



**HIV Section Medication Formulary Workgroup (HSMFW)
September 10, 2021**

Members Present:

Jonathan Applebaum, MD, FACP, AAHIVS
FSU, College of Medicine

Paul Arons, MD
Volunteer, HIV/AIDS Section

Ken Bargar
PWH

Jeff Beal, MD, AAHIVS
*Co-chair, Medical Director, HIV/AIDS
Section*

David Brakebill
PWH

Michael D'Amico, PharmD
Pharmacy Director, Sarasota CHD

Terry Dudley, RN
Bay CHD

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*

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

Donna Sabatino, RN, ACRN
*Director of State Policy & 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:

Debby Carscallen, APRN, FNP-BC
*ADAP Coordinator, Comprehensive Health
Care*

Michael D'Amico, PharmD
Pharmacy Director, Sarasota CHD

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

Members Excused:

Erika Cruz-Martinez, APRN
Hendry CHD

Allison Lloyd, PhD, RPH, AAHIVP
Pharmacy Director, Duval CHD

Guests Present:

Kayra Jackson
Pam McGowen
Kim Molnar



Call to Order

Jeffrey Beal, co-chair, called the meeting to order at 10:03 a.m. Kim Molnar, The AIDS Institute, conducted a roll call and established quorum. Dr. Beal thanked members for their responsiveness and cooperation on matters brought before the workgroup. Members were reminded that the workgroup 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 Administration.

Minutes from the March 29, 2021, HSMFW Meeting and Summary of Email Votes Conducted in February 2021 and May 2021

Dr. Beal announced that approval of the March 29, 2021, HSMFW meeting minutes and summaries from the February and May 2021 email votes would occur via an electronic vote that would be distributed by The AIDS Institute on Monday, September 13, 2021.

ADAP Formulary Additions Approved

allopurinol	dulaglutide	prednisone
ammonium lactate	empagliflozin	propranolol
apixaban	fexofenadine	psyllium
baclofen	frovatriptan	rivaroxaban
benztropine	hydralazine	rizatriptan
bisacodyl	hydroxyzine	semaglutide
bupirone	labetalol	sofosbuvir/velpatasvir
calcium polycarbophil	latanoprost	sofosbuvir/velpatasvir/ voxilaprevir
canagliflozin	liraglutide	sucralfate
carvedilol	magnesium oxide	sumatriptan
chlorthalidone	measles, mumps, rubella vaccine	tenofovir alafenamide



clopidogrel	methylcellulose	testosterone enanthate
cyclobenzaprine	montelukast	topiramate
cyproheptadine	naltrexone (oral)	SARS-CoV-2 (COVID-19) Vaccine
dabigatran	naltrexone ER/bupropion ER	
dapagliflozin	naratriptan	
dicyclomine	nicotine	
disulfiram	orlistat	
docusate sodium	oxybutynin	
doxepin	prasugrel	

The anticipated updated formulary release date: September 15, 2021. Information will be distributed to the workgroup when it becomes available.

It was noted that all formulations of listed drugs, unless otherwise specified, are included on the Formulary.

Drugs Recommended by HSMFW Pending Submission to Pharmacy & Therapeutics (P&T) Committee

The HSMFW previously recommended the addition of the following:

- buprenorphine
- buprenorphine/naloxone

These drugs were not approved to move forward since they could not be supplied by CVS Specialty Pharmacy. ADAP is transitioning from CVS Specialty Pharmacy to a pharmacy benefit management (PBM) company with a network of pharmacies that can fill prescriptions for uninsured ADAP clients. As a result, these drugs are being submitted for the October 18, 2021, P&T committee meeting. If approved by the P&T committee, the drugs will become available after the new PBM contract is in place.

