HIV Section Medication Formulary Workgroup (HSMFW)
February 8, 2022

Members Present:
Jonathan Applebaum, MD, FACP, AAHIVS
FSU, College of Medicine
Paul Arons, MD
Volunteer, HIV/AIDS Section
Steven Badura
ADAP Operations and Compliance Manager, HIV/AIDS Section
Jeff Beal, MD, AAHIVS
Co-Chair, Medical Director, HIV/AIDS Section
Ken Bargar
PWH
David Brakebill
PWH
Jeanette Cancel, MD
Medical Director, CAN Community Health
Debby Carscallen, APRN, FNP-BC
ADAP Coordinator, Comprehensive Health Care
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, PhD, RPH, AAHIVP
Pharmacy Director, Duval CHD
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:
Alberto Jose Perez-Bermudez
PWH
Michael D'Amico, PharmD
Pharmacy Director, Sarasota CHD
Danyelle Williams, PharmD, AAHIVP
Pharmacy Director, Bureau of Public Health Pharmacy

Guests Present:
Kim Molnar

Call to Order
Jeffrey Beal, Co-Chair, called the meeting to order at 2:04 pm and welcomed the group. Kim Molnar, The AIDS Institute, conducted a roll call.

Welcome New Members
Dr. Beal welcomed two new members to the workgroup, Jeanette Cancel, MD, Medical Director at CAN Community Health and Alberto Jose Perez-Bermudez, person living with HIV (PWH).

Minutes from September 10, 2021
The minutes from the September 10, 2021 meeting have been approved and posted to the HIV/AIDS Section's Clinical Resources website at http://www.floridahealth.gov/diseases-and-conditions/aids/Clinical_Resources/_documents/summary-hsmfw-9-10-21.pdf

Summary of Email Votes Conducted in July and November 2021
The summary of email votes conducted for July and November 2021 were distributed to workgroup members prior to the meeting for their review. The information will be appended to the minutes of this meeting.

ADAP Formulary
- **Drugs recommended by HSMFW that are pending addition to ADAP formulary**
  - *The addition of these drugs has been put on hold pending implementation of the new pharmacy benefit management contract*

amoxicillin	famciclovir	pancrelipase (amylase, lipase, protease)
amoxicillin/clavulanate	fluticasone (nasal spray)	penicillin
amphetamine/dextroamphetamine	fluticasone (oral inhaled)	polyethylene glycol and electrolyte oral solution
atomoxetine	hydrocortisone	prazosin
brexpiprazole	ivabradine	rifapentine
buprenorphine	lansoprazole	sacubitril/valsartan
buprenorphine/naloxone	levofloxacin	temazepam
cefixime	lidocaine	tinidazole
chlorhexidine gluconate (0.12%)	lurasidone	tiotropium
ciprofloxacin	mesalamine	travoprost
clonazepam	mometasone	tretinoin
diclofenac	moxifloxacin	vitamin B complex
donepezil	naloxone	vitamin C
dorzolamide/ timolol	nepafenac	voriconazole
doxycycline		

- **ADAP Formulary Annual Review**
  Dr. Joanne Urban reminded the group that an annual review of the ADAP Formulary was required. Dr. Urban asked that workgroup members review the list above and the current formulary (https://www.floridahealth.gov/diseases-and-conditions/aids/adap/_documents/adap_formulary.pdf). Members were encouraged to get feedback from providers in their respective areas.

  Dr. Beal asked the workgroup to also look for combination products that could be added. Dr. Beal noted that combination products could be added if the components are already on the formulary without going to the Bureau of Public Health Pharmacy and Therapeutics Committee for approval. The recommendation to add combination products would still be required to undergo a programmatic fiscal impact review and be approved by ADAP staff.

  Dr. Carina Rodriguez requested the following additions: oral contraceptive pills (OCPs) as specified in the Family Planning Formulary, topical mupirocin, and permethrin.

A follow-up email will be distributed to workgroup members following the meeting. The email will contain the information above, encourage discussion within the group and offer the opportunity to submit recommended additions or deletions. The email will also contain a link to the Formulary Change Request form that allows providers to submit requests at any time.

- **Pneumococcal conjugate vaccines-PCV 15 and PCV 20**
  - PCV 15 (Prevnar 15) and PCV 20 (Prevnar 20) are approved for use for the prevention of invasive pneumococcal infection in adults.
  - https://www.cdc.gov/mmwr/volumes/71/wr/mm7104a1.htm
  - The Advisory Committee on Immunization Practices (ACIP) recommends either PCV 20 alone or PCV 15 followed by pneumococcal polysaccharide vaccine (PPSV-23) in the following patients:
    - All adults ≥ 65 years old if they have not previously received PCV vaccine or if vaccination history is unknown
    - Adults 19-64 years old with certain conditions, including HIV infection if they have not received PCV vaccine prior or if vaccination history is unknown.
    - If they received PCV 13 prior, they should receive PPSV-23
    - PCV 13 will still be used for individuals under 18 years

The committee agreed to postpone its recommendation until the ACIP releases its 2022 guidelines. If necessary, an email discussion and vote will be conducted.

