HHSC: Texas HIV Medication Advisory Committee

November 5, 2021

Texas HIV Medication Advisory Committee 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
Houston, Texas
Term expires 2020

Frank Rosas - Committee Vice-Chair
San Antonio, Texas
Term expires 2022

Margaret Adjei
San Antonio, Texas
Term expires 2022

Ogechika Karl Alozie
El Paso, Texas
Term expires 2022

Gloria Heresi
Houston, Texas
Term expires 2024

Lionel Hillard
Dallas, Texas
Term expires 2022

Susana Lazarte
Dallas, Texas
Term expires 2020

Nancy Miertschin
Houston, Texas
Term expires 2024

Ray Moore
Granbury, Texas
Term expires 2024

Yolanda Rodriguez-Escobar
San Antonio, Texas
Term expires 2024

Demetra Tennison
Austin, Texas
Term expires 2024

1. Call to Order and Welcome – The meeting was convened by Natalie Vanek, M.D., Committee Chair

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

3. Consideration of July 30, 2021, Meeting Minutes (Vote Required) – Sallie Allen, Advisory Committee Coordination Office, HHSC The minutes were postpone to the following meeting

4. Department of State Health Services updates – Imelda Garcia, MPH Associate Commissioner of Laboratory and Infectious Disease Services (LIDS). Data was not made available to the public

Staffing Updates. There are new staff that are not reflected on the org chart which appears below.

Budget Update: Tables presented were ilegible and not immediately made available to the public. One table is now included since they became available January 20, 2022. Only the tables made availlable are presented. Several other tables were not made available.

Monthly TMHP Financial Report

ABEST Fund	ABEST Fund Description	BY 2021 EXPENDED	BY 2022 BUDGETED	BY 2022 OBLIGATED	BY 2022 EXPENDED	BY 2022 REMAINING
001	General Revenue	$1,500,000	$5,693,151			$5,693,151
8005	GR Match/MOE for HIV Care Formula Grants	$11,622,507	$14,018,462	$10,296,859	$772,358	$2,949,246
8149	HIV Vendor Drug Rebates	$8,125,377	$15,552,875	$9,000,000	$89,445	$6,463,430
0325	21.019.119 -Coronavirus Relief Fund*	$34,400,000	$14,832,669			$14,832,669
555	93.917.000 - HIV Care Formula Grants	$70,825,343	$85,120,394	$58,218,829	$14,419,869	$12,481,696
	93.994.000 – Maternal & Child Hlth Srvcs Block Grant	$4,800,000				
666	Appropriated Receipts – Misc (Rx refunds; 3rd party	$700,000				
	Total All Funds	**$131,973,227**	**$135,217,551**	**$77,515,688**	**$15,218,672**	**$42,420,191**

Notes:

State Budget Year (BY) September 1 – August 31 annually. Obligated funding is on a PO for the current BY.
Due to rebate shortfall, BY2021 had one-time funding from other DSHS appropriations in addition to Coronavirus Relief Funds that are not typically available within this appropriation including the $1.5M GR fund.
Total EI for FY22 is $8,164,958
EI is represented in FY22 budget as Fund 001 for $5,693,151 and Fund 8005 for $2,471,807
*Coronavirus Relief Funds not received for FY22 – still pending approval
Budgeted & expended included in all THMP activities

HIV Budget report. Not made available by DSHS.

September 29, 2021, Partnership meeting summary update. Not made available by DSHS.

5. THMP Update - Rachel Sanor, THMP Manager

MAC appointment process—waiting on the approval from the Executive Commissioner for the MAC appointments

