



**HIV/AIDS Section Medication Formulary Workgroup (HSMFW)  
September 8, 2023, Meeting Summary**

**Members Present:**

**Jonathan Applebaum, MD, FACP, AAHIVS**

*FSU, College of Medicine*

**Ken Bargar**

*PWH*

**Jeanette Cancel, MD**

*Medical Director, CAN Community Health*

**Ana Conde, MD**

*Infectious Disease Specialist, Project Response, Inc.*

**LaCandria Churchill**

*ADAP Business & Data Integrity Coordinator*

**Cathy Frazier, DNP, MSN, BSN, ADN, RN, ARPRN, FNP-C**

*HIV Telehealth APRN, HIV/AIDS Section*

**Beth Gadkowski, MD, MPH, MS**

*Associate Professor, University of Florida*

**Audreanna Garcia**

*Peer Navigator, Project Response, Inc.*

**Andrea Levin, PharmD, BCACP**

*Assistant Professor, Nova Southeastern University*

**Allison Lloyd, PhD, RPH, AAHIVP**

*Pharmacy Director, Duval CHD*

**Randall Lucero**

*Metropolitan Jacksonville Area HIV Services Planning Group*

**Stephen Renae, MD**

*Infectious Diseases Specialist, Infections Managed*

**Mohammed Reza, MD**

*Mayo Clinic*

**Carina Rodriguez, MD**

*Professor of Pediatrics, University of South Florida*

**Donna Sabatino, RN, ACRN**

*Director of State Policy & Advocacy, The AIDS Institute*

**Andrea Sciberras, DO**

*Co-Chair, Medical Director, HIV/AIDS Section*

**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*

**Terin Vovata**

*RN Case Manager, Unconditional Love, Inc.*

**Dan Wall**

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

**Members Excused:**

**Paul Arons, MD**

*Volunteer, HIV/AIDS Section*

**David Brakebill**

*PWH*

**Members Absent:**

**Debby Carscallen, APRN, FNP-BC**

*ADAP Coordinator, Comprehensive Health Care*

**Jimmy LLaque**

*Interim HIV/AIDS Section Administrator & Florida HIV Patient Care and Treatment Access Program Director*

**Danyelle Williams, PharmD, AAHIVP**

*Pharmacy Director, FDOH*

**Guests Present:**

*Kim Molnar, The AIDS Institute*

*Jeannette Begault, MSN, BSN, RN,*

*RN Consultant, HIV/AIDS Section*

### **Call to Order**

Joanne Urban, Co-Chair, called the meeting to order at 11:04 AM and welcomed the group. Kim Molnar, The AIDS Institute, conducted a roll call.

### **Minutes from Previous Meetings/Votes**

The minutes from the December 13, 2022, meeting and February 2023 vote have been approved and posted to the HIV/AIDS Section's Clinical Resources website at [https://www.floridahealth.gov/diseases-and-conditions/aids/Clinical\\_Resources/hsmfw-minutes.html](https://www.floridahealth.gov/diseases-and-conditions/aids/Clinical_Resources/hsmfw-minutes.html). All approved meeting minutes can be found at the link above.

***Dr. Beth Gadkowski made a motion to approve the June 2023 Action Item Vote Summary. Dr. Elizabeth Sherman seconded the motion. Dr. Andrea Levin and Dr. Michael Sension abstained from the vote. All others voted in favor of approval. The motion carried.***

A member asked for clarification regarding medications available through issuance vs. samples and vouchers. Dr. Urban noted that medications available through issuance are those that can be ordered through the state system to be stocked at the County Health Department and issued to the patient the same day. Providers can order, from pharmaceutical companies, samples to issue to patients the same day or vouchers which can be used to pay for a medication at a local or mail order pharmacy. These voucher usually only allow for a one-time fill per patient per lifetime.

### **ADAP Formulary**

Drugs recommended for formulary addition by vote in February 2023 were added to ADAP formulary effective July 1, 2023 <https://www.floridahealth.gov/diseases-and-conditions/aids/adap/adap-formulary.html>

The following drugs were recommended for removal:

- Abacavir/lamivudine/zidovudine and simvastatin
  - Notices have been sent to prescribers who have patients currently one of these medications.
  - These drugs will be removed from the ADAP formulary effective November 1, 2023
- Zidovudine
  - 3 patients receiving zidovudine, 22 patients receiving zidovudine/lamivudine.
  - We may consider keeping on the formulary since HSMFW members expressed there may sometimes be a need for this medication.
  - Dr. Urban will review further and bring back her findings to the group for discussion.
- Gemfibrozil
  - 102 patients receiving
  - We may consider keeping it on the formulary and providing details on situations when other agents are preferred.

- Dr. Urban will review further and bring back her findings to the group for discussion.
- Oxandrolone
  - The FDA withdrew approval of brand and generic oxandrolone products effective June 28, 2023, related to safety concerns. The full details are provided in the [FDA Announcement](#).
  - Oxandrolone is a synthetic testosterone analogue that has been used to treat AIDS associated wasting syndrome (off-label use). The Florida ADAP formulary contains testosterone which is indicated as replacement therapy for males with hypogonadism.
  - Oxandrolone is no longer on the Florida ADAP formulary.
  - Notices are being sent to prescribers with patients (4 patients) who have received oxandrolone in the past 2 months.
  - It was noted that there are other forms of testosterone on the Formulary.