In the meantime, Dr. Beal will request that ADAP staff assess if the vaccine is affordable.

Dr. Beal reminded the group that guidance could be provided for how the vaccines should be used by either instituting a prior authorization or asking the pharmacy benefits manager (PBM) to monitor usage and review findings.

- **ADAP Formulary expansion-potential to adopt Florida Medicaid Formulary**
  Dr. Joanne Urban thanked the following pharmacist members of the workgroup for their efforts on the formulary comparison – Dr. Elizabeth Sherman, Dr. Andrea Levin, and Dr. Allison Lloyd.
  The ADAP and Medicaid formularies were reviewed to identify drugs that should require a prior authorization. Feedback was also received from ADAP

regarding additional drugs that would need to have a Prior Authorization (PA) process due to cost.

Drugs that will require PA

- Intravenous electrolyte and nutritional infusions
- Drugs/vitamins designated for cystic fibrosis diagnosis only (except those already on ADAP such as calcium/vitamin D, vitamin D, omeprazole)
- Drugs/vitamins approved by Medicaid for use in pediatric patients only
- Intravenous drugs to treat heart failure, and pulmonary hypertension
- Antineoplastic agents
- Antibiotics that are only available intravenously
- Drugs that are used to treat very rare conditions that we do not anticipate a need for in Florida ADAP clients
- Drugs that were removed from the ADAP formulary for clinical reasons
- Drugs already designated as requiring a PA for ADAP (i.e., ibalizumab-uiyk)
- Drugs deemed high cost

The workgroup members were asked if they recommended that the program pursue adopting the Florida Medicaid formulary.

It was asked if drugs designated for a specific clinical usage be allowed on the ADAP Formulary for another clinical usage. For example, some drugs used to treat erectile dysfunction appear on the Medicaid Formulary for pulmonary fibrosis and requires a prior authorization (PA). Dr. Urban clarified that Medicaid has both auto PAs and clinical PAs. An auto PA looks at the billing history to look for diagnosis and other medications used to treat that diagnosis. A clinical PA requires that a form be completed and submitted. Dr. Urban informed the group that the workgroup could submit a recommendation on how restricted use of medication is handled.

Members expressed concerns over the fiscal implications of matching the Medicaid Formulary by adding additional drugs to the ADAP Formulary. It was recommended that a rigorous fiscal review be conducted. Dr. Beal reminded the group that any recommendation made by HSMFW would undergo a thorough fiscal review by ADAP staff. Steven Badura commented that a preliminary review of the Medicaid Formulary showed most of the additional

medications fell under the $600/per month threshold. It was also noted that with the new PBM, the ADAP program will be able to access utilization reports.

Concern was also raised over the requirement for a PA for drugs/vitamins approved by Medicaid for use in pediatric patients only. Dr. Rodriguez agreed to review the list and provide comments.

Dr. Arons noted that vaccines are not noted on the Medicaid Formulary. Dr. Urban clarified that any recommendation made would include keeping all current medications and vaccines on the ADAP Formulary.

APA Formulary

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

Baby RxPress Formulary

This is now expected to be an open formulary in that any medication can be requested on a case-by-case basis. The change will not occur until the new contract is finalized in June 2022. No changes to discuss at this time unless the open formulary concept is not approved by the DOH attorney.

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

PrEP Formulary

- **Cabotegravir** (Apretude) is now approved by the FDA for pre-exposure prophylaxis and is a recommended option per the 2021 PrEP Guidelines
    - https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf
    - https://apretude.com/?gclsrc=aw.ds&gclid=EAIaIQobChMIplHfw-rc9QIVwsqGCh0yBgmAEAAYASAAEgKG_PD_BwE
    - The HIV/AIDS Section has received information on pricing, but we do not know the plan for implementation of Apretude in CHDs. We have been informed that the PAP process for cabotegravir (Apretude) will mirror the PAP for Cabenuva.

A recommendation to add cabotegravir to the PrEP Formulary was made by Dr. Jonathan Appelbaum and seconded by Dr. Elizabeth Sherman. A formal vote will take place via email.

Dr. Paul Arons noted three anecdotal cases in which individuals taking Cabenuva suffered from increased depression, suicidal ideation, and in one case an individual was involved in a domestic dispute. Dr. Beal informed the group that the cases of mood disorders reported for cabotegravir were less than 1% compared to Cabenuva.

Donna Sabatino requested information on how clinics are handling the costs associated with injectables such as office visits and staff time. HIV/AIDS Section leadership is working on gathering this information from county health departments. It was suggested that the topic be brought up for discussion during the upcoming Florida Comprehensive Planning Network's Medication Access Committee meeting.

- **PrEP Formulary Annual Review**
  Workgroup members were asked to review the current formulary located at https://www.floridahealth.gov/diseases-and-conditions/aids/Clinical_Resources/_documents/Pre-ExposureProphylaxisFormulary.pdf

  A follow-up email will be distributed to workgroup members following the meeting. The email will contain the information above and encourage discussion within the group and offer the opportunity to submit feedback.