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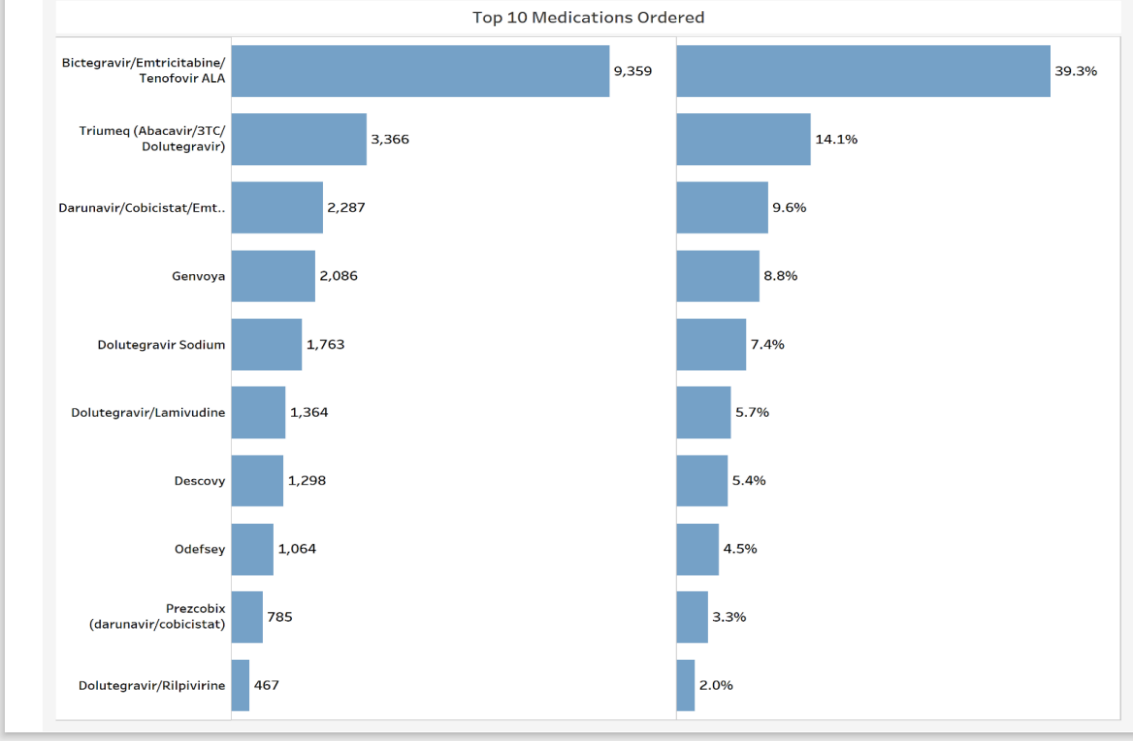
THMP - Projections and Demographic information

ADAP Utilization

Month	Clients Served	Prescriptions Filled
Apr 2021	10,747	13,964
May 2021	10,112	13,010
Jun 2021	10,235	13,561
Jul 2021	9,444	12,324
Aug 2021	8,992	11,727
Sept 2021	8,415	10,918