The group next discussed lenacapavir which was approved by the FDA December 22, 2022.

- HIV-1 capsid inhibitor, first in class, HRSA will require addition to ADAP formulary.
- Indicated for use in combination with other antiretrovirals in heavily treatment-experienced adults with multi-drug resistant HIV.
- Long-acting injection administered subcutaneously every 6 months.
- Prior authorization will be required for use.

The group reviewed the proposed prior authorization form. The following items were noted:

- Concerns were raised over the criteria of the most recent viral load being greater than or equal to 400 copies/ml. It was clarified that it would only apply to the first prior authorization.
  - A timeline for viral load should be stated. It was suggested that the viral load should be within 8 weeks.
  - It was also suggested that the language regarding viral load and failing a current regimen for 8 weeks should be clearly stated (referencing the CAPELLA Study).
- It is anticipated that prior authorization will be processed in 48-72hours.
- Dr. Urban and Dr. Sciberras will be reviewing the prior authorizations for approval. Dr. Elizabeth Sherman volunteered to assist.
- Concerns were raised about where the medication would be delivered. It was clarified that the medication would be sent to the provider.
- It was suggested to remove “drug access” from criteria four.
- Due to the complexities of prescribing and administering, provider and patient education was suggested. Dr. Urban suggested a protocol for the medication be developed and distributed.

- It was also suggested that the form be fluid and that it be updated, as appropriate, after it has been implemented.

#### **APA Formulary**

- Drugs added to the ADAP formulary were removed from the APA Formulary.

#### **Test and Treat Formulary**

- Fluconazole and trimethoprim/sulfamethoxazole were approved for addition to the Test and Treat formulary issuance program.
- Notification of addition will be sent along with the updated Test and Treat Guidance (expected to be released later this month)

#### **PrEP Formulary**

- Cabotegravir (Apretude) is approved by the FDA for pre-exposure prophylaxis and is a recommended option per the 2021 PrEP Guidelines
- Cabotegravir (Apretude) pilot project currently underway in Alachua, Hillsborough, and Miami-Dade, Monroe, Palm Beach, and Sarasota.
- <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>
- [https://apretude.com/?gclid=EA1aIQobChMIpIHfw-rc9QIVwsqGCh0yBgmAEAAYASAAEgKG\\_PD\\_BwE](https://apretude.com/?gclid=EA1aIQobChMIpIHfw-rc9QIVwsqGCh0yBgmAEAAYASAAEgKG_PD_BwE)
- Descovy currently available through Readysetprep program <https://readysetprep.hiv.gov/> or Gilead patient assistance program but not currently available through issuance.

#### **nPEP Formulary-no updates**

- Establishment of formulary is pending direction from HIV/AIDS Section leadership.
- Recommended regimens (voted on by HSMFW):

<b>nPEP DRAFT Medication Formulary Revised September 2021</b>			
<b>Generic Name</b>	<b>Brand Name</b>	<b>Therapeutic Class</b>	<b>Pharmacologic Class</b>
bictegravir/emtricitabine/ tenofovir alafenamide	<b>Biktarvy</b>	antiretroviral	INSTI/NRTI combo
dolutegravir	<b>Tivicay</b>	antiretroviral	INSTI
tenofovir disoproxil fumarate/lamivudine	<b>Cimduo</b>	antiretroviral	NRTI combo
tenofovir disoproxil fumarate/lamivudine	<b>Temixys</b>	antiretroviral	NRTI combo
Preferred regimen: tenofovir disoproxil fumarate/lamivudine (Cimduo or Temixys) PLUS dolutegravir (Tivicay) OR Alternative regimen: bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy)			

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**Other Business**

**Member Recruitment**

- 5 HSMFW members have terms ending Jan 1, 2024
- Notices will be sent out asking if any of these members would like to be considered for re-appointment.
- Call for applications and re-appointments will be sent out and will be due December 15, 2023

Dr. Urban added that the group would be reviewing the ADAP Formulary late this year or early next year.

**Updated Attendance**

Kim Molnar, The AIDS Institute, updated the attendance for those members who joined the call after roll call.

**Public Comments**

Dr. Sension noted that the group should consider reviewing tirzepatide and other drugs that are being used for weight loss given their role in helping to mitigate co-morbidities. It was suggested that safeguards be put in place given the high demand for these medications. Dr. Urban noted that semaglutide is on the ADAP Formulary.

Dan Wall thanked the group for their work. He asked that the results of all email votes be shared with the group to be fully transparent. It was noted that all results from email discussions and votes are summarized and shared with the full membership of the HSMFW. The summary of the June 2023 Email Vote is appended to the end of the current meeting summary.

**Announcements**

**Next scheduled Statewide P&T Meetings:**

- October 16 ,2023, action items due September 18, 2023 (action items due to HIV Patient Care and Treatment Access Program Director August 28, 2023). There are no HSMFW items pending for submission.
- January 22, 2024 (holiday, date change may occur-action items due December 22, 2023) action items due to HIV Patient Care and Treatment Access Program Director December 1, 2023

The timeline for the next meeting of the HSMFW is still to be determined.

With no other business to conduct, the call ended at 12:05 PM (ET).

**Meeting summary emailed to HSMFW members on Nov 8, 2023 with response deadline of Nov 21, 2023. Members voted to approve the meeting summary.**