



**HIV/AIDS Section Medication Formulary Workgroup (HSMFW)
April 30, 2024
Meeting Summary**

Members Present:

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

Paul Arons, MD
Volunteer, HIV/AIDS Section

Jeanette Cancel, MD
Medical Director, CAN Community Health

Ana Conde, MD
Infectious Disease Specialist, Project Response, Inc.

LaCandria Churchill
Development, Implementation & 340B Compliance Manager, HIV/AIDS Section

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

Randall Lucero
Metropolitan Jacksonville Area HIV Services Planning Group

Nilbia Arevalo Munoz, RN
Community Health Nurse, FDOH Hendry/Glades County

Zenaida Quinn, PharmD
Clinical Pharmacist, FDOH Hillsborough County, Specialty Care Clinic

Stephen Renae, MD
Infectious Diseases Specialist, Infections Managed

Mohammed Reza, MD
Mayo Clinic

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

Andrea Sciberras, DO
Co-Chair, Medical Director, Division of Disease Control and Health Protection

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:

David Brakebill

PWH

Donna Sabatino, RN, ACRN

Director of State Policy & Advocacy, The AIDS Institute

Members Absent:

Ken Bargar

PWH

Tammy Cuyler

HIV/AIDS Section Administrator of Operations

Jimmy LLaque

Florida HIV Patient Care and Treatment Access Program Director, HIV/AIDS Section

Allison Lloyd, PhD, RPH, AAHIVP

Pharmacy Director, Duval CHD

Alaina McCorvey

Administrator of Partnerships, HIV/AIDS Section

Michael Sension, MD

CAN Community Health

Terin Votava, BSN, RN, ACRN, CEI

Assistant Clinical Services Supervisor, Unconditional Love, Inc.

Danyelle Williams, PharmD, AAHIVP

Pharmacy Director, FDOH

Guests Present:

David Cavalerri, The AIDS Institute

Kim Molnar, The AIDS Institute

Call to Order

Joanne Urban, Co-Chair, called the meeting to order at 8:03 AM and welcomed the group. Kim Molnar, The AIDS Institute, conducted a roll call.

Minutes from Previous Meetings/Votes

The minutes from the December 19, 2024, meeting and January 2024 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.

New Members

Joanne Urban welcomed newly appointed members Nilbia Arevalo Munoz, RN, Community Health Nurse, FDOH Hendry/Glades County, and Zenaida Quinn, PharmD, Clinical Pharmacist, FDOH Hillsborough County.

HSMFW Overview

Joanne Urban reminded members of the following resources:

- The HSMFW Charter which covers how the HSMFW conducts business and votes https://www.floridahealth.gov/diseases-and-conditions/aids/Clinical_Resources/documents/hsmfw-charter.pdf
- Formulary Change Request Form - https://www.floridahealth.gov/diseases-and-conditions/aids/Clinical_Resources/documents/FormularyChangeRequest.pdf

Old Business

- The following changes were made to the ADAP Formulary effective February 28, 2024
 - Lenacapavir-added, prior authorization required [LenacapavirPAJan2024.pdf \(floridahealth.gov\)](https://www.floridahealth.gov/diseases-and-conditions/aids/adap/documents/LenacapavirPAJan2024.pdf)
 - Abacavir/lamivudine/zidovudine-deleted (removed from market)
 - Ranitidine-deleted (removed from market)
- The following drugs were recommended for ADAP Formulary addition (January 2024 HSMFW vote) but have not been added to the formulary (pending administrative review/approval)
 - silver sulfadiazine
 - RSV vaccine, adjuvanted (Arexvy)
 - RSV vaccine (Abrysvo)
 - chlordiazepoxide/clidinium
- The following drug was recommended for ADAP formulary addition in February 2023, but the drug was not commercially available until 2024 and has not been added to the formulary (pending administrative review/approval)
 - ablutero/budesonide

ADAP Formulary

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

The following drugs/vaccines have been recommended for formulary **addition** as part of the annual formulary review or provider-submitted request:

Drugs on Medicaid Formulary-HSMFW previously recommended ADAP formulary mirror Florida Medicaid when clinically appropriate-formulary addition request were submitted to administration
apremilast
azathioprine
cinacalcet
cyclosporine
fluticasone
insulin aspart protamine/insulin aspart (Novolog 70/30)
insulin lispro protamine/insulin lispro (Humalog Mix)
lacosamide
methotrexate
mycophenolate
paliperidone
posaconazole
sirolimus
tacrolimus
ticagrelor

Drugs/Vaccines Requested-Pending HSMFW Review
denosumab
monkey pox/small pox vaccine
pramoxine
resmetiron
silodosin
tesamorelin
tirzepatide

The Co-Chairs reviewed each of the medications and asked members to comment as appropriate. See the supplemental details regarding each medication beginning on page 7.