Medication Utilization



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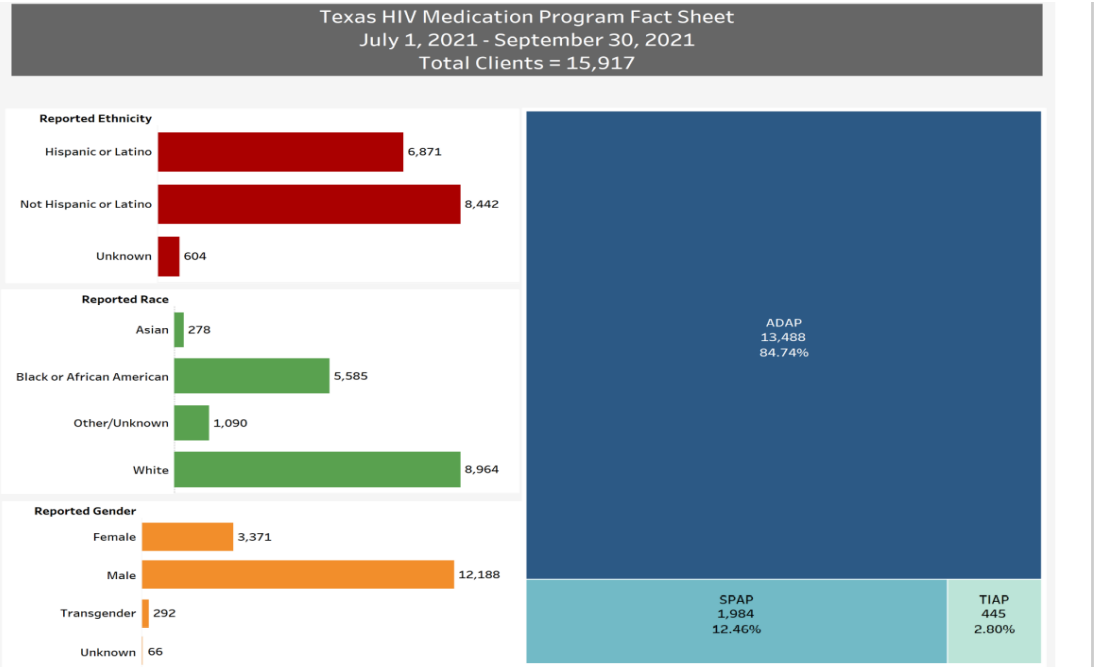
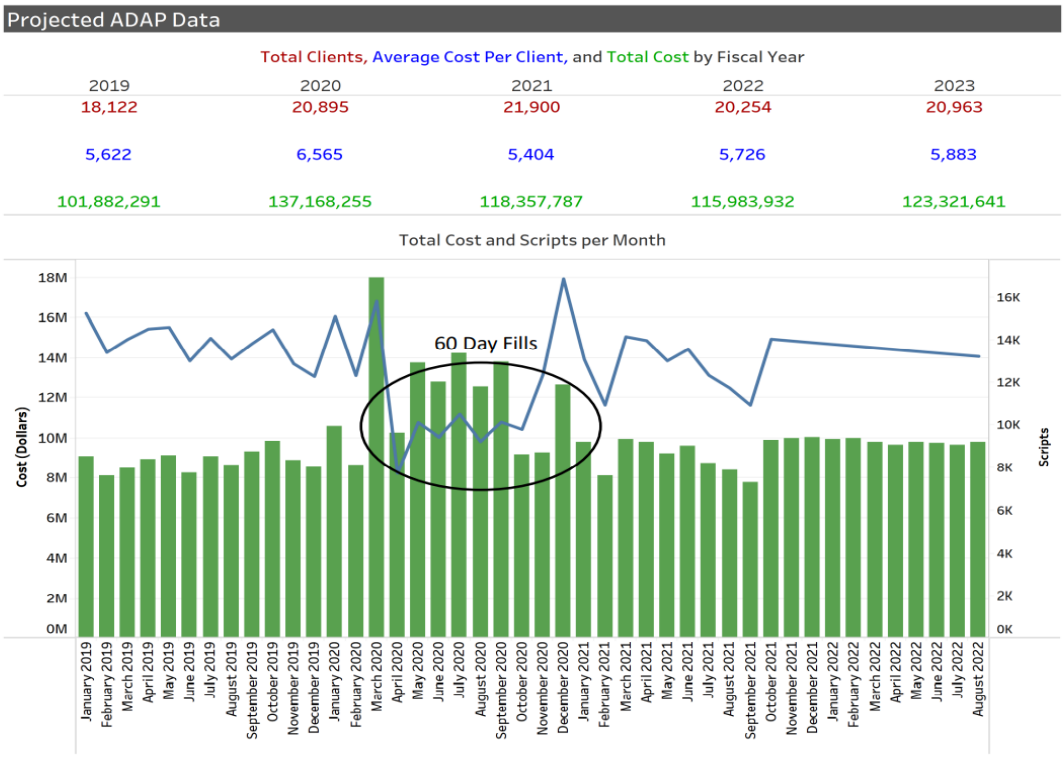
Program Demographics—No Change in Utilization



Projections:



