Top 10 medications are available on the local pharmaceutical assistance program - sub-committee did not recommended to remove any of the Top 10 medications at that time
- Discussed Top Four single tablet regimens which have a higher utilization (80% of clients in FY2020 had at least one fill of the Top Four). It was noted that high utilization of these medications is the biggest expense for the THMP.
- Discussed Cabenuva which was FDA approved but did not have task force pricing at that time

March:

Reviewed the formulary medication priorities: 1, 2, or 3 (1 being highest priority and 3 lowest priority); sub-committee reassigned some medications to reflect: priority 1= HIV and opportunistic infections; priority 2= opportunistic medications and HIV associated medications; priority 3= non-HIV medications. The sub-committee discussed that if THMP must remove medications for cost savings measure that priority 3 would be removed first, then priority 2 if needed would be removed. Priority 1 medications would not be removed as these are essential to treating HIV.

April:

Discussed pharmacy inventory software glitch and potential ADAP waitlist; exceptions for a potential waitlist were identified: Patients with AIDS diagnosis – based on CD4 count (<100 vs 200); Patients with opportunistic infections (OI) – based on qualifying medications; Pregnant women – documented on MCF; Children/adolescents (American Academy of Pediatrics guidelines states up to 21 years); Chronic Hep B co-infection; Cancer or transplant patients on treatment

The Sub-committee reviewed Cabenuva following approval of task force price agreement; discussed eligibility criteria: eligible clients have to be virally

undetectable, have oral lead in dose, clients have to be willing to come into provider 12 times a year for medication administration, medication must be cold chain shipped; sub-committee discussed potential for pilot program; but tabled the topic

The second meeting in April was an emergency meeting requested by THMP:

The Sub-committee reviewed IV medications on formulary and recommended to suspend Amphotericin-B which has not been recently requested and typically used for inpatient setting and suspend Interferon – alpha which was previously used for HCV and not currently a recommended course of treatment

Medications previously recommended for deletion the sub-committee were changed to suspend them due to the fluid financial situation of THMP. Suspended medications could quickly be restored to the formulary as the THMP budget allows.

The Sub-committee reviewed Top 10 medications (non-HIV medications) to avoid implementation of a potential waitlist; while THMP does incur shipping costs of the medications, the sub-committee noted that these medications are of great value to the clients especially the psych meds (Entecavir) and Gabapentin which is used for both psych and neuro indications and has replaced opiate medications and sub-committee indicated keeping this medication was a good public health practice given the opioid crisis. Sub-committee did request that THMP provide clients a 90-day notice for all suspended medications with the intent of restoring the medication to the formulary as the THMP budget allows.

Summary of medications recommended for suspension by sub-committee:

Hepatitis B Medication: Vemlidy

HIV Side-Effect Medications: Mytesi and Egrifta

Injection Opportunistic Therapy Medications: Amphotericin B and Interferon alpha

Chronic Condition Medications - Hypertension: Lisinopril, Hydrochlorothiazide, Amlodopine, Metoprolol

Statins: Atorvastatin, Pitavastatin

Diabetes: Metformin

Discussion:

Mr. Rosas wanted to note that the formulary sub-committee no longer has a consumer member and felt strongly that another consumer member be on this sub-committee. Mr. Rosas nominated MAC member, Lionel Hillard, to the Formulary sub-committee.

Governance and Data sub-committee - Ms. Nancy Miertschin, Chair – provided: The sub-committee met once in the last quarter. Items discussed included: Town Hall Updates, potential ADAP waitlist and exceptions. Additionally, THMP discussed budgetary analysis underway by Rudd and Wisdom, restructuring of THMP to allow for insurance purchasing, contract reductions that would reduce staff dedicated to MAC and frequency of sub-committee meetings. It was also noted that the importance of the consumer’s voice in the sub-committees continue to be heard to

provide input to advisory committees. Dr. Vanek requested that the DSHS organizational chart be reviewed at each MAC meeting to discuss impact of staffing changes. THMP reported that they have approved an electronic MCF to help streamline the medication ordering process for providers. Members also reviewed a statement to be distributed to non-MAC sub-committee members that provides guidance on that specific role.

Eligibility sub-committee - Mr. Frank Rosas, Chair – provided:

In the February meeting, members reviewed information pertaining to clients dropped from ADAP due to the automatic eligibility extension that ended at the end of December. There was also discussion on the process for clients who are waiting for ADAP who may qualify for pharmaceutical assistance and the ADAP liaisons that are assisting providers with PAPs. Mr. Rosas also mentioned the possibility of inviting a pharmacist to participate on the sub-committee.

The March sub-committee meeting reviewed similar topics from February meeting.

At the April meeting, the sub-committee discussed waitlist exceptions, heard from the HIV Care Services Manager who clarified the eligibility process for Part B Ryan White service providers.

Agenda Item 9: Committee to vote on addition of Cabotegravir-Rilpivirine to the THMP formulary

Dr. Vanek led the discussion regarding the medication *Cabotegravir-Rilpivirine* and asked for a motion to add it to the THMP formulary.

Highlights and committee member discussion included:

Mr. Hillard expressed concerns about clients that may incur a cost for this medication. Ms. Sanor stated that while the cost of the medication would be covered by THMP (if medication is added to the formulary), the administration cost of the medication would most likely be covered by the clinic or site providing the medication through Ryan White funding. Coverage of costs would be addressed with the client/agency prior to medication administration. Mr. Hillard also expressed concern about rural areas keeping medication refrigerated as required.

Dr. Margaret Adjei inquired about how the shipping cost will be recovered from pharmacies if they ship to another site? Ms. Sanor stated that this detail has not been finalized and still needs to be worked out.

Dr. Susana Lazarte shared challenges and concerns about the medication through the lens of the consumers: dosing requirements, funding that is contingent on Ryan White to cover the administration of the medication, as well as the expense to THMP to maintain this injectable medication. Additionally, current recertification requirements from THMP is set for every six months. If a client does not recertify by their due date, Dr. Lazarte expressed concerns that program could be setting clients up for treatment failure or treatment resistance because they have missed one or more doses due to certification requirements.

Dr. Gloria Heresi seconded Dr. Lazarte’s concerns. Dr. Heresi also stated that her adolescent patients are excited about the possibility of this medication. She also echoed concerns about THMP funding for this medication.

Members discussed the possibility of introducing the medication as a pilot project in specific locations. The Formulary sub-committee would assist THMP with outlining details of the pilot program. It was noted that members did not want the medication to be unavailable due to some rural areas not being able to accommodate the medication shipping and administration requirements.

Motion – Add Cabotegravir-Rilpivirine

Mr. Rosas motioned to approve a pilot program for the Cabotegravir-Rilpivirine medication. Mr. Lionel Hillard seconded the motion. Ms. Allen conducted a roll call vote, and the motion carried unanimously to conduct a pilot program for the Cabotegravir-Rilpivirine medication.

Agenda Item 10: Committee to vote on removal and/or suspension of certain medications from the THMP formulary

Dr. Vanek led the discussion regarding the removal and/or suspension of following medications.

Hepatitis B Medication: Vemlidy

HIV Side-Effect Medications: Mytesi, Egrifta

Injection Opportunistic Therapy Medications: Amphotericin B, Interferon alpha

Chronic Condition Medications - Hypertension: Lisinopril, Hydrochlorothiazide, Amlodopine, Metoprolol,

Statins: Atorvastatin, Pitavastatin

Diabetes: Metformin

Highlights and committee member discussion included:

MAC members agreed that suspending medications would be preferable to removing them from the THMP formulary. As the THMP budget allows, suspended medications would be restored to the formulary. Members agreed to consider all the medications together in one vote.

Mr. Rocha reminded MAC members that the process for medication removal/suspension/addition requires that THMP draft a memo with the MACs recommendations. The final decision will be determined by the Dr. Hellerstedt, DSHS Commissioner.

Motion – Suspension of the eleven medications presented

Mr. Lionel Hillard motioned to suspend the eleven medications from the THMP

formulary until finances are available to add them back to the formulary. Dr. Susana Lazarte seconded the motion. Ms. Allen conducted a roll call vote, and the motion carried unanimously to suspend the eleven medications listed above from the THMP formulary.

Agenda Item 11: Public Comment

Written comment was received from:

- Januari Fox, MSW Director of Policy & Advocacy, Prism Health North Texas
- Cordella Lyon, Baptist Hospitals of Southeast Texas

Oral comment was received at the meeting from:

- Josh Mica – consumer, and advocate for Texas Strikeforce

Agenda Item 12: Action Items and agenda topics for next scheduled meeting, July 30, 2021

Dr. Vanek, Chair, asked Mary Richards and Liza Hinojosa for action items and agenda topics for the next meeting.

Ms. Richards provided the following items for next meeting.

- Review and verify minutes from January 29, 2021, Agenda item 5 and present at July meeting for review and approval
- Committee requested quarterly budget report
- Share the procedures for electing new officers before the July meeting
- Provide updated DSHS organizational chart

Mr. Hillard stated he is willing to serve on the Formulary Subcommittee.

Agenda Item 13: Adjournment

Dr. Vanek, Chair, thanked the members and the public and advised next meeting is scheduled for July 30, 2021, and she adjourned the meeting at 4:43pm.

To view and listen to the archived video of the April 19, 2021, Texas HIV Medication Advisory Committee meeting in its' entirety, click on the link below.

<https://texashsc.swagit.com/play/05032021-1114>