- Smallpox and monkey pox vaccine:
 - It was noted that the smallpox and monkeypox vaccine was available at some CHDs administration was piloted with some CHDs as part of the Health and Human Services vaccine program but is now commercially available which is why it is being suggested for addition to the ADAP Formulary. There are some CHD's that still have supplies of vaccine on hand.
 - Concerns were raised that with recent outbreaks, it was imperative for the vaccine to be added to the formulary as soon as possible.

- Tesamorelin:
 - Several members noted a resurgence in the medication for those individuals who do not qualify for semaglutide. It was also noted that patients are not seeing the results that they were hoping for. Elizabeth Sherman reported that two of her patients on the medication developed hyperglycemia while others noted experienced joint pain.
 - **Elizabeth Sherman motioned to exclude tesamorelin from the list of medications considered for recommended addition to the ADAP Formulary. Jonathan Applebaum seconded the motion. The motion passed unanimously.**

- Tirzepatide:
 - Members agreed that their preference was to keep semaglutide on the formulary as opposed to adding tirzepatide.
 - **Andrea Levin motioned to exclude tirzepatide from the list of medications considered for recommended addition to the ADAP Formulary. Elizabeth Sherman seconded the motion. The motion passed with Aureanna Garcia, Carina Rodriguez, and Jonathan Applebaum abstaining.**

The following drugs were recommended for **deletion** from the ADAP Formulary following the annual review:

Drugs Recommended for Deletion from ADAP Formulary
doxazosin
terazosin
elbasvir/grazoprevir
orlistat
insulin detemir
gemfibrozil

See supplemental information regarding the rationale for removing each drug from the formulary beginning on page 9.

Paul Arons suggested that unless there was a contraindication, medications should not be removed from the formulary. He suggested that the decision be up to the provider and patient. The group agreed.

- Doxazosin and terazosin:
 - **Andrea Levin motioned to exclude doxazosin and terazosin from the list of medications considered for recommended removal from the ADAP Formulary. Jonathan Applebaum seconded the motion. The motion passed unanimously.**

- Gemfibrozil:
 - **Jonathan Applebaum motioned to keep gemfibrozil on the formulary but if a patient is also on a statin, recommend the use of fenofibrate instead. Jeanette Cancel seconded the motion. The motion passed unanimously.**

- **APA Formulary – No updates**
 - https://www.floridahealth.gov/diseases-and-conditions/aids/Clinical_Resources/ documents/APAFormulary.pdf
 - **Annual formulary review**
 - No additions/deletions recommended through annual review.
 - Note: Any drugs added to the Florida ADAP Formulary will be removed from the APA Formulary
- **Test and Treat Formulary – No updates**
 - https://www.floridahealth.gov/diseases-and-conditions/aids/Clinical_Resources/ documents/TestandTreatFormulary.pdf
- **PrEP Formulary- No updates**
 - 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 several counties
 - <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>
 - 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): ***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)			

Updated Attendance

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

Announcements

The timeline for the next meeting of the HSMFW is still to be determined. Kim Molnar, The AIDS Institute will distribute a voting poll for members to vote on items discussed during the meeting.

The call ended at 9:09 AM (ET) with no other business to conduct.