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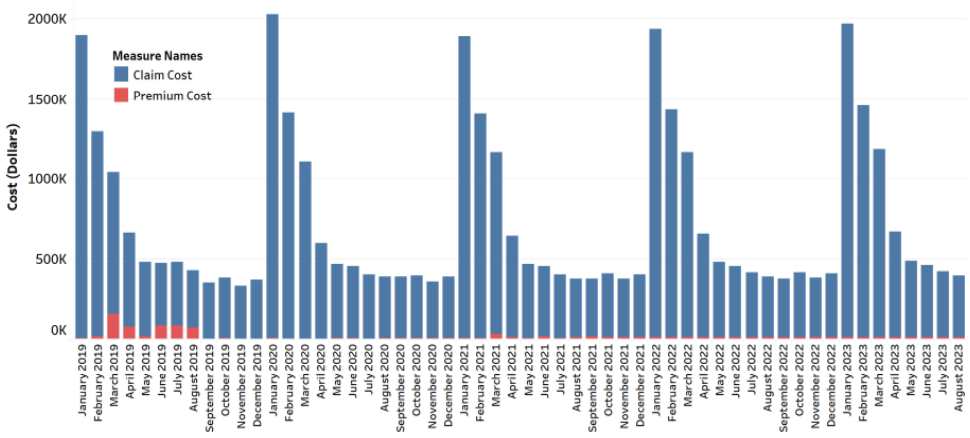
Projected SPAP Data

Total Clients, Average Cost of Client, and Total Cost Per Year

2019	2020	2021	2022	2023
2230	2135	2089	2089	2089
305.52	322.68	331.28	332.66	338.40
8,175,634	8,267,164	8,304,478	8,339,226	8,483,023

Actual and Projected Total Cost Per Month

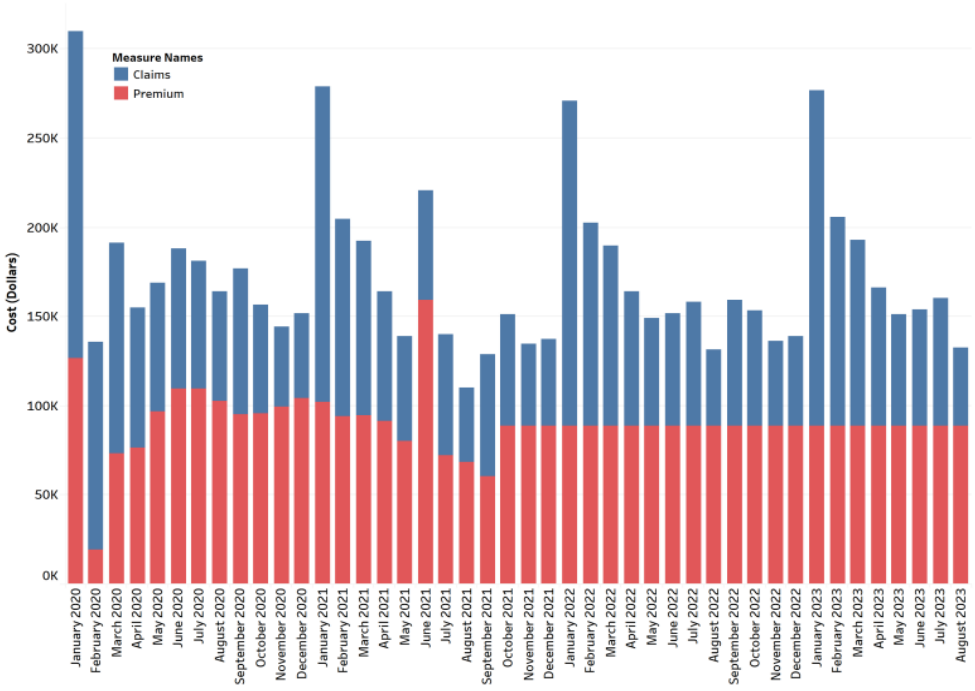


TIAP Projection Data

Total Clients, Average Cost of Client, and Total Cost Per Year

2020	2021	2022	2023
458	416	420	424
362.04	416.21	390.56	397.81
1,989,768	2,077,721	1,969,185	2,025,787

Total Cost in Hundreds of Thousands By Month, Projected data for 10/2021 and Beyond



THMP Operations Update

Application Backlog Update

THMP hired six new contractor staff to assist with the backlog.

