

HHSC: Texas HIV Medication Advisory Committee, February 4_{th}, 2020



The <u>Texas HIV Medication Advisory Committee</u> advises in the development of procedures and guidelines for the Texas HIV Medication Program, reviews program's goals and aims, evaluates ongoing efforts, and recommends short-range and long-range goals and objectives. **Members include:**

Natalie Vanek - Committee Chair	Susana Lazarte Dallas, Texas
Houston, Texas	Term expires 2020
Term expires 2020	Nancy Miertschin
Frank Rosas - Committee	Houston, Texas
Vice-Chair	Term expires 2024
San Antonio, Texas	Ray Moore
Term expires 2022	Granbury, Texas
Margaret Adjei	Term expires 2024
San Antonio, Texas	Yolanda Rodriguez-Escobar
Term expires 2022	San Antonio, Texas
Ogechika Karl Alozie	Term expires 2024
El Paso, Texas	Demetra Tennison
Term expires 2022	Austin, Texas
Gloria Heresi	Term expires 2024
Houston, Texas	
Term expires 2024	
Lionel Hillard	
Dallas, Texas	
Term expires 2022	

1. Call to Order and Welcome. The meeting was called to order by Dr. Natalie Vanek, M.D., Committee Chair on January 24th, 2020.

2. Logistical Announcement and Roll Call. Sallie Allen, Advisory Committee Coordination Office, HHSC.

3. Review and Approval of October 18, 2019, Meeting Minutes (Vote Required). The minutes were approved as written.

4. Commissioners Updates. Imelda Garcia, Associate Commissioner, DSHS provided the following updates:

Site Visit related to Ryan White funding. There was a site visit with a contractor, and they were complimentary of the work going on in the field and the efforts to make people eligible



in the field. Texas had been on restricted federal draw down. A formal site visit report will be forthcoming with some programmatic improvement recommendations.

Making progress on technology and systems. A request for offers has been made and has closed and it is anticipated that the systems updates will begin later this year.

ITEAMS has been funded a replacement system to move medication out to the community through the Pharmacy. It is in the planning phases right now.

The DSHS Inventory Tracking Electronic Asset Management System (ITEAMS) vision is to create a solution that consolidates overlapping business units' processes into one integrated system. DSHS reviewed current processes and determined that replacing existing aged systems with an integrated solution would be beneficial for our business and provide a cost-efficient technology solution for the following programs:

- Emergency Preparedness
- Hansen's Disease
- HIV Prevention and Care
- Immunization Texas Vaccines for Children Program
- Pharmacy Branch
- Sexually Transmitted Disease (STD) Prevention
- Strategic National Stockpile (SNS)
- Tuberculosis (TB) Elimination
- Women's Health
- Zoonosis Control

Based upon the expanding business requirements and functionality of DSHS Programs, **ITEAMS** will provide an integrated solution with the capacity to build for future requirements and functionality.

Mr. Rosas inquired about the timeline for implementation of the initiatives. Staff stated that it will take about two years for development and testing. They want to take the time to ensure a quality product.

Dr. Vanek, Chair, asked when the formal report will be out. Staff stated that it should be sometime in February.



5. Budget Update – Felipe Rocha, MSSW Director TB/HIV/STD Section.

Texas HIV Medication Program (THMP) Quarterly MAC Report (2nd Quarter) ADAP & SPAP Expenditure Data Run on 12/07/2019

Funding and Collected Revenues	FY2018 YTD	FY2019 YTD	FY 2020 Projected
1. General Revenue	23,497,040	23,497,040	23,497,040
2. Federal Ryan White ADAP Funding (converted to State Fiscal Year)	79,684,172	75,221,330	86,261,491
3. Part A Donations	300,800	350,668	0
4. HIV Rebates Earmarked for THMP	8,514,016	6,747,822	2,030,913
4a. HIV Rebates Earmarked for Other HIV Projects (Other approved HIV projects, such as service expansion and contract increases)	10,541,391	11,283,423	13,284,767
5. Total Funding and Revenue Allocated to THMP (Does not include rebate funds for other HIV projects)	\$111,996,028	\$105,816,860	\$111,789,444
Expenditures	FY2018 YTD	FY2019 YTD	FY 2020 Projected
1. Non Medication Expenditures (Operating & Salaries)	\$1,560,735	\$2,352,144	2,140,630
2. Medication Expenditures (ALL funding sources)	88,036,635	67,492,327	92,878,649
3. Medication Co-payment, Insurance Deductible, & COBRA Expenditures (SPAP & TIAP)	10,651,221	10,042,239	10,594,562
4. Total Expenditures	\$100,248,590	\$79,886,711	\$105,613,842
ADAP Medication Dispensed	FY2018 YTD	FY2019 YTD	FY 2020 Projected
1. ADAP Medications Dispensed	101,604,838	101,858,225	105,630,227
ADAP Medication Inventory	FY2018 YTD	FY2019 YTD	FY 2020 Projected
1. ADAP Medications Inventory	70,986,328	36,176,416	38,166,119

HOTES: Federal Ryan White Emergency Relief Funds applied for in FY 2020 but funds not reflected in the \$86,261,491. Includes projected ADAP Supplemental in \$86,261,491. FY19 Medication expenditures decreased due to use of inventory. DSHS did not request ADAP Supplemental funds for federal RW grant year 4/1/18-3/31/19 FY19 M

All the tables are a snapshot in time. There are assumptions built into each of the categories. The Committee has outgrown this format, and he asked what the committee would want in the future. The last column above is the 2020 projected amount. General revenue for 2020 is \$23.5 million and has remained stable. However, over time, GR has been shrinking. Ryan White funding includes additional funding that has been requested but not awarded yet. Donations are not certain, so they are reported at zero. Rebates earmarked for this are at \$2.0 million and other rebates are at \$13.3 million. The expenditures are reported below the revenue portion of the table. Total expenditures have grown, and the expenditures compared to revenue are favorable. ADAP medications dispensed are those that are shipped across the state and the inventory is a dramatic increase from a few years ago.



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Mr. Rosas asked about the state allocation and requested an update on how the decisions are made. The budget cycle was described. The funding for HIV is included in the STD strategy.

Medication Dispensed and Inventory

ADAP Medication Dispensed	FY2018	FY2019	FY 2020
	YTD	YTD	Projected
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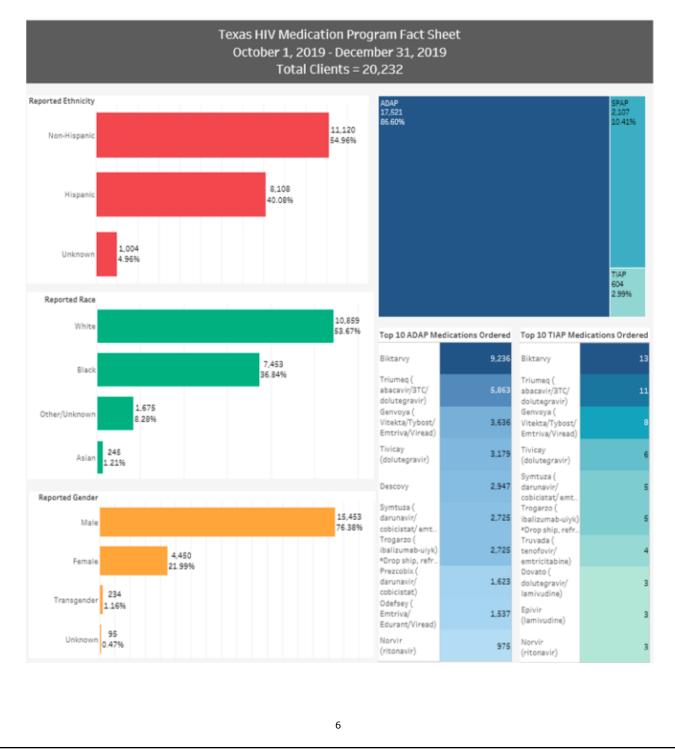
Staff stated that the market is changing for medications and this is impacting the table above. They have to be smarter about their medication purchases and keep an eye on what may be shifting. She commented on the shift to opportunistic infections medications, and the impact on overall purchasing.