HIV/AIDS Section Medication Formulary Workgroup (HSMFW)

Summary of Email Vote on May 2024 Action Items

As a follow-up to the April 30, 2024, meeting, Kim Molnar, The AIDS Institute, sent an email to HSMFW members on May 9, 2024. In the email, members were asked to vote on May 2024 action items. The items included the approval of the summary from the HSMFW meeting that took place on April 30, 2024, and drugs that should be considered for addition or removal to the ADAP Formulary. These drugs were discussed extensively during the April 30, 2024, HSMFW meeting. A reminder email was distributed on May 15, 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 April 2024 HSMFW meeting?		
	Response Percent	Response Count
Yes	100.00%	15
No	0.00%	0
Abstain		1
Total Votes		16

Please indicate whether you recommend the following drugs for addition to the Florida ADAP Formulary:						
	Yes		No		Abstain	
	Response Percent	Response Count	Response Percent	Response Count	Response Count	Total Votes
denosumab	92.31%	12	7.69%	1	2	15
monkey pox/small pox vaccine	93.75%	15	6.25%	1	0	16
pramoxine	100.00%	14	0.00%	0	1	15
resmetiron	92.31%	12	7.69%	1	2	15
silodosin	92.31%	12	7.69%	1	3	16

Please indicate whether you recommend the following drugs for removal from the ADAP Formulary.						
	Yes		No		Abstain	
	Response Percent	Response Count	Response Percent	Response Count	Response Count	Total Votes
elbasvir/grazoprevir, Hepatitis C antiviral	93.33%	14	6.67%	1	1	16
orlistat	100.00%	15	0.00%	0	1	16
insulin detemir (Levemir)	69.23%	9	30.77%	4	3	16

SUMMARY

The meeting minutes from the April 30, 2024, HSMFW meeting were approved.

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

- denosumab
- monkey pox/small pox vaccine
- pramoxine
- resmetiron
- silodosin

The following drugs were recommended for removal from the ADAP Formulary:

- elbasvir/grazoprevir, Hepatitis C antiviral
- orlistat
- insulin detemir (Levemir)

Supplemental Information-Drugs Considered for Addition to the ADAP Formulary

- **Denosumab subcutaneous injection**
 - **Description:** Monoclonal antibody-inhibits osteoclast formation, function and survival leading to decreased bone resorption and increased bone mass. Denosumab is administered by healthcare provider via subcutaneous injection.
 - **Indication(s):** treatment of postmenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men with osteoporosis at high risk for fracture, of glucocorticoid-induced osteoporosis in men and women at high risk for fracture, to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer, to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer
 - **Place in Therapy:** According to guidelines from the American College of Physicians and Endocrine Society, denosumab is considered second-line/alternative treatment for osteoporosis in patients who have contraindications to or who experience adverse effects to bisphosphonates
 - **Potential interaction with ARVs:** none expected
- **Smallpox and Monkeypox vaccine (Jynneos)**
 - **Description:** Attenuated, live, non-replicating vaccine against smallpox and monkeypox viruses.
 - **Indication(s):** Prevention of smallpox and monkeypox in adults ≥ 18 years of age
 - **Place in Therapy: Recommended by the Advisory Committee on Immunization Practices (ACIP) for prevention of Mpox infection in patients at risk:**
 - Persons who are gay, bisexual, and other MSM, transgender, or nonbinary people who in the past 6 months have had:
 - A new diagnosis of at least 1 sexually transmitted disease
 - More than 1 sex partner
 - Sex at a commercial sex venue
 - Sex in association with a large public event in a geographic area where Mpox transmission is occurring
 - Persons who are sexual partners of the persons described above.
 - Persons who anticipate experiencing any of the situations described above.
 - <https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf>
 - **Note:** Prior to April 1, 2024, Jynneos was only available through the HHS Mpox Vaccination program which is being phased out. As of April 30, 2024, HHS vaccine supply can be requested if commercial supply is not available. Jynneos is expected to be available through the CDC's routine vaccination program effective August 1, 2024. <https://aspr.hhs.gov/mpox/OperationalGuidance/Pages/default.aspx>
 - Pharmacists in Florida cannot administer Jynneos as it was not included in the 2022 ACIP vaccination schedule. This will be considered at the June 2024 Board of Pharmacy meeting.
 - **Potential interaction with ARVs:** none expected

Pramoxine

- **Description:** Local anesthetic
- **Indication(s):** Temporary relief of pain and itching associated with hemorrhoids.
- **Potential interaction with ARVs:** none expected