Test & Treat (T&T) Formulary

- **Drugs recommended by HSMFW for addition to T&T formulary**
    - *The addition of these drugs is pending approval from administration and cannot occur until after the new PBM is in place. These drugs will not be part of the issuance program (i.e., not stocked at the CHDs)**

acyclovir	famciclovir	pyridoxine
amoxicillin	fluconazole	pyrimethamine
amoxicillin/clavulanate	isoniazid	rifabutin
atovaquone	itraconazole	rifampin
azithromycin	leucovorin	rifapentine
ciprofloxacin	levofloxacin	rilpivirine
clarithromycin	moxifloxacin	sulfadiazine
clindamycin	nystatin	sulfamethoxazole/trimethoprim
dapsone	prednisone	valacyclovir
doxycycline	primaquine	valganciclovir
ethambutol	pyrazinamide	voriconazole

* It was clarified that all other medications on the Test and Treat Formulary would be stocked at county health departments

- **Annual review of T&T Formulary**
  Workgroup members are asked to review the above list and current formulary located at https://www.floridahealth.gov/diseases-and-conditions/aids/Clinical_Resources/_documents/TestandTreatFormulary.pdf

  A follow-up email will be distributed to workgroup members following the meeting. The email will contain the information above and encourage discussion within the group and offer the opportunity to submit recommendations for additions or deletions.

nPEP Formulary

The establishment of the nPEP formulary is pending direction from the HIV/AIDS Section Administrator. nPEP regimens recommended are based on the HSMFW vote that took place on July 27, 2021.

Other Business

- **Drugs to treat COVID**
  We received guidance that these drugs cannot be considered for formulary addition until approved by the FDA. All currently have "Emergency Use Authorization" but not FDA approval
- **Addition of drugs for erectile dysfunction**
  A member has asked that we discuss the possible addition of these drugs. We have requested guidance from ADAP Director as to whether these drugs are permitted on ADAP formularies. We have not found any other state ADAP that have the ED drugs on formulary. The issue will be brought up during the next HRSA Project Officer call and any information received will be shared with HSMFW members.

Public Comments

There were no public comments.

Announcements

- **Next scheduled Statewide P&T Meetings:**
  - April 18, 2022 (action items due March 21, 2022, action items due to ADAP Director [for ADAP formulary] February 28, 2022.
  - July 18, 2022 (action items due June 20, 2022, action items due to ADAP Director [for ADAP formulary] May 30, 2022.
- **Next HSMFW meeting** - The HSMFW will meet again before June 30, 2022. More information will follow. Email discussions will continue to occur between meetings.

With no other business to conduct, the call ended 3:00 PM.

Approved by HSMFW March 18, 2022.

HIV Section Medication Formulary Workgroup (HSMFW)
Email Vote on Nonoccupational Postexposure Prophylaxis (nPEP) Formulary

On July 14, 2021, HIV Section Medication Formulary Workgroup Co-Chairs, Jeffrey Beal and Joanne Urban, Co-Chair initiated, via email, a discussion of establishing a Nonoccupational Postexposure Prophylaxis (nPEP) Formulary. Members were asked to participate in a dialogue related to the pros and cons of the regimens being considered for inclusion.

DRAFTNonoccupational Postexposure Prophylaxis (nPEP) Formulary ***DRAFT***	
Preferred	
Option 1	Tenofovir disoproxil fumarate/emtricitabine (Truvada) **PLUS** dolutegravir (Tivicay)
Option 2	Tenofovir disoproxil fumarate/lamivudine (Cimduo or Temixys) **PLUS** dolutegravir (Tivicay)
Alternative	
Option 1	Tenofovir disoproxil fumarate/emtricitabine (Truvada) **PLUS** darunavir (Prezista) **PLUS** ritonavir (Norvir)
Option 2	Tenofovir disoproxil fumarate/lamivudine (Cimduo or Temixys) **PLUS** darunavir (Prezista) **PLUS** ritonavir (Norvir)
Option 3	Elvitegravir/cobicistat/tenofovir alafenamide/emtricitabine (Genvoya)

The following comments/questions were submitted:

- Is Cimduo/Temixys more cost-effective than generic Truvada? (Sherman)
- I agree with Liz. I vote for Preferred Option 2, and Alternative Option 3 (people will be more adherent if they have to take a single tablet rather than 2) (Appelbaum)
- I agree with Jon and Liz .....I would decide upon Preferred option 1 and 2 based upon cost savings and agree with Alternative option 3 based upon STR advantage recognizing that there is a tradeoff re: genetic barrier with elvitegravir vs darunavir. (Sension)

