



**HIV/AIDS Section Medication Formulary Workgroup (HSMFW)
December 19, 2023, Meeting Summary**

Members Present:

Paul Arons, MD

Volunteer, HIV/AIDS Section

Ken Bargar

PWH

David Brakebill

PWH

Ana Conde, MD

Infectious Disease Specialist, Project Response, Inc.

LaCandria Churchill

ADAP Business & Data Integrity Coordinator

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

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

Dan Wall

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

Members Excused:

Jonathan Applebaum, MD, FACP, AAHIVS

FSU, College of Medicine

Randall Lucero

Metropolitan Jacksonville Area HIV Services Planning Group

Members Absent:

Brent Anderson, RPh, CPh, RN

Midland Pharmacy

Jeanette Cancel, MD

Medical Director, CAN Community Health

Debby Carscallen, APRN, FNP-BC

ADAP Coordinator, Comprehensive Health Care

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

HIV Telehealth APRN, HIV/AIDS Section

Jimmy LLaque

Florida HIV Patient Care and Treatment Access Program Director

Terin Votava, BSN, RN, ACRN, CEI

Assistant Clinical Services Supervisor, Unconditional Love, Inc.

Danyelle Williams, PharmD, AAHIVP

Pharmacy Director, FDOH

Guests Present:

Letisha Banks, HIV/AIDS Section

Guillermo Gonzalez, HIV/AIDS Section

Alaina McCorvey, HIV/AIDS Section

Kim Molnar, The AIDS Institute

Call to Order

Joanne Urban, Co-Chair, called the meeting to order at 11:02 AM and welcomed the group. Kim Molnar, The AIDS Institute, conducted a roll call.

Minutes from Previous Meetings/Votes

The minutes from the September 8, 2023, meeting and June 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. All approved meeting minutes can be found at the link above.

Member Recruitment

Joanne Urban announced that member recruitment was currently underway. Five HSMFW members have terms expiring on January 1, 2024. Of those, four have requested reappointment. A new member recruitment email is pending approval before distribution.

ADAP Formulary

https://www.floridahealth.gov/diseases-and-conditions/aids/adap/ documents/adap_formulary.pdf

- The following medications will no longer be marketed in the US and were removed:
 - Abacavir/lamivudine/zidovudine
 - Ranitidine
- Formulary updated to include available dosage forms.
- Drugs/Vaccines under consideration for addition
 - Silver sulfadiazine
 - Description: antibacterial, topical
 - Indication(s): 2nd-3rd degree burns
 - Place in therapy (including guidelines recommendations if applicable): first line for treatment of 2nd degree burns
 - Potential interaction with ARVs: none
 - Coverage on other formularies:
 - Florida Medicaid (_Y_)
 - PAP availability: N
 - Chlordiazepoxide/clidinium
 - Description: anticholinergics, benzodiazepine (mild)
 - Indication(s): treatment of irritable bowel syndrome
 - Place in therapy (including guidelines recommendations if applicable): alternative to anticholinergics/antispasmodics
 - Potential interaction with ARVs: CYP3A4 inhibitors may enhance effects of chlordiazepoxide
 - Coverage on other formularies:
 - Florida Medicaid (_N_)
 - PAP availability: N

- Respiratory syncytial virus vaccine adjuvanted (Arexvy)
 - Description: vaccine for prevention of RSV
 - Indication(s): Prevention of RSV in adults ≥ 60 years of age
 - Place in therapy: ACIP/CDC recommends using shared clinical decision-making to determine whether patient will receive RSV vaccine
 - https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm#B1_down
 - Potential interaction with ARVs: none expected
 - Coverage on other formularies:
 - Florida Medicaid: formulary does not list vaccines
 - PAP availability: N
- Respiratory syncytial virus vaccine (Abrysvo)
 - Description: vaccine for prevention of RSV
 - Indication(s): Prevention of RSV in adults ≥ 60 years of age, prevention of RSV in infants < 6 months of age (use in pregnant women at 32 to 36 weeks gestation)
 - Place in therapy: ACIP/CDC recommends using shared clinical decision-making to determine whether patients ≥ 60 years of age will receive RSV vaccine. ACIP/CDC recommends RSV vaccine for all pregnant women at 32-36 weeks gestation
 - https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm#B1_down
 - <https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm>
 - Potential interaction with ARVs: none expected
 - Coverage on other formularies:
 - Florida Medicaid: formulary does not list vaccines
 - PAP availability: Y

Key discussion points were:

- Members recommended having both versions of the RSV vaccine available.
- It was clarified that the use of the vaccine in pregnant women is to protect the unborn baby.
- Paul Arons suggested consideration be given to adding the monoclonal antibody for RSV to the ADAP Formulary as well.
 - It was noted that ADAP cannot support medications given in an in-patient setting and that medications on the formulary should be HIV-related.
 - It was also noted that the antibodies are extremely difficult to access due to the limited supply.
- Members commented that the vaccines are often covered by Medicaid or some other payer source.
- Annual ADAP formulary review

Once a year the ADAP formulary is reviewed to identify drugs that should be considered for addition or deletion. As part of this review, Part A programs were asked to submit their lists of the top 10 high-cost or high-use drugs for consideration for ADAP formulary addition. The lists from this year

are being reviewed to determine which drugs should move forward for consideration for addition to ADAP formulary.