Application Type	New	Self-Attestation	Renewals
Processing on time?	✗	✓	✓
Applications Backlogged	1,574	0	0
Date Processing	August 24th	October due dates	October due dates

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All the pending and backlog applications must be caught up before the new system rolls out. The plan is to clear the back log by the end of December.

Tentative New Timeline for Shift from Spend Down to Standard Deduction

- February 2022- Presentation at HHSC Executive Council
- March 2022- Texas Register issue Date - Public Comment Period starts
- April 2022- Public Comment Period ends
- May 2022- 60-day notification of Standard Deduction calculation methodology
- July 2022- Rules Effective Date

THMP is continuing the spend down for the ADAP through at least February 28, 2022.
THMP will process all applications using the spend down criteria through February 28, 2022.
THMP will communicate any changes between now and the end of February

90-Day Supply Suspension

Rationale:

- Prevent a waiting list
- Prevent shortages; and
- Ensure payer of last resort/reduce wasted medications.

No consideration for change until after February 2022. An analysis of the suspension is being conducted.

Questions/Answers/Comments

A member stated that this is being seen as another barrier to care. There should be more stakeholder meetings on this. The focus should be on the consumer.

It is disappointing we still do not have the cost analysis. This should be a top priority. Program staff stated that they will make sure that this kind of mess up does not happen again. That is why they are taking time to do it right.

6. Pharmacy Annual Inventory Update & Report – Joshua Hutchison, Pharmacy Director

Pharmacy State Fiscal Year (FY) 2021

Data Notations

- Inventory was counted on August 31, 2021.

- Values of drugs are obtained from the current contractor Morris & Dickson and represents the "current invoice price that the supplier would charge for the drugs."
- This is the only report which uses this evaluation methodology. These figures will be different than other calculations.

PROGRAM	INVENTORY TOTAL
HIV MEDICATION PROGRAM	$12,670,552.45
TUBERCULOSIS ELIMINATION	$857,602.72
ZOONOSIS CONTROL	$301,736.31
IMMUNIZATION PROGRAM	$184,571.10
STD PROGRAM	$147,827.59
HANSEN'S DISEASE	$8,509.39
INFECTIOUS DISEASE CONTROL PROGRAM	$182.34
PUBLIC HEALTH EMERGENCY	$0.00
COVID-19 VACCINES	$0.00
CAPITOL FIRST AID STATION	$0.00
TOTAL	$14,170,981.90

PROGRAMS	**FY2020 YEAR END BALANCE	FY2021 PURCHASES	**FY2021 YEAR END BALANCE	*FY2021 AMOUNTS DISTRIBUTED
	(Column A)	(Column B)	(Column C)	(A+B-C=D)
HIV MEDICATION PROGRAM	$5,776,820.59	$117,693,296.07	$12,670,552.45	$110,799,564.21
TUBERCULOSIS ELIMINATION	$1,695,531.15	$1,188,565.81	$857,602.72	$2,026,494.24
ZOONOSIS CONTROL	$474,050.59	$575,967.15	$301,736.31	$748,281.43
IMMUNIZATION PROGRAM	$470,147.11	$162,470.00	$184,571.10	$448,046.01
STD PROGRAM	$148,497.99	$264,457.26	$147,827.59	$265,127.66
HANSEN'S DISEASE	$10,091.93	$11,819.90	$8,509.39	$13,402.44
INFECTIOUS DISEASE CONTROL PROGRAM	$771.97	$5.34	$182.34	$594.97
PUBLIC HEALTH EMERGENCY	$0.00	$0.00	$0.00	$0.00
COVID-19 VACCINES	$0.00	$0.00	$0.00	$0.00
CAPITOL FIRST AID STATION	$0.00	$0.00	$0.00	$0.00
Total	$8,575,911.33	$119,896,581.53	$14,170,981.90	$114,301,510.96

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There is an increased inventory to $12.7 million the plan is to purchase additional inventory, so we have a better cushion. Expiring medications becomes an issue if the inventory gets too large. There is a monthly reconciliation of boxed inventory, but the full inventory is just once a year.