- **Note: Formulary currently contains pramoxine/hydrocortisone but not pramoxine alone**
- **Resmetiron**
 - **Description:** Thyroid receptor -beta agonist, recently granted accelerated approval by the FDA
 - **Indication(s):** In conjunction with diet and exercise, treatment of adults with noncirrhotic, nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (stages F2 to F3)
 - **Place in Therapy:** This is the first drug to receive FDA approval for the treatment of NASH, no referred to as metabolic dysfunction-associated steatohepatitis (MASH)
 - **Potential interactions. Should not be used with strong CYP2C8 inhibitors (eg. gemfibrozil),** levels may be increased by atazanavir (CYP 2C8 inhibition), may increase levels of some statins (rosuvastatin and simvastatin-limit dose to 20 mg, atorvastatin, and pravastatin-limit dose to 40 mg)
- **Silodosin**
 - **Description:** Alpha-1 adrenergic receptor antagonist
 - **Indication(s):** Treatment of benign prostatic hyperplasia (BPH)
 - **Place in Therapy:** Guidelines from the American Urologic Association considered there to be no difference in efficacy among alpha blockers. Certain alpha blockers (e.g., silodosin) and tamsulosin are more selective for alpha receptors in the prostate which results in lower risk of orthostatic hypotension compared to terazosin and doxazosin) [https://www.auanet.org/guidelines-and-quality/guidelines/benign-prostatic-hyperplasia-\(bph\)-guideline#x8196](https://www.auanet.org/guidelines-and-quality/guidelines/benign-prostatic-hyperplasia-(bph)-guideline#x8196). Drugs that are more selective for the alpha1a vs alpha 1b receptor are more likely to cause ejaculatory dysfunction (i.e., tamsulosin, silodosin). Silodosin may be preferred when treating patients with BPH who are on multiple anti-hypertensives or who have orthostatic hypotension.
 - **Potential interaction with ARVs: Do not use or use with low doses with caution with drugs that are strong CYP3A4 inhibitors (e.g., protease inhibitors, cobicistat)**
- **Tesamorelin**
 - **Description:** Growth hormone releasing factor analog
 - **Indication(s):** Reduce excess abdominal fat in patients with HIV and lipodystrophy
 - **Place in Therapy:** management of lipodystrophy is discussed in the IAS-USA Metabolic complication guidelines (2002). There is not a one size fits all approach. Growth hormone can be considered but is not recommended for general use. There are concerns due to reversal of effects following discontinuation and potential adverse effects (e.g. insulin resistance, arthralgias, fluid accumulation in extremities. [Management of Metabolic Complications Associated With Antiretroviral Therapy for HIV-1 Infection - IAS-USA \(iasusa.org\)](https://www.iasusa.org/management-of-metabolic-complications-associated-with-antiretroviral-therapy-for-hiv-1-infection))
 - **Note: This drug was reviewed by HSMFW in 2018 and was not recommended for formulary addition**
 - **Potential interaction with ARVs:** none expected
 - **Note:** There is a patient assistance program available (eligibility criteria not disclosed)

- **Tirzepatide**
 - **Description:** Glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptor agonist
 - **Indication(s):** Type 2 diabetes (Mounjaro), weight loss (Zepbound)
 - **Place in Therapy:** Tirzepatide and semaglutide (GLP-1 RA) that is currently on the ADAP Formulary are approved for use in type-2 diabetes particularly when weight loss is necessary. Semaglutide has proven cardiovascular risk reduction benefits (studies ongoing with tirzepatide)
 - **Potential interaction with ARVs:** none expected
 - **Note: If added, this drug will replace semaglutide and will require prior authorization when used for weight loss**

Supplemental Information: Drugs Being Considered for Removal from ADAP Formulary

Alpha-1 blockers-doxazosin, terazosin

- There are concerns regarding orthostatic hypotension with alpha-1 blockers which may be more prominent in elderly patients. Current hypertension treatment guidelines recommend these drugs only be considered as second-line agents for treatment of hypertension in patients who also have benign prostatic hyperplasia (BPH).
- **There are 53 patients receiving doxazosin or terazosin through Florida ADAP (all male birth gender). 16 of these patients are age ≥ 65 years**
- Note: Prazosin is also used to treat post-traumatic stress disorder and is on the ADAP Formulary
- **Hypertension Treatment Guidelines:**
 - 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults list alpha blockers as second line agents for treatment of hypertension in patients who have concomitant benign prostatic hyperplasia (BPH)

Alpha-1 blockers	Doxazosin	1-16	1	These are associated with orthostatic hypotension, especially in older adults. They may be considered as second-line agent in patients with concomitant BPH.
	Prazosin	2-20	2 or 3	
	Terazosin	1-20	1 or 2	

- See <https://www.jacc.org/doi/epdf/10.1016/j.jacc.2017.11.006#page=40>
 - Note: Drugs that are more selective for the alpha1a vs alpha 1b receptor are more likely to cause ejaculatory dysfunction (i.e., tamsulosin, silodosin). [https://www.auanet.org/guidelines-and-quality/guidelines/benign-prostatic-hyperplasia-\(bph\)-guideline#x8196](https://www.auanet.org/guidelines-and-quality/guidelines/benign-prostatic-hyperplasia-(bph)-guideline#x8196).
- American Geriatrics Society 2023 updated AGS Beers Criteria® for potentially inappropriate medication use in older adults American recommend avoiding use as an anti-hypertensive in patients ≥ 65 years old. <https://aqsjournals.onlinelibrary.wiley.com/doi/epdf/10.1111/jgs.18372>

Elbasvir/grazoprevir, Hepatitis C antiviral

- There no longer appears to be a need for elbasvir/grazoprevir due to changes in the HCV treatment guidelines.

- In prior HCV treatment guidelines, elbasvir/grazoprevir was a recommended treatment option in patients with genotype 1 or 4 with severe renal impairment (CKD stage 4/5) .
- All of the currently recommended agents for HCV treatment can be used regardless of CKD stage.
- One patient received elbasvir/grazoprevir through ADAP during this past year (none currently)

Orlistat, anti-obesity agent (lipase inhibitor)

- Can impact the absorption of medications including many antiretrovirals.
- Dosing should be separated by 4-5 hours
- 2 patients received orlistat through ADAP this past year (none currently)

Insulin detemir (Levemir)

- **Novo Nordisk** announced this insulin product will be removed from the market effective December 31, 2024. The flexpen is being discontinued effective April 2024.
- There are 40 patients receiving insulin detemir through Florida ADAP
- An email notice (general for the Patient Care email distribution list) and patient/provider specific memos/letters (for providers currently prescribing insulin detemir for one of their patients) has been drafted and is undergoing review.

<https://www2.diabetes.org/sites/default/files/2022-03/Switching-Between-Insulin-Products-in-Humanitarian-Response-2022-Easter-Europe-3-18-2022-DDRC-English-v3.pdf>

Cobicistat

- This drug is approved for use as a pharmacokinetic enhancer with atazanavir or darunavir
- We currently have atazanavir/cobicistat (Evotaz) and darunavir/cobicistat (Prezcobix) on the formulary, in addition to some single tablet regimens containing cobicistat
- There is currently one patient receiving cobicistat through ADAP
- There is a patient assistance and copay assistance program

Elizabeth Sherman motioned to exclude cobicistat from the list of medications considered for recommended removal from the ADAP Formulary. Paul Arons seconded the motion. The motion passed unanimously.

It was suggested that the program contact the provider to gather additional information.

Gemfibrozil

- Fibrates gemfibrozil and fenofibrate are both on the Florida ADAP Formulary.
- The majority of patients on ADAP are receiving fenofibrate which has once-daily dosing and is preferred if fibrate is used with a statin

Drug	Patients
Fenofibrate	485
Gemfibrozil alone	50

Gemfibrozil with statin	32
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- Letters/memos have been drafted to notify prescribers of patients receiving gemfibrozil with a statin.
- *Can we reconsider keeping gemfibrozil on the formulary but if a patient is on a statin, provide a recommendation to use fenofibrate instead?*
- According to the 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol. A Report by the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, if fibrate therapy is necessary for the treatment of persistently elevated triglycerides in a patient on a statin, fenofibrate is preferred over gemfibrozil due to a lower risk of severe myopathy.
 - See https://www.jacc.org/doi/pdf/10.1016/j.jacc.2018.11.003?_ga=2.26086971.762044773.1711395245-535586157.1655907657#page=35