- I concur. We can select between the two preferred regimens and Genvoya. (Llyod)
- Agree with all replies. BTW, can Prescobix be substituted for darunavir/ritonivir in alternative option 2 to reduce the pill burden?
  Either way, I think the single tablet regimens (preferred option 2 w/generics, alternative option 3) would be best. (Arons)
- Since Dr. Sension brought up the genetic barrier to resistance with EVG, has there been any thought to using Biktarvy in its place? Or was the EVG option chosen due to cost? https://www.croiconference.org/abstract/safety-and-tolerability-of-once-daily-bic-ftc-taf-for-postexposure-prophylaxis/ (Sherman)
- I'm assuming it's cost….Otherwise it would definitely get my vote for Preferred! Ken Mayer presented compelling data at CROI this year on the cohort they have used Biktarvy for nPEP with. (Sension)
- I would second Biktarvy better than Genvoya as alternative. Hopefully this gets incorporated in next CDC guidelines. Seen CROI data from Ken Mayer, and anxiously waiting on published data from their trial. Having seen elvitegravir resistance in naive pts, yet to see with bictegravir makes much more sense as STR acknowledging gap in impact of TAF level in vaginal secretions for prevention in women. (Rodriguez)
- I would vote for Preferred option #2 and Alternative option #3. I agree that a single tablet regime would be the best option for medication adherence. (Carscallen)
- I would have to vote for Preferred option 1 and 2 and Alternative 1. I push back a bit on STR being best for adherence, I believe QD is VERY important, but does it really matter if its 1 pill or 2 as long as it QD? Many people take medications for other comorbidities that increase pill burden already. To me the genetic barrier to resistance is very important. And of course, the cost concern is very valid. (Sabatino)
- Good afternoon, there is a cost difference between generic Truvada and both Cimduo and Temixys, however, the financial impact will depend on what the expected usage will be and will it be similar to the historical utilization of the PrEP or Test & Treat programs. Also, if these medications will be provided through our Issuance program, I would suggest regimens with the least number of medications so that the CHDs have less inventory to manage. With that being said, I agree with preferred option 2 and alternative option 3. (Williams)
- Is Cimduo/Temixys more cost-effective than generic Truvada? YES, both Cimduo and Teixys are more cost-effective than generic Truvada.

  Re Single Tablet option: I agree most prefer one tablet option and realize the options below are for consideration and discussion. Does HSMFW want to maintain compliance with currently published guidelines? Or does HSMFW want to decide based upon reported, to be published data as has been offered by Ken Myer at CROI? You may

submit a motion we consider Biktarvy in the Vote as a better one pill once per day option than Stribild.

May I suggest we consider voting on one preferred option and one alternative option. For the alternative option, we can add Biktarvy for consideration and vote. Since time is important and voting is to start today, I will present the options in this way for your vote.

Vote to disseminate later today and thank you all for the discussions. (Beal)

- I would amend my previous vote Biktarvy instead of Stribild As the alternative choice with the dolutegravir based preferred choice being the most cost effective one. (Sension)

On July 20, 2021, Kim Molnar, The AIDS Institute, distributed an email vote asking members to select one preferred regimen and one alternative regimen from the list below by the established deadline of July 23, 2021.

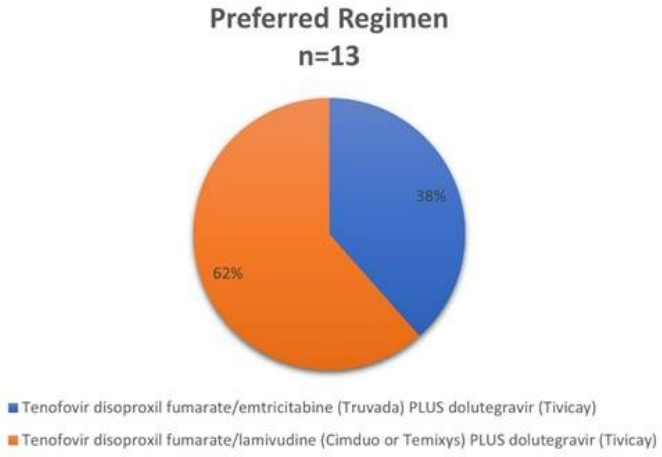
DRAFTNonoccupational Postexposure Prophylaxis (nPEP) Formulary ***DRAFT***	
Preferred	
Option 1	Tenofovir disoproxil fumarate/emtricitabine (Truvada) **PLUS** dolutegravir (Tivicay)
Option 2	Tenofovir disoproxil fumarate/lamivudine (Cimduo or Temixys) **PLUS** dolutegravir (Tivicay)
Alternative	
Option 1	Tenofovir disoproxil fumarate/emtricitabine (Truvada) **PLUS** darunavir (Prezista) **PLUS** ritonavir (Norvir)
Option 2	Tenofovir disoproxil fumarate/lamivudine (Cimduo or Temixys) **PLUS** darunavir (Prezista) **PLUS** ritonavir (Norvir)
Option 3	Elvitegravir/cobicistat/tenofovir alafenamide/emtricitabine (Genvoya)
Option 4	Bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy)

Additional information on Biktarvy was provided to members on July 21, 2021.