Drugs Under Consideration for Addition

The following drugs were requested by providers:

- **Donepezil**



- **Description:** Cholinesterase inhibitor
- **Indication(s):** Mild to severe Alzheimer's dementia and dementia with Lewy bodies
- **Place in therapy (including guidelines recommendations if applicable):** **Guidelines suggest patient with Alzheimer's should be offered a trial of a cholinesterase inhibitor to see if effective and tolerated.**
aafp.org/afp/2011/0615/p1403.html
- **Potential interaction with antiretroviral ARVs:** Levels may be increased by cobicistat (through CYP3A4 and 2D6 inhibition), increased QT prolongation risk (e.g., with rilpivirine)
- **Coverage on other formularies:**
 - Florida Medicaid (_Y_), Florida Blue (_Y_)
- **Patient Assistance Program (PAP) availability:** No

Dr. Appelbaum raised concerns about prescribing limits. He is a geriatrician and although there is a recommendation to offer a trial of these medications, he finds that the drug is often prescribed ongoing without clinical benefit. Dr. Beal requested that Dr. Appelbaum put his concerns in an email to be addressed by the HSMFW and potentially forwarded to the AIDS Drug Assistance Program (ADAP) program.

- **Clonazepam**
 - **Description:** benzodiazepine
 - **Indication(s):** treatment of panic disorder, seizure disorders
 - **Place in therapy (including guidelines recommendations if applicable):** Effective in reducing anxiety symptoms but long-term use generally not recommended due to risk of abuse and adverse effects. For seizure disorders, primarily used as an adjunctive therapy for myoclonic and atonic seizures.
 - **Potential interaction with ARVs:** Levels may be increased by CYP 3A4 inhibitors such as protease inhibitors and cobicistat
 - **Coverage on other formularies:**
 - Florida Medicaid (_Y_), Florida Blue (_Y_)
 - **PAP availability:** No
- **Dextroamphetamine-amphetamine**
 - **Description:** non-catecholamine sympathomimetic agents that stimulate the release of norepinephrine (NE) and other biologic amines from central adrenergic receptors
 - **Indication(s):** Treatment of Attention Deficit-Hyperactivity Disorder (ADHD) and narcolepsy



- **Place in therapy (including guidelines recommendations if applicable):** Stimulant medications (long-acting preferred due to lower abuse potential) are recommended options for the treatment of ADHD in adults and children. aafp.org/family-physician/patient-care/prevention-wellness/emotional-wellbeing/adhd-toolkit/treatment-and-management.html
- **Potential interaction with ARVs:** not expected
- **Coverage on other formularies:**
 - Florida Medicaid (_Y_), Florida Blue (_Y_)
- **PAP availability:** No

Concerns were raised related to access since dextroamphetamine-amphetamine is a Schedule II medication which mail order pharmacies usually cannot provide. Dr. Beal indicated that there is a process for patients to access medications that are not available through CVS specialty pharmacies (i.e., using the ADAP Same Day Card). When there is a new PBM in place, there will be a network of pharmacies, so access will not be as much of a concern.

- **Tinidazole**
 - **Description:** nitroimidazole antimicrobial
 - **Indication(s):** Treatment of trichomoniasis, giardiasis, amebiasis, bacterial vaginosis
 - **Place in therapy (including guidelines recommendations if applicable):** Tinidazole is more expensive than metronidazole but may be needed for the treatment of metronidazole refractory trichomoniasis infection. cdc.gov/std/treatment-guidelines/trichomoniasis.htm
 - **Potential interaction with ARVs:** Levels may be increased by protease inhibitors and cobicistat
 - **Coverage on other formularies:**
 - Florida Medicaid (_Y_), Florida Blue (_N_)
 - **PAP availability:** No

Beth Gadkowski requested that Atomoxetine also be considered for recommended addition to the Formulary. Information on atomoxetine can be found below:

- **Atomoxetine**
 - **Description:** non-stimulant, selective norepinephrine reuptake inhibitor
 - **Indication(s):** Treatment of ADHD
 - **Place in therapy (including guidelines recommendations if applicable):** Nonstimulant medications are recommended options for the treatment of ADHD in adults and children, especially if there is a history of substance abuse. aafp.org/family-physician/patient-