Members are asked to review the formulary (https://www.floridahealth.gov/diseases-and-conditions/aids/adap/_documents/adap_formulary.pdf) to determine drugs that should be considered for addition or deletion. Members are asked to share the formulary with colleagues in their region so that they can provide input on drugs to be considered.

Members are asked to submit their recommendations no later than Wednesday, January 31, 2024. Please note that HSMFW members do not need to fill out a formulary change requests form when submitting requests during an annual review.

A follow-up email will be distributed with additional information.

APA Formulary

Members are asked to conduct their annual review of the APA formulary (https://www.floridahealth.gov/diseases-and-conditions/aids/Clinical_Resources/_documents/APAFormulary.pdf) to determine drugs that should be considered for addition or deletion. Members are asked to share the formulary with colleagues in their region so that they can provide input on drugs to be considered.

Members are asked to submit their recommendations no later than Wednesday, January 31, 2024.

A follow-up email will be distributed with additional information.

Test and Treat Formulary

https://www.floridahealth.gov/diseases-and-conditions/aids/Clinical_Resources/_documents/TestandTreatFormulary.pdf

- Fluconazole and sulfamethoxazole/trimethoprim were added to the formulary through issuance.
- Formulary file updated to include only drugs available through issuance.

PrEP Formulary

No updates were provided.

nPEP Formulary

Establishment of formulary is pending direction from HIV/AIDS Section leadership. Recommended regimens (voted on by HSMFW): Will be reviewed again before moving forward.

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

Other Business

Prior Authorization Forms – lenacapavir and semaglutide

Andrea Sciberras, Co-Chair, led the group in a review and discussion of the draft prior authorization forms for both lenacapavir and semaglutide.

The following feedback was provided for the prior authorization form for lenacapavir:

- Change “Coverage for Insured Clients” to “For Insured Clients Only”
- Be consistent with HIV-1 RNA
- Concerns were raised over the frequency of viral load testing noted on the bottom of page 1. Consider changing it to “every 3 months or as clinically indicated” or make it consistent with the guidelines.
- At the top of page 2 the second bullet should read “case by case **basis**”
- A question was raised as to why the viral load requirement is within 8 weeks of the request for continuation. Consider changing to 8-12 weeks.
- A member asked why a prior authorization form was even necessary. Candy Churchill noted that other ADAP’s around the country were also instituting prior authorization forms for the medication to ensure that the provider is aware of the prescribing indications and the methods that medication is made accessible to the client.

The following feedback was provided for the prior authorization form for semaglutide:

- It was clarified that the prior authorization was only necessary for Wegovy and not for Ozempic. That will be added to the form.
- Change “Coverage for Insured Clients” to “For Insured Clients Only”.
- Members expressed concerns that the co-morbidities should come first and not weight.
- Concerns were raised that the BMI threshold was too high. It was suggested that “2 or more” be changed to “1 or more”.

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- The importance of educating providers on the difference between Ozempic and Wegovy was noted.
- Add contraindication of history of thyroid cancer.

Elizabeth Sherman agreed to send some additional suggested changes to Drs. Sciberras and Urban.

Updated Attendance

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

Member Comments

Andrea Levin noted that Levemir will be phased out by December 2024.

Announcements

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

The call ended at 12:02 PM (ET) with no other business to conduct.

**HIV/AIDS Section Medication Formulary Workgroup (HSMFW)
Summary of Email Vote on January 2024 Action Items**

As a follow-up to the December 19, 2023, meeting, Kim Molnar, The AIDS Institute, sent an email to HSMFW members on January 8, 2024. In the email, members were asked to vote on January 2024 action items. The items included the approval of the summary from the HSMFW meeting that took place on December 19, 2023, and drugs that should be considered for addition to the ADAP Formulary. These drugs were discussed extensively during the December HSMFW meeting. A reminder email was distributed on Tuesday, January 16, 2024.

For voting purposes, abstentions are not counted towards consensus. The results of the vote were as follows:

Do you approve the minutes from the December 2023 HSMFW meeting?		
	Response Percent	Response Count
Yes	100.00%	8
No	0.00%	0
Abstain	0.00%	0

Please indicate whether you recommend the following drugs be added to the Florida ADAP Formulary:						
	Yes		No		Abstain	
	Response Percent	Response Count	Response Percent	Response Count	Response Percent	Response Count
silver sulfadiazine	75.00%	6	25.00%	2	0.00%	0
chlordiazepoxide/clidinium	66.67%	4	33.33%	2	0.00%	2
Respiratory syncytial virus vaccine adjuvanted (Arexvy)	87.50%	7	12.50%	1	0.00%	0
Respiratory syncytial virus vaccine (Abrysvo)	87.50%	7	12.50%	1	0.00%	0

SUMMARY

The meeting minutes from the December 19, 2023, HSMFW meeting were approved.

The following drugs were recommended for addition to the ADAP Formulary:

- silver sulfadiazine
- chlordiazepoxide/clidinium
- respiratory syncytial virus vaccine adjuvanted (Arexvy)
- respiratory syncytial virus vaccine (Abrysvo)