



**HIV Section Medication Formulary Workgroup (HSMFW)
March 29, 2021**

Members Present:

Jonathan Applebaum, MD, FACP, AAHIVS
Florida State University, College of Medicine

Jeffrey Beal, MD, AAHIVS
*Co-Chair, Medical Director, HIV/AIDS
Section*

Ken Bargar
Consumer

David Brakebill
Consumer

Debby Carscallen, APRN, FNP-BC
*AIDS Drug Assistance Program Coordinator,
Comprehensive Health Care*

Michael D'Amico, PharmD
*Pharmacy Director, Sarasota County Health
Department*

Terry Dudley, RN
Bay County Health Department

Beth Gadkowski, MD, MPH, MS
Associate Professor, University of Florida

Jeannette Iriye, MSN, BSN, RN
RN Consultant, HIV/AIDS Section

Andrea Levin, PharmD, BCACP
*Assistant Professor, Nova Southeastern
University*

Allison Lloyd, PharmD, RPH, AAHIVP
*Pharmacy Director, Duval County Health
Department*

Laura Reeves
HIV/AIDS Section Administrator

Carina Rodriguez, MD
*Professor of Pediatrics, University of South
Florida*

Donna Sabatino, RN, ACRN
*Director of State Policy and Advocacy, The
AIDS Institute*

Michael Sension, MD
CAN Community Health

Elizabeth Sherman, PharmD, AAHIVP
*Associate Professor, Nova Southeastern
University*

Joanne Urban, PharmD, AAHIVP
*Co-Chair, Clinical Pharmacist, HIV/AIDS
Section*

Dan Wall
*Assistant Director, Miami-Dade County
Office of Management and Budget*

Members Absent:

Paul Arons, MD
HIV Clinician

Steven Badura
*AIDS Drug Assistance Program Operations
and Compliance Manager, HIV/AIDS
Section*

Erika Cruz-Martinez, APRN
Hendry County Health Department

Danyelle Williams, PharmD, AAHIVP
*Pharmacy Director, Bureau of Public Health
Pharmacy*

Guests Present:

Kim Molnar
Sandy Noel
Michelle Scavnicky



Call to Order

Dr. Jeffrey Beal, co-chair, called the meeting to order at 2:05 p.m. and provided a brief overview of the workgroup's roles and responsibilities. Kim Molnar of the AIDS Institute conducted a roll call and provided housekeeping notes. HIV/AIDS Section Administrator Laura Reeves welcomed the group.

Review of HSMFW Teams Site, HSMFW Charter, Formularies, and AIDS Drug Assistance Program (ADAP) Change Request Form

Dr. Beal provided a brief overview of the [HSMFW Teams Site](#). Individuals who experience technical difficulties accessing the HSMFW Teams Site were asked to contact Kayra Jackson (kayra.jackson@flhealth.gov).

Next, the HSMFW Charter was reviewed. The group was reminded that members are selected based on the area of the state that they work in as well as their area of expertise. HSMFW serves in an advisory capacity to the HIV/AIDS Section and makes recommendations for the Section to consider. Final decisions are made by the HIV/AIDS Section. Previous ADAP Formulary Workgroup members will serve two-year terms and newly selected individuals will serve three-year terms.

There are several formularies that the group will be monitoring:

- ADAP
- AIDS Pharmaceutical Assistance (APA)
- Baby RxPress (Expectation that this formulary will be switched to "open" by mid-2021)
- Pre-exposure Prophylaxis (PrEP)
- Test and Treat (T&T)

The addition of an nPEP formulary is in discussion.

Medication formularies and the Formulary Change Request Form can be found at floridaaids.org/Clinical_Resources.

Formulary Review

HIV/AIDS Section Clinical Pharmacist Joanne Urban reported that all formularies would be reviewed once per year at a minimum. The group was reminded that there was a mechanism to add or delete medications from any of the mentioned formularies.

The proposed schedule of review was presented:

- ADAP – March through May
- APA – September through November



- T&T, PrEP, and Baby RxPress – July

A summary of the review process was also given:

- Notice to all HSMFW members to review and get feedback from their area
- HSMFW pharmacists meet to review and divide up by therapeutic categories to perform a more comprehensive review
- Review utilization data
- Report back to HSMFW members

Following the meeting, the AIDS Institute will distribute a Doodle poll to participating pharmacists to schedule a meeting to review the ADAP formulary in April 2021.

ADAP Formulary

Cabenuva

Jeannette Iriye, RN consultant with the HIV/AIDS Section, recapped the workgroup's recent activities related to Cabenuva (cabotegravir/rilpivirine) and Vocabria (cabotegravir), which were approved by the Food and Drug Administration on January 21, 2021.