[care/prevention-wellness/emotional-wellbeing/adhd-toolkit/treatment-and-management.html](#)

- **Potential interaction with ARVs:** Levels may be increased by cobicistat and protease inhibitors (weak potential interaction) through 2D6 inhibition, increased QT prolongation risk (e.g., with rilpivirine)
- **Coverage on other formularies:**
 - **Florida Medicaid (_Y_), Florida Blue (_Y_)**
- **PAP availability: Yes**

Dr. Beal reminded the group that prescribers can request any medication not on an approved formulary through emergency financial assistance. The patient could be provided access to the medication for a limited time (e.g., 3–6 months) that would allow time for the medication to be requested for the ADAP Formulary or AIDS Pharmaceutical Assistance (APA) Formulary. A vote on the recommended addition of the drugs listed above will take place electronically via an email distributed by The AIDS Institute on September 13, 2021.

APA Formulary

No requests received. Any drug recommended for addition to ADAP formulary can be placed on APA formulary, if appropriate, until added to ADAP.

Baby RxPress Formulary

- The following information was provided by Mara Michniewicz, Prevention Program Manager: *Due to the fact this is done through a Purchase Order (PO), we had to list medications but the PO states this is an open formulary and includes any Health and Human Services (HHS) -approved medication. We've also stated that this is not inclusive of all acceptable medications and may be subject to change, depending on availability, policy change, new medications and upon approval of the Department. We have also spoken with participating pharmacies to ensure they have additional billing codes in place to dispense medications. So, although the formulary is provided for reference, any medication outside of that can be presented to the pharmacy but will need Department approval prior to filling. This was effective July 1, 2021.*

It was clarified that HHS-approved refers to the medications included in the [Perinatal HIV Clinical Guidelines](#). Dr. Beal noted that other medications necessary to treat exposed infants would be approved.

PrEP Formulary

- No changes

Test and Treat Formulary Drugs Under Consideration for Addition



- **Rilpivirine-** consider addition with the following caveat: must be a client who was on Cabenuva injection and requiring oral medication to cover a gap in care. A prior authorization will be required.

A vote on the recommended addition of the rilpivirine will take place electronically via an email distributed by The AIDS Institute on September 13, 2021.

- **Opportunistic infection medications-** Workgroup members were asked to consider a recommendation of addition for drugs that should be available for a patient entering care for treatment of an active opportunistic infection (OI) to prevent gaps in treatment. HSMFW members are asked to review the [DHHS OI guidelines](#) and recommend additional drugs that should be added to the list below.

- acyclovir
- atovaquone
- azithromycin
- clarithromycin
- dapsone
- ethambutol
- famciclovir
- fluconazole
- itraconazole
- leucovorin
- prednisone
- pyrimethamine
- rifabutin
- sulfadiazine
- TMP-SMX
- valacyclovir
- valganciclovir

Members were enthusiastic about adding OI medications to the Test and Treat Formulary. Members are asked to provide feedback by October 11, 2021.

Non-occupational Pre-Exposure Prophylaxis (nPEP) Formulary

Establishment of the formulary is pending direction from Interim HIV/AIDS Section Administrator. It appears that the formulary will move forward. Further information will be provided as it becomes available.

Other Business



ADAP Formulary Expansion

Joanne Urban noted that there has been discussion regarding expanding the ADAP Formulary with the possibility of adopting the Florida Medicaid Formulary.

The HIV/AIDS Section medical team is in the process of reviewing the Florida Medicaid Formulary to determine drugs that may require a prior authorization from a clinical perspective. The programmatic team is in the process of determining drugs that may need to be considered for a prior authorization from a cost perspective.

This list is under review by the pharmacist members of the HSMFW. Dr. Beal and Joanne thanked Liz Sherman, Allison Lloyd, and Andrea Levin for their work. Once completed, the information will be routed to the full membership of the HSMFW for review and input.

It is anticipated that information will be shared with the HSMFW on October 20 with feedback returned by December 1, 2021.

Dr. Beal noted that a shift to a more open ADAP Formulary would eliminate the need for approval by the Pharmacy and Therapeutics Committee but would not eliminate the need for the HSMFW. HSMFW members will help determine which drugs require a prior authorization as well as provide input on drug utilization evaluation.

Public Comments

Dr. Paul Arons asked if work needed to be done to add the 2021–2022 flu season formulations of the influenza vaccine. Joanne Urban clarified that the ADAP Formulary includes influenza vaccine (including high dose) and the specific products that are ordered each year are determined by what is available.

Announcements

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

- October 18, 2021 (action items due September 20, 2021, action items due to ADAP Director [for ADAP formulary] August 31, 2021)
- January 24, 2022 (action items due December 27, 2021, action items due to ADAP Director [for ADAP formulary] December 6, 2021)

With no other business to conduct, the call ended 11:00AM. The specific date and time of the next meeting are still to be determined. Additional information will follow.



Any questions and concerns can be sent to Jeff Beal (jeff.beal@flhealth.gov), Joanne Urban (joanne.urban@flhealth.gov), or Jeannette Iriye (jeannette.iriye@flhealth.gov).

September 13, 2021

Email sent by Kim Molnar (The AIDS Institute) to HSMFW members to request vote on action items (deadline Friday, September 24, 2021).

September 20, 2021

Reminder email sent by Kim Molnar (The AIDS Institute) to HSMFW members to request vote on action items (deadline Friday, September 24, 2021).

September 28, 2021

Results of voting survey sent to HSMFW Co-Chairs Jeffrey Beal and Joanne Urban by Kim Molnar.



Please see below the results from the vote on September Action Items of the HSMFW:

The minutes of the HSMFW meeting that took place on March 29, 2021, summary of the vote on February Action Items, and summary of the vote on May Action Items were unanimously approved.

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

- Donepezil
- Clonazepam
- Dextroamphetamine-amphetamine
- Tinidazole
- Atomoxetine

The following medication was recommended for addition to the Test and Treat Formulary:

- Rilpivirine



Do you approve the meeting minutes from the March 29, 2021 meeting of the HSMFW?		
Answer Choice	Response Count	Response Percentage
Yes	13	100%
No	0	0%
Abstain	0	0%
Total Responses	13	

Do you approve the minutes of the February 2021 email vote?		
Answer Choice	Response Count	Response Percentage
Yes	13	100%
No	0	0%
Abstain	0	0%
Total Responses	13	

Do you approve the minutes of the May 2021 email vote?		
Answer Choice	Response Count	Response Percentage
Yes	13	100.0%
No	0	0.0%
Abstain	0	0.0%
Total Responses	13	

Do you recommend the addition of Donepezil to the ADAP Formulary?		
Answer Choice	Response Count	Response Percentage
Yes	11	84.62%
No	1	7.69%
Abstain	1	7.69%
Total Responses	13	



Do you recommend the addition of Clonazepam to the ADAP Formulary?		
Answer Choice	Response Count	Response Percentage
Yes	11	84.6%
No	2	15.4%
Abstain	0	0.0%
Total Responses	13	

Do you recommend the addition of Dextroamphetamine-amphetamine to the ADAP Formulary?		
Answer Choice	Response Count	Response Percentage
Yes	7	53.8%
No	5	38.5%
Abstain	1	7.7%
Total Responses	13	

Do you recommend the addition of Tinidazole to the ADAP Formulary?		
Answer Choice	Response Count	Response Percentage
Yes	12	92.3%
No	1	7.7%
Abstain	0	0.0%
Total Responses	13	

Do you recommend the addition of Atomoxetine to the ADAP Formulary?		
Answer Choice	Response Count	Response Percentage
Yes	11	84.6%
No	2	15.4%
Abstain	0	0.0%
Total Responses	13	



Do you recommend the addition of Rilpivirine to the Test and Treat Formulary?		
Answer Choice	Response Count	Response Percentage
Yes	11	84.6%
No	0	0.0%
Abstain	2	15.4%
Total Responses	13	