The results from the vote are listed below:

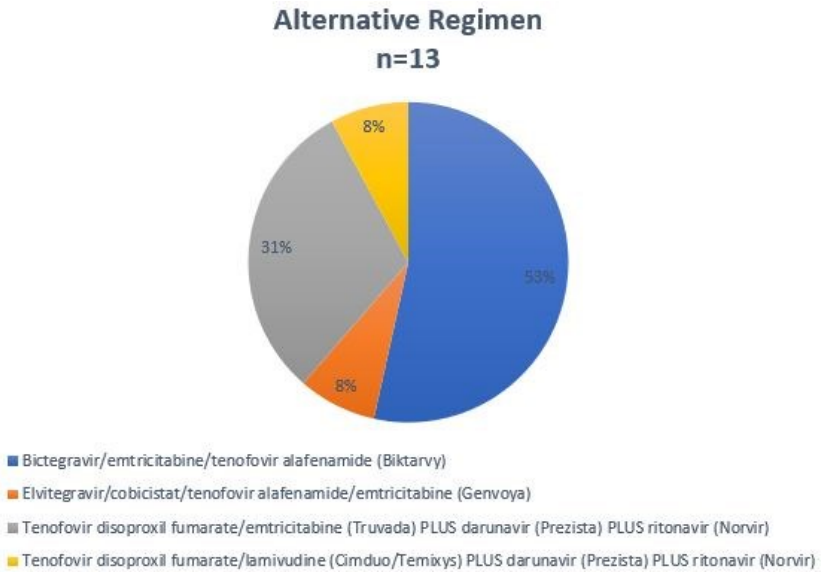
Preferred Regimen

- 62% - Tenofovir disoproxil fumarate/lamivudine (Cimduo or Temixys) PLUS dolutegravir (Tivicay)
- 38% - Tenofovir disoproxil fumarate/emtricitabine (Truvada) PLUS dolutegravir (Tivicay)



Alternative Regimen

- 53% - Bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy)
- 31% - Tenofovir disoproxil fumarate/emtricitabine (Truvada) PLUS darunavir (Prezista) PLUS ritonavir (Norvir)
- 8% - Elvitegravir/cobicistat/tenofovir alafenamide/emtricitabine (Genvoya)
- 8% - Tenofovir disoproxil fumarate/lamivudine (Cimduo/Temixys) PLUS darunavir (Prezista) PLUS ritonavir (Norvir)



In summary, the Workgroup recommended Tenofovir disoproxil fumarate/lamivudine (Cimduo or Temixys) PLUS dolutegravir (Tivicay) as the **preferred** nPEP regimen and Bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy) as an **alternative** nPEP regimen.

The Workgroup's recommendations were forwarded to the Co-Chairs on July 27, 2021.

HIV Section Medication Formulary Workgroup (HSMFW)
Summary of Vote on November 2021 Action Items

On November 15, 2021, HIV Section Medication Formulary Workgroup Co-Chairs, Jeffrey Beal and Joanne Urban, initiated, via email, a vote asking members of the HIV Section Medication Formulary Workgroup (HSMFW) to review medications for consideration for addition to the ADAP Formulary – November 2021.

ADAP Formulary Additions

Note: If recommended for addition and approved by HIV/AIDS Section administration, all brands, dosage forms, and strengths will be added to the Formulary unless any specific brands or forms are not recommended by the HSMFW or if fiscal or programmatic constraints prevent addition of specific dosage forms or brands.

Drugs from the Part A Most Expensive and/or Most Commonly Prescribed Drug Lists

Amylase, lipase, protease

- **Description:** pancreatic enzyme replacement
- **Indication(s):** pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis or other conditions
- **Place in therapy (including guidelines recommendations if applicable):** vary products, which are not interchangeable, are available. Dosing is individualized based on patient symptoms.
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (yes)
- **PAP availability:** yes

Brexpiprazole

- **Description:** Atypical antipsychotic
- **Indication(s):** Major depressive disorder (in combination with antidepressants) and schizophrenia
- **Place in therapy (including guidelines recommendations if applicable):** Recommended option for adjunctive treatment of depression (along with antidepressants) or and schizophrenia
- **Potential interaction with ARVs:** Metabolized by CYP 3A4 and 2D6, PIs and cobicistat may increase levels
- **Coverage on other formularies:**
  - Florida Medicaid (_no_), Florida Blue (_yes_)
- **PAP availability:** yes

Carbamazepine

Note: The preliminary recommendation provided for this drug was to NOT add it to the ADAP formulary due to concerns about interactions with most ARVs.

- **Description:** Anticonvulsant
- **Indication(s):** bipolar disorder, epilepsy, trigeminal neuralgia
- **Place in therapy (including guidelines recommendations if applicable):** Recommended option for treatment of acute manic and mixed episodes of bipolar disorder, epilepsy (partial or generalized seizures), trigeminal neuralgia
- **Potential interaction with ARVs:** Potent CYP3A4 inducer and not recommended for use with most ART (i.e., PIs, NNRTIs, TAF, Biktarvy)
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** yes

Cefixime

- **Description:** Cephalosporin antibiotic
- **Indication(s):** Bacterial infections including acute exacerbation of chronic obstructed pulmonary disease, gonorrhea, otitis media, pharyngitis, urinary tract infection
- **Place in therapy (including guidelines recommendations if applicable):** Alternative option for treatment of gonorrhea https://www.cdc.gov/std/treatment-guidelines/gonorrhea-adults.htm
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Chlorhexidine gluconate