The members of HSMFW voted on February 16, 2021, to recommend the addition of Cabenuva and Vocabria to the ADAP formulary. The voting results are summarized as follows:

- Recommend the addition of Cabenuva
 - Yes – 12
 - Abstain – 2
- Recommend the addition of Vocabria
 - Yes – 12
 - Abstain – 2

On March 24, 2021, ADAP price negotiations were completed, and a decision has been made to add the medications to the ADAP formulary. Paperwork was submitted to the Pharmacy and Therapeutics (P&T) Committee on March 25, 2021.

ViiV's Patient Assistance Program (PAP) is **not currently available to clients on ADAP**. Full information regarding the PAP is available on the [ViiVConnect website](#) and is also outlined on the 5 Barriers Resource Document, which is currently routing for approval through the Department of Health.



A brief summary was provided on eligibility for ViiV's PAP. To qualify, the patient MUST:

- Live in one of the 50 states, the District of Columbia, or Puerto Rico
- Have a household income less than or equal to 500% of the Federal Poverty Level based on household size
- Not be eligible for Medicaid or Puerto Rico's Government Health Plan, Mi Salud
- Meet one of the following:
 - Have no prescription drug coverage
 - Have a Medicare Part B, Medicare Part D, or Medicare Advantage Plan and have spent at least \$600 or more on out-of-pocket prescription expenses during the current calendar year
 - Have a private insurance plan limited to generic-only coverage, outpatient use only, or therapeutic class exclusion (non-coverage) of drug

The PAP decision will be provided after all information is confirmed. Information on PAP is located on Section 8 of the ViiV enrollment form.

The ViiV Bridge Program provides support for clients with a primary insurance payer (excluding Medicare, Medicaid and ADAP enrollees) where a coverage decision is still pending. This program is only available for one year from client program enrollment; however, the coverage period may end prior to the year expiration dependent on the final determination from the primary insurance. Please note: the final determination is reflective of any coverage decision (add, omit or PA) by the primary insurance/payer.

ViiV Connect Copay Card Program: A copay card is available to any person living with HIV who is enrolled with a primary insurance payer, excluding Medicare and Medicaid recipients. The copay card has an annual limit of \$7500. **Please Note: Florida ADAP clients must use their CVS card from ADAP instead of the ViiV Connect Copay Card Program card to cover out-of-pocket costs of the medication.** If a client does not have a copy of this card, you may obtain a copy for the client from the local ADAP office or by calling 1-844-381-2327 Monday through Friday 8:00 a.m. through 5:00 p.m. ET.

It was clarified that Cabenuva will be dispensed as per the prescriber's recommendation (either 30-day or two-month interval). There were concerns over the logistics of variations in doses. Dr. Beal verified that the every-two-month dosing could be done using one of the currently available dosage forms.

Drugs Recommended for Addition in March 2020 and March 2018



Due to programmatic and fiscal restraints, drugs that were previously recommended for addition by the ADAP Formulary Workgroup were not added to the ADAP formulary. Workgroup members were asked to review Attachment 1 - ADAP Drugs Recommended for Addition - March 2020 to determine if there were any drugs that should be recommended for addition at this time.

NOTE: In cases where multiple drugs are listed within a class (e.g., triptans, oral direct-acting anticoagulants, the program may opt to choose one or two options within the class based on cost). Feedback should be provided to Kim Molnar (kmolnar@taimail.org) by May 10, 2021.

In addition, workgroup members were asked to review the following list of medications that were recommended for addition in 2018 to determine if they should be recommended for addition at this time:

Tenofovir alafenamide	Vemlidy
Sofosbuvir	Sovaldi
Sofosbuvir/velpatasvir	Epclusa
Sofosbuvir/velpatasvir/ voxilaprevir	Vosevi

Feedback on these medications should be provided to Kim Molnar (kmolnar@taimail.org) by May 10, 2021.

Drugs to Consider for Deletion

Workgroup members were asked to consider the following drugs for deletion from the ADAP formulary:

Indinavir

- Antiretroviral (ARV) agent that is no longer recommend for use by the Department of Health and Human Services ([DHHS\) Guidelines for Use of Antiretroviral Agents in Adults and Adolescents Living with HIV](#) (ARV Guidelines).
- There are no ADAP clients currently on this drug. No PAP is available, only copay assistance.

Nelfinavir

- ARV that is no longer recommended for use by the ARV Guidelines.
- Two ADAP clients are on nelfinavir (both are copay/deductible clients).
- PAP: Available to those with FPL < 500%.



Action item for voting: Workgroup members will vote on deletion of these drugs and a timeline for notice to providers and patients regarding drug removal for any patients who are on the drugs. During the meeting, the group discussed a 3-month notice of drug removal.

APA Formulary

The APA formulary is designed to provide medications that patients need on a chronic basis that are not on the ADAP formulary.

Request for Formulary Additions

There has been a request to add the following medications: diazepam, guanfacine, and sucralfate.

Note: The submitter withdrew the requests for diazepam and guanfacine.

Sucralfate

- Description: Gastrointestinal agent indicated for the treatment of duodenal ulcers.
- Potential interaction with ARVs: May decrease levels of integrase strand transfer inhibitors (INSTIs) since chemical structure contains aluminum, which can bind INSTIs. Dosing separation necessary (take INSTI at least 2 hours before or 6 hours after sucralfate).
- Coverage on other formularies: Florida Medicaid (yes), Florida Blue (yes).
- PAP availability: yes.

Dr. Urban agreed to follow up on the requests for guanfacine and diazepam to see how the medication was being used for patients. The requests for these medications came from a medical case manager. We are in the process of reaching out to the prescriber(s) to determine the indications for these drugs.

There was a comment that the medications are often requested when a patient is in dire straits and needs access to the medication. Emergency financial assistance has become much more stringent in only allowing assistance for a given medication for 3–6 months.

Action item for voting: Workgroup members will be asked to vote on the addition of sucralfate to the APA formulary.

NOTE: The voting survey that was disseminated inadvertently asked whether members approved of sucralfate being added to the Florida ADAP formulary



and members approved. By standard procedure, if sucralfate is not added to ADAP formulary, it will be added to APA formulary.

Baby RxPress Formulary

- There is an expectation that this formulary will be switched to “open” by mid-2021.

PrEP Formulary

- No changes.

T&T Formulary

- No changes.

Other Business

ADAP Regimen Alerts

The HIV/AIDS Section Medical Team has identified triggers that indicate possible regimen issues based on ADAP drug dispense data in the ADAP database (e.g., two or more INSTIs, two or more non-nucleoside reverse transcriptase inhibitors [NNRTIs], two or more PK boosters, emtricitabine with lamivudine). When a potential issue is identified, the provider and/or pharmacy are contacted and advised that the chosen medications are not a DHHS recommended regimen. The regimen is usually modified.

There are some grey areas in determining drug combinations that are not appropriate (e.g., proton pump inhibitor use with rilpivirine in patients who have remained suppressed, use of darunavir/cobicistat and etravirine in patients who have remained suppressed). Some workgroup members commented that even if the patient has been doing well on the combination, it should not be allowed to continue if it is not consistent with DHHS guidelines. Some combinations are clearly inappropriate as they are therapeutic duplications (e.g., lamivudine/emtricitabine, two INSTIs, two NNRTIs).

The members of the workgroup felt strongly that ADAP should not allow this to occur, citing diversion and higher risk of toxicity/side-effects. Further, members expressed that it was the duty of this workgroup to make recommendations that are in the best interest of both the client and ADAP. The group also felt strongly that the program not only contact the provider but also contact the client to explain what the potential implications are of taking these drug combinations.

In summary, the workgroup made the following recommendations:

- 1) ADAP be given the authority to remove medications that are no longer recommended under the DHHS guidelines.



- 2) Providers be given a 3-month notice that the medication will no longer be available on the ADAP formulary and that there is a change in regimen.
- 3) Through regimen alerts, providers and patients be notified that they are on a non DHHS-recommended regimen.

The Medical Team will draft a formal recommendation for the HIV/AIDS Section to consider.

Public Comments

There were no public comments.

Announcements

Next scheduled Statewide P&T Meetings:

- April 19, 2021 (action items were due March 22, 2021)
- July 19, 2021 (action items due June 21, 2021, action items due to ADAP Director [for ADAP formulary] June 1, 2021)
- October 18, 2021 (action items due September 20, 2021, action items due to ADAP Director [for ADAP formulary] August 31, 2021)

With no other business to conduct, the call ended 3:08 p.m. The next meeting will be held in August or September 2021. The specific date and time are still to be determined. Additional information will follow.

Email discussions will likely continue to occur between meetings.

May 4, 2021

Final tabulation of votes received. Recommendations were sent to ADAP Director Jimmy Llaque by email.



*Do you recommend deletion of Indivavir from the Florida ADAP Formulary?

Answer	0%	100%	Number of Response(s)	Response Ratio
Yes			10	100.0 %
No			0	0.0 %
Abstain			0	0.0 %
No Response(s)			0	0.0 %
Totals			10	100%

*Do you recommend the deletion of Nelfinavir from the Florida ADAP Formulary?

Answer	0%	100%	Number of Response(s)	Response Ratio
Yes			10	100.0 %
No			0	0.0 %
Abstain			0	0.0 %
No Response(s)			0	0.0 %
Totals			10	100%

*Do you recommend the addition of Sucralfate to the Florida ADAP Formulary?

Answer	0%	100%	Number of Response(s)	Response Ratio
Yes			10	100.0 %
No			0	0.0 %
Abstain			0	0.0 %
No Response(s)			0	0.0 %
Totals			10	100%