~~7. Election of Officers~~ ~~– Sallie Allen, Advisory Committee Coordination Office, HHSC.~~ This item was tabled.

8. Subcommittee reports

a. Governance/Data – Nancy Miertschin was not present, so the chair gave the update. They reviewed the Mac Bylaws were reviewed. Legal authority and member terms were discussed, and partial terms do not count toward the six year terms. Member attendance language will be updated including member expectations.

THMP recruitment process was discussed. Rules will be effective in July. Currently the subcommittee meets monthly so they will be moving to quarterly meetings. There might have to be flexibility based on need.

A proposal was made to move the public comment period to the beginning of the meeting, this will require further discussion.

b. Eligibility – Frank Rosas stated that they receive updates on back log and eligibility.

C. Formulary Sub-committee – Natalie Vanek, M.D. the committee met twice. Pediatric medications were discussed.

1. Recommendation to approve pediatric medications and MAC approval was sought
    a. Raltegravir 25mg (new dosage)
    b. Tivicay (new dosage)
2. Impact of suspended medications. There were 17 medications. The medications were projected for the viewing audience but were too blurry to read. Members had a hard copy list available; to them.
3. Status of 90 day supply was discussed

9. Committee to vote on addition of Raltegravir 25 mg and Tivicay PD to THMP formulary (Vote Required)

Raltegravir

Indication ISENTRESS and ISENTRESS HD (Raltegravir) are indicated in combination with other antiretroviral (ARV) agents for the treatment of HIV-1 infection in adult patients.

Selected Safety Information

- Severe, potentially life-threatening and fatal skin reactions have been reported. This includes cases of Stevens-Johnson syndrome, hypersensitivity reaction and toxic epidermal necrolysis. Immediately discontinue treatment with ISENTRESS or ISENTRESS HD and other suspect agents if severe hypersensitivity, severe rash, or rash with systemic symptoms or liver aminotransferase elevations develops and monitor clinical status, including liver aminotransferases closely.
- Immune reconstitution syndrome can occur, including the occurrence of autoimmune disorders with variable time to onset, which may necessitate further evaluation and treatment.
- ISENTRESS chewable tablets contain phenylalanine, a component of aspartame, which may be harmful to patients with phenylketonuria.
- Coadministration of ISENTRESS or ISENTRESS HD with drugs that are strong inducers of uridine diphosphate glucuronosyltransferase (UGT) 1A1 may result in reduced plasma concentrations of raltegravir. Coadministration of ISENTRESS or ISENTRESS HD with drugs that inhibit UGT1A1 may increase plasma levels of raltegravir.
- Coadministration of ISENTRESS or ISENTRESS HD and other drugs may alter the plasma concentration of raltegravir. The potential for drug-drug interactions must be considered prior to and during therapy. Coadministration or staggered administration of aluminum and/or magnesium-containing antacids and ISENTRESS or ISENTRESS HD is not recommended. Coadministration of ISENTRESS HD with calcium carbonate antacids, tipranavir/ritonavir, or etravirine is also not recommended.
- Rifampin, a strong inducer of UGT1A1, reduces plasma concentrations of ISENTRESS and ISENTRESS HD. Therefore, the dose of ISENTRESS for adults should be increased to 800 mg twice daily during coadministration with rifampin. There are no data to guide coadministration of ISENTRESS with rifampin in patients below 18 years of age. Coadministration with rifampin is not recommended with ISENTRESS HD.
- The impact of other strong inducers of drug metabolizing enzymes on raltegravir is unknown (e.g., Carbamazepine, Phenobarbital, and Phenytoin). Coadministration of ISENTRESS or ISENTRESS HD with other strong inducers is not recommended.
- The most commonly reported (≥2%) drug-related clinical adverse reactions of moderate to severe intensity in treatment-naïve adult patients receiving ISENTRESS compared with efavirenz were headache (4% vs 5%), insomnia (4% vs 4%), nausea (3% vs 4%), dizziness (2% vs 6%), and fatigue (2% vs 3%), respectively. The most commonly reported (≥2%)

clinical adverse reactions of all intensities (Mild, Moderate, and Severe) in treatment-naïve adult patients receiving ISENTRESS HD or ISENTRESS were abdominal pain, diarrhea, vomiting, and decreased appetite. Intensities were defined as follows: Mild (awareness of sign or symptom, but easily tolerated); Moderate (discomfort enough to cause interference with usual activity); or Severe (incapacitating with inability to work or do usual activity).

- Grade 2–4 creatine kinase laboratory abnormalities were observed in subjects treated with ISENTRESS and ISENTRESS HD. Myopathy and rhabdomyolysis have been reported. Use with caution in patients at increased risk of myopathy or rhabdomyolysis, such as patients receiving concomitant medications known to cause these conditions and patients with a history of rhabdomyolysis, myopathy or increased serum creatine kinase.
- There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ISENTRESS or ISENTRESS HD during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263.
- Women infected with HIV-1 should be instructed not to breastfeed if they are receiving ISENTRESS or ISENTRESS HD due to the potential for HIV transmission.
- No dosage adjustment of ISENTRESS is necessary for patients with mild to moderate hepatic impairment. No hepatic impairment study has been conducted with ISENTRESS HD and therefore administration in patients with hepatic impairment is not recommended. The effect of severe hepatic impairment on the pharmacokinetics of raltegravir has not been studied.
- **Before prescribing ISENTRESS or ISENTRESS HD, please read the accompanying Prescribing Information. The Patient Information and Instructions for Use also are available.**

Dosing for ISENTRESS® (raltegravir) and ISENTRESS® HD (raltegravir) Tablets | Official Site (merckconnect.com)

Tivicay PD

Indication

- TIVICAY and TIVICAY PD are human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitors (INSTIs) indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults (treatment-naïve or -experienced) and in pediatric patients (treatment-naïve or -experienced, but INSTI-naïve) aged ≥4 weeks and weighing ≥3 kg
- TIVICAY is indicated in combination with rilpivirine as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for ≥6 months with no history of treatment failure or known substitutions associated with resistance

Home | TIVICAY Official HCP Website (tivicayhcp.com)

MOTION: Add both medications to the formulary prevailed.

10. Public Comment – Sallie Allen, Advisory Committee Coordination Office, HHSC

Josh Micah, Texas Strikeforce stated that delay of 8 months seems to be a way of denying access to medication. He stated that there is delay after delay. He stated that public comment should be moved to the front of the meeting.

Andrew Edmonson, Texas Strikeforce stated that even with medications that have been recommended t remain on the formulary but are not available. He requested that the Executive Commissioner meet with stakeholders. He wondered why the exceptional item was not appropriated for HIV but was made available for COVID. He asked why the EI was not funded. He asked for the EC to meet with stakeholders.

Tana Pardia, Positive Women's Network commented on budget concerns and future solvency. Regular budget updates should be made and responsive to public comment. We want no change to the formulary as far as restricting medications. Meaningful involvement is necessary and is not occurring.

Helen Turner, AIDS Survivor stated her support for the comments from Ms. Pardia. She added that she had difficulty filling out the form to testify. Uploading documents and other challenges have created barriers to participation. She stated that she is losing three medications.

Ruston Taylor, Legacy Community Health stated their concern about suspension of medications on the formulary (blood pressure, behavioral health). The budget is improved and the medications that were proposed for suspension should be maintained.

Crystal Townsend, Texas Strikeforce many issues we see today have been raised by them. There should be a community discussion concerning the solvency of the HIV medication program. Involving people with HIV in the discussions would be important.

11. Action items and agenda topics for next scheduled meeting: January 22, 2022 – Natalie Vanek, M.D., Committee Chair

- Public Comment issues
- Suspended medications and 90 day supply issues with cost analysis

- Membership of the committee
- Confirm the information in the minutes
- Officer Elections
- Next meeting will be on Friday January 28, 2022.

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

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