Q: Does the average number of people served change? The growth is approximately 5.5% now. New funding from the federal government may push the growth rate higher, especially in the Part A entities.



Mr. Rosas asked about Rapid Start and the growth in the number of recipients. Staff stated that they have a lot more experience in accessing new medications at a faster pace.

6. Texas HIV Medication Program (THMP) Update – Rachel Sanor, THMP Manager





Above is the medication fact sheet for the most recent quarter. There has not been much change in the different categories. TIAP has a more open formulary and there has not been much change here either.

The table below shows the new medications that were just added in the middle of December. That being the case, there have not been orders in any significant amount.

Top 10 ADAP Medications Ordered New Medications Ordered			Medications Ordered for Drug IDs:						
Drug_Name	# Meds Ordered	% Meds Ordered	Drug_Name			233-302, 304 & 308 by Day Supply Days_			
	ordered	ordered	1			Drug_Name	Code	30	90
Grand Total	43,686	100.00%	Amlodipin			Atripla-90Day	267		3
		_	Atorvastati			Biktarvy-90Day	301	3	11
Biktarvy	9,236	21.14%				Combivir-90Day (AZT/3TC)	244		1
			Hydrochlorothiazide (HCTZ		í.	Complera-90Day	280		3
Triumeq (abacavir/3TC/ dolutegravir)	5.863	13.42%				Descovy-90Day	293		1
		_	Lisinopri		L.	Emtriva-90Day	259		1
Genvoya (Vitekta/Tybost/ Emtriva/Viread)	3,636	8.32%	Metformin HCL 1		8	Fluconazole-90Day	243		1
cmonvay vireacy				0 1	2	Genvoya-90Day	291	1	3
Tivicay (dolutegravir)	3,179	7.28%	# Meds Ordered			Intelence-900ay	277		4
			TIAP Medications Or	dered		Isentress-90Day	270		1
		Drug_Name	# Meds Ordered	% Meds Ordered	Juluca-90Day	300		1	
Descovy	2,947	6.75%	Grand Total	77	100.0%	Norvir-90Day	276		1
Symtuza			Biktarvy	13	16.9%	Odefsey-90Day	292		1
(darunavir/cobicistat/ emtricatabine/tenofovir)	2,725	6.24%	Triumeq (abacavir/3TC/d Genvoya (Vitekta/Tybost	11	14.3%	Prezcobix-900ay	288		1
Trogarzo			Tivicay (dolutegravir)	6	7.8%	Prezista-90Day	273		1
(ibalizumab-uiyk) *Drop ship, refrigerated-requires	2,725	6.24%	Symtuza (darunavir/cobi	5	6.5%		282		
special handling			Trogarzo (ibalizumab-uiy	5	6.5%	Selzentry-90Day	272		
Prezcobix	1,623	3.72%	Truvada (tenofovir/emtr	4	5.2%		485		
(darunavir/cobicistat)	(darunavir/cobicistat)		Dovato (dolutegravir/la		3.9%	Tivicay-90Day	283		1
			Epivir (lamivudine)	3	3.9%	Triumeq-90Day	284	4	5
Odefsey (Emtriva/Edurant/Viread)	1,537	3.52%	Norvir (ritonavir)	3	3.9%	Truvada-90Day	263		4
			Prezcobix (darunavir/co	3	3.9%	Valtrex-90Day	274		3
			Prezista (darunavir)	3	3.9%				
Norvir (ritonavir)	975	2.23%	Sustiva (efavirenz)	3	3.9%		275		-
			Viread (tenofovir)	з	3.9%	Viread-90Day	254		
			in and (rendram)		4.4.16	encen sovel	A.M. 1		



Ms. Lazarte asked about the approval process for the different medications. Staff replied that they receive a medical certification form and then an update based on the provider recommendation. They usually approve the recommendation of the provider.

Ms. Miertschin asked about the number of prescriptions. Staff stated that there are more than 200,000 prescriptions annually.

Mr. Rosas asked about the inclusion of transgender data. Staff stated that they have transgender data, but they do not have the sex at birth and current gender data. However, that will be included in the new technological updates. Mr. Rosas asked if the age ranges could be broken down. Staff answered in the affirmative. Staff stated that they will be happy to add what the members want in the data that they report. Mr. Rosas inquired about the number of people dropped from the program. Staff stated that that is not included now, but some local areas have been asking for this data. Staff stated that the new system should be able to get out cleaner data that will address this request.

7. Sub-Committee Assignments — Members and Non-Members — Dr. Natalie Vanek, M.D., Committee Chair. The Chair stated that there are three subcommittees. Members include MAC and non-MAC members. This item was included with the following item below, 8. Subcommittee Reports.

8. Sub-Committee Reports

Governance/Data. Nancy Miertschin (new members: Susana Lazarte; Yolanda Rodriguez-Escobar). The committee deals with topics of member attendance, policies on attendance, removal and replacement of absent members; and processes for recruitment and appointment. They have not spent a lot of time on data recently. They have covered a great deal of territory getting membership on the committee stabilized.

Eligibility. Frank Rosas, Chair (members include — Ogechika Karl Alozie, MD and non-MAC members: Gary Benecke, Rachel Figueroa, Marcus Benois, Laura Gesso). Mr. Rosas stated that their focus has been to represent different parts of the state. They have been reviewing eligibility and the need for an online portal. They meet monthly. There appears to be a full committee now.

Formulary. Dr. Natalie Vanek, M.D. stated that they work on medications and the formulary. (Members include Ray Moore and Gloria Heresi, Margaret Adjei, Ruston Taylor. Lester Matson also assists the subcommittee). They have revised the MedCert Form and are addressing the long-acting medications.



9. Medication Advisory Committee (MAC) to vote on addition of the following medications to THMP formulary.

Livalo—Livalo (pitavastatin) is a drug used together with a proper diet to lower <u>cholesterol</u> and triglyceride (fat) levels in the blood. Livalo is less popular than comparable drugs. There is currently no generic alternative for Livalo.

Zypitamag—Zypitamag[™] is indicated as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C) in adult patients with primary hyperlipidemia or mixed dyslipidemia.

The Chair stated that these two medications have been previously discussed and can be voted on together or separately if the committee would like to separate them.

There was concern expressed about the cost this would add to the program. The Chair stated that the drugs are on the Texas Medicaid formulary.

MOTION: Add both medications to the formulary - prevailed.

10. Removal of medications from THMP formulary.

Since no one is presently on the medications under consideration for removal, the following medications were proposed to be removed:

- Elvitegravir (EVG)
- Fuzeon
- Cobicistat (alone as a drug though it is a boosting agent)

Elvitegravir (EVG) is an integrase inhibitor used to treat HIV infection. It was developed_[1] by the pharmaceutical company <u>Gilead Sciences</u>, which licensed EVG from <u>Japan Tobacco</u> in March 2008._{[2][3][4]} The drug gained approval by the U.S. Food and Drug Administration on August 27, 2012 for use in adult patients starting HIV treatment for the first time as part of the fixed dose combination known as <u>Stribild.[5]</u> On September 24, 2014 the FDA approved Elvitegravir as a single pill formulation under the trade name Vitekta.[6] On November 5, 2015 the FDA approved the drug for use in patients affected with HIV-1 as a part of a second fixed dose combination pill known as <u>Genvoya</u>.

Fuzeon is a medicine called an HIV (human immunodeficiency virus) fusion inhibitor. And is always used with other anti-HIV medicines to treat adults and children ages 6 years and older with HIV infection. Fuzeon blocks HIV's ability to infect healthy CD4 cells. When used with other anti-HIV medicines, Fuzeon can reduce the amount of HIV in the blood and increase the number of CD4 cells. This may keep your immune system healthy, so it can help fight infection.



Cobicistat, with trade name Tybost (formerly GS-9350) is a licensed drug for use in the treatment of human immunodeficiency virus infection (HIV/AIDS). Its major mechanism of action is through the inhibition of human CYP3A proteins. Like ritonavir (Norvir), cobicistat is of interest for its ability to inhibit liver enzymes that metabolize other medications used to treat HIV, notably elvitegravir, an HIV integrase inhibitor. By combining cobicistat with elvitegravir, higher concentrations of the latter are achieved in the body with lower dosing, theoretically enhancing elvitegravir's viral suppression while diminishing its adverse side-effects. In contrast with ritonavir, the only other booster approved for use as a part of HAART, cobicistat has no anti-HIV activity of its own.

Cobicistat is a component of three four-drug, fixed-dose combination HIV treatments. The first, <u>elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil</u>, is marketed as *Stribild* and was approved by the FDA in August 2012 for use in the United States. The second, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide, is marketed as *Genvoya* and was approved by the FDA in November 2015 for use in the United States. Both Stribild and Genvoya are owned by <u>Gilead Sciences</u>. The third, cobicistat, darunavir, emtricitabine, and tenofovir alafenamide, is marketed as Symtuza and was FDA approved July 17, 2018 and is owned by Janssen Pharmaceuticals.

MOTION: Removal from the formulary of all three medications listed above - prevailed.

11. Public Comment.

Gary Benecke, Resource Center in Dallas and Vice Chair of the Eligibility Committee, stated that he has no public comment in particular.

12. MAC January 2021 meeting date. The committee decided on January 29th.

13. Action items and agenda topics for next scheduled meeting April 17, 2020.

- Look into current membership and attendance
- Look at Stavudine being removed from the formulary
- Disaster Preparedness presentation
- Additional data elements wanted by the Committee
- (One inaudible item)

Stavudine is used with other <u>HIV medications</u> to help control <u>HIV</u> infection. It helps to decrease the amount of HIV in your body so your <u>immune system</u> can work better. This lowers your chance of getting HIV complications (such as new infections, <u>cancer</u>) and improves your quality of life. <u>Stavudine</u> belongs to a class of drugs known as nucleoside reverse transcriptase inhibitors (NRTI). Stavudine is not a cure for HIV infection. To decrease your risk of spreading HIV disease to others, do all of the following: (1) continue to take all HIV medications exactly as prescribed by your doctor, (2) always use an effective barrier method (latex or polyurethane <u>condoms</u>/dental dams) during all sexual activity, and (3) do not share personal items (such as needles/syringes, <u>toothbrushes</u>,



and razors) that may have contacted <u>blood</u> or other body fluids. Consult your doctor or <u>pharmacist</u> for more details.

14. Adjourn. There being no further business, the meeting was adjourned.

This summary contains supplemental information from third-party sources where that information provides clarity to the issues being discussed. Not every comment or statement from the speakers in these summaries is an exact transcription. For the purpose of brevity, their statements are often paraphrased. These documents should not be viewed as a word-for-word account of every meeting or hearing, but a summary. Every effort has been made to ensure the accuracy of these summaries. The information contained in this publication is the property of Texas Insight and is considered confidential and may contain proprietary information. It is meant solely for the intended recipient. Access to this published information by anyone else is unauthorized unless Texas Insight grants permission. If you are not the intended recipient, any disclosure, copying, distribution or any action taken or omitted in reliance on this is prohibited. The views expressed in this publication are, unless otherwise stated, those of the author and not those of Texas Insight or its management.