- **Description:** Topical/oral anti-infective
- **Indication(s):** Oral (gingivitis and periodontitis), topical (skin cleansing)
- **Place in therapy (including guidelines recommendations if applicable):** Topical chlorhexidine considered to be one of the most effective and safest topical antiseptics. Oral chlorhexidine mouth rinse is effective in decreasing formation of plaque and controlling gingivitis.
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Diclofenac

- **Description:** Non-steroidal anti-inflammatory drug (NSAIDS)
- **Indication(s):** Pain including osteoarthritis, rheumatoid arthritis, dental pain and migraines, eye pain (ophthalmic formulation)
- **Place in therapy (including guidelines recommendations if applicable):** Various guidelines recommend NSAIDS as options for pain management.
- **Potential interaction with ARVs:** NSAIDs may increase the risk of kidney failure in patients taking tenofovir disoproxil fumarate
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Dorzolamide/timolol

- **Description:** ***Ophthalmic Carbonic anhydrase inhibitor, beta-blocker***
- **Indication(s):** Ocular hypertension, open angle glaucoma
- **Place in therapy (including guidelines recommendations if applicable):** Beta-blockers (e.g., timolol) are considered to be first line for treatment of open angle glaucoma and a second agent (e.g., Carbonic anhydrase inhibitor such as dorzolamide) is added if control is not achieved with beta-blocker alone.
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
    - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Doxycycline

Note: A provider also recently submitted an ADAP Formulary addition request for doxycycline.

- **Description:** Tetracycline antibiotic
- **Indication(s): Various infections including chlamydia, gonorrhea, atypical pneumonia, skin infections, sinusitis, syphilis (when penicillin allergy)**
- **Place in therapy (including guidelines recommendations if applicable):** Recommended in various guidelines including sexually transmitted infections https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf and skin/soft tissue infections. https://www.idsociety.org/practice-guideline/skin-and-soft-tissue-infections/
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
    - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Fluticasone

- **Description:** Corticosteroid
- **Indication(s):** Allergic rhinitis, asthma, atopic dermatitis
- **Place in therapy (including guidelines recommendations if applicable):** Oral inhaled corticosteroid are recommended to control asthma symptoms. Asthma treatment guidelines https://www.nhlbi.nih.gov/files/docs/guidelines/asthma_qrg.pdf. Allergic rhinitis treatment review https://www.aafp.org/afp/2010/0615/p1440.html.
- **Potential interaction with ARVs:** Fluticasone levels may be increased by PIs and elvitegravir/cobicistat (combination not recommended)
- **Coverage on other formularies:**
    - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Hydrocortisone

- **Description:** Adrenal corticosteroid
- **Indication(s):** Indicated to treat a variety of conditions due to anti-pruritic, anti-inflammatory, vasoconstricting and salt-retention properties.

- **Place in therapy (including guidelines recommendations if applicable):** Oral, topical and injectable formulations available and selection depends on conditions being treated. Topical formulations are most commonly used.
- **Potential interaction with ARVs:** PIs and cobicistat may increase levels of injectable and oral formulations
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Ivabradine

- **Description:** Hyperpolarization-activated cyclic nucleotide-gated channel blocker
- **Indication(s):** Chronic heart failure
- **Place in therapy (including guidelines recommendations if applicable):** Treatment of chronic heart failure in patients with ejection fraction of 35% or less who are on maximally tolerable beta-blacker doses or in patients who have a contraindication to beta-blocker use.
- **Potential interaction with ARVs:** Contraindicated with PIs and Elvitegravir/cobicistat since ivabradine levels are expected to be increased.
- **Coverage on other formularies:**
  - Florida Medicaid (_no_), Florida Blue (_yes_)
- **PAP availability:** yes

Ivermectin

Note: One or more members brought up concerns about the use of this drug for the treatment of COVID-19 infection since this is NOT a recommended treatment. If added, some members propose having a prior authorization requirement.

- **Description:** Antiparasitic agent
- **Indication(s):** Treatment of various parasitic infections including cutaneous larva migrans, enterobiasis, strongyloidiasis, and scabies
- **Place in therapy (including guidelines recommendations if applicable):** Alternative option for the treatment of pediculosis pubis and scabies. https://www.cdc.gov/std/treatment-guidelines/ectoparasitic.htm. **Note:** Ivermectin has been used for the treatment of COVID-19 infection although data do not support its use. The Infectious Diseases Society of America (IDSA) and Food and Drug Administration (FDA) recommend against its use for COVID 19 infection outside of a clinical trial. See https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/ and https://www.fda.gov/animal-veterinary/product-safety-information/fda-letter-stakeholders-do-not-use-ivermectin-intended-animals-treatment-covid-19-humans.
- **Potential interactions with ARVs:** Levels may be increased by PIs and cobicistat (not expected to be clinically significant when ivermectin is used as a single dose for its approved indications.
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** yes

Lansoprazole

- **Description:** Proton pump inhibitor (PPI)
- **Indication(s):** Ulcers, esophagitis, gastroesophageal reflux disease, heartburn
- **Place in therapy (including guidelines recommendations if applicable):** PPIs are recommended for severe gastroesophageal reflux disease
- **Potential interaction with ARVs:** Cannot be used with oral rilpivirine or atazanavir
- **Coverage on other formularies:**
    - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** yes

Lidocaine

- **Description:** Anesthetic
- **Indication(s):** Anesthesia of mucous membranes, oropharynx (viscous lidocaine), local anesthesia to the skin, postherpetic neuralgia, diabetic neuropathy, ventricular arrhythmias
- **Place in therapy (including guidelines recommendations if applicable):** Patch formulation used for pain (e.g., post-herpetic neuralgia and diabetic neuropathy), various dosage forms used for anesthesia
- **Potential interaction with ARVs:** Levels may be increased by PIs and cobicistat (more potential concern for systemic administration)
- **Coverage on other formularies:**
    - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Lurasidone

- **Description:** Atypical antipsychotic
- **Indication(s):** Bipolar depression, schizophrenia
- **Place in therapy (including guidelines recommendations if applicable):** Can be used as monotherapy or adjunctive therapy for the treatment of depressive episodes in patients with bipolar disorder. Recommended option for treatment of schizophrenia.
- **Potential interaction with ARVs:** Metabolized by CYP 3A4, PIs and cobicistat may increase levels
- **Coverage on other formularies:**
    - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** yes

Mesalamine

- **Description:** 5-aminosalicylate
- **Indication(s):** Ulcerative colitis, ulcerative proctitis
- **Place in therapy (including guidelines recommendations if applicable):** Recommended option for patients with less severe ulcerative colitis. https://www.gastrojournal.org/article/S0016-5085(20)30018-4/fulltext
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
    - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** yes

Mometasone

- **Description:** Corticosteroid
- **Indication(s):** Allergic rhinitis, asthma, inflammatory hyperkeratotic dermatosis
- **Place in therapy (including guidelines recommendations if applicable):** Oral inhaled corticosteroid are recommended to control asthma symptoms. Asthma treatment guidelines https://www.nhlbi.nih.gov/files/docs/guidelines/asthma_qrg.pdf. Allergic rhinitis treatment review https://www.aafp.org/afp/2010/0615/p1440.html.
- **Potential interaction with ARVs:** Mometasone levels may be increased by PIs and elvitegravir/cobicistat (combination not recommended)
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** yes

Morphine

Note: One or more members brought up concerns about the high abuse potential for morphine and recommended it not be added to the Florida ADAP formulary.

- **Description:** Opiate analgesic
- **Indication(s):** Chronic severe or intractable pain, moderate to severe pain not responsive to non-narcotic analgesics
- **Place in therapy (including guidelines recommendations if applicable):** Various guidelines exists regarding use of opioid analgesics in management of chronic non-cancer pain due to opioid epidemic and risk of abuse, overdose, and death. See https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
- **Potential interaction with ARVs:** Levels may be increased by PIs and cobicistat due to p-glycoprotein inhibition
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Naloxone

- **Description: Opioid antagonist**
- **Indication(s):** Suspected or known opiate overdose, reversal of opiate activity/respiratory depression with therapeutic opioid use
- **Place in therapy (including guidelines recommendations if applicable):** Health and Human Services recommends prescribing naloxone to patients at high risk of an opioid overdose. See https://public3.pagefreezer.com/browse/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/about/news/2018/12/19/hhs-recommends-prescribing-or-co-prescribing-naloxone-to-patients-at-high-risk-for-an-opioid-overdose.html
- **Potential interaction with ARVs:** Levels may be decreased by ritonavir-boosted PIs
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Nepafenac

- **Description:** Ophthalmic Non-steroidal anti-inflammatory drug
- **Indication(s):** Eye pain
- **Place in therapy (including guidelines recommendations if applicable):** Indicated for pain following cataract extraction
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
    - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Penicillin

- **Description:** Beta-lactam antibiotic
- **Indication(s):** Variety of infections including syphilis, pharyngitis, pneumonia
- **Place in therapy (including guidelines recommendations if applicable):** Recommended for treatment of all stages of syphilis Recommended in various guidelines including sexually transmitted infections https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf. Guidelines for management of Group A Strep Pharyngitis. https://www.idsociety.org/practice-guideline/streptococcal-pharyngitis/.
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
    - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Polyethylene glycol and electrolyte oral solution

- **Description:** Osmotic laxative
- **Indication(s):** Preparation for barium enema or colonoscopy
- **Place in therapy (including guidelines recommendations if applicable):** Used to cleanse bowel for barium enema, colonoscopy or elective colonic surgery
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
    - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Prazosin

- **Description:** Anti-hypertensive, alpha-blocker
- **Indication(s):** Hypertension
- **Place in therapy (including guidelines recommendations if applicable):** In addition to hypertension, also used to treat benign prostatic hyperplasia and post-traumatic stress disorder.
- **Potential interaction with ARVs:** Levels may be increased by PIs or cobicistat (theoretical, no data)
- **Coverage on other formularies:**
    - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** yes

Sacubitril/valsartan

- **Description:** Neprilysin inhibitor/angiotensin II receptor blocker
- **Indication(s):** Chronic heart failure
- **Place in therapy (including guidelines recommendations if applicable):** Can reduce risk of cardiovascular death and hospitalization in patients with heart failure and left ventricular ejection fraction
- **Potential interaction with ARVs:** Levels may be increased by PIs, start dose low and titrate slowly
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** yes

Temazepam

- **Description:** Benzodiazepine
- **Indication(s):** Short-term treatment of insomnia
- **Place in therapy (including guidelines recommendations if applicable):** Due to high abuse/dependence potential, should only be used for short-term. See American Family Physician review article on management of insomnia. https://www.aafp.org/afp/2017/0701/p29.html
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Tiotropium

- **Description:** Anti-cholinergic (long-acting muscarinic antagonist [LAMA]), oral inhaled
- **Indication(s):** Chronic obstructive pulmonary disease, asthma
- **Place in therapy (including guidelines recommendations if applicable):** Although FDA-approved for asthma, not current in asthma guidelines https://www.nhlbi.nih.gov/files/docs/guidelines/asthma_qrg.pdf. COPD treatment guidelines (https://goldcopd.org/wp-content/uploads/2020/03/GOLD-2020-POCKET-GUIDE-ver1.0_FINAL-WMV.pdf) recommend the use of LAMAs in COPD as they have been shown to improve symptoms, decrease hospitalizations and exacerbations.
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** yes

Travoprost

- **Description:** Ophthalmic prostaglandin
- **Indication(s):** Open angle glaucoma or ocular hypertension
- **Place in therapy (including guidelines recommendations if applicable):** Can be used in combination with other agents (e.g., beta-blocker) or as monotherapy. http://www.icoph.org/downloads/ICOGlaucomaGuidelines.pdf
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**

  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** yes

Tretinoin

- **Description:** Anti-acne retinoid
- **Indication(s):** Acne (also use to treat acute promyelocytic leukemia, oral formulation)
- **Place in therapy (including guidelines recommendations if applicable):** Topical retinoids are a recommended treatment option for acne per guidelines from the American Academy of Dermatology. https://www.jaad.org/article/S0190-9622(15)02614-6/fulltext
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Vitamin B complex

- **Description:** vitamin B supplement, combination of variety of vitamin B types
- **Indication(s): Vitamin B supplementation**
- **Place in therapy (including guidelines recommendations if applicable):** Patients who do not have adequate dietary intake or those with certain conditions (e.g., pregnant or breastfeeding, celiac disease, alcoholism). Vitamin B complex has also been shown to improve symptoms of depression and anxiety. See https://www.healthline.com/nutrition/vitamin-b-complex.
- **Potential interaction with ARVs*:*** none expected
- **Coverage on other formularies:**
  - Florida Medicaid (_no_), Florida Blue (_no_)
- **PAP availability:** no

Vitamin C

- **Description:** vitamin C supplement
- **Indication(s): vitamin C supplementation**
- **Place in therapy (including guidelines recommendations if applicable):** Supplementation in patients who do not get enough vitamin D from dietary sources. https://www.mayoclinic.org/drugs-supplements-vitamin-c/art-20363932
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
  - Florida Medicaid (_no_), Florida Blue (_no_)
- **PAP availability:** no

Opportunistic Infections (OI) Medications

- ***The following drugs were recently recommended by HSMFW for addition to Test and Treat Formulary and these are not currently on the Florida ADAP Formulary***
- **See the Opportunistic Infection Treatment Guidelines for recommendations for use of these agents for treatment of various OIs in patients living with HIV. *https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections***

Amoxicillin

- **Description:** Beta-lactam antibiotic
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Amoxicillin/clavulanate

- **Description:** Beta-lactam antibiotic/beta-lactamase inhibitor
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Ciprofloxacin

- **Description:** Quinolone antibiotic
- **Potential interaction with ARVs:** Risk of QT prolongation with some ARVs.
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Famciclovir

- **Description:** Antiviral
- **Potential interaction with ARVs:** none expected
- **Coverage on other formularies:**
  - Florida Medicaid (_no_), Florida Blue (_yes_)
- **PAP availability:** no

Levofloxacin

- **Description:** Quinolone antibiotic
- **Potential interaction with ARVs:** Risk of QT prolongation with some ARVs.
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Moxifloxacin

- **Description:** Quinolone antibiotic
- **Potential interaction with ARVs:** Levels may be decreased by ritonavir. Risk of QT prolongation with certain ARVs.
- **Coverage on other formularies:**
  - Florida Medicaid (_yes_), Florida Blue (_yes_)
- **PAP availability:** no

Rifapentine

- **Description:** Antimycobacterial
- **Potential interaction with ARVs:** Only recommended for treatment of latent tuberculosis infection (LTBI) due to drug interactions with ARVs. May decrease levels of PIs, some NNRTIs and TAF.
- **Coverage on other formularies:**
  - Florida Medicaid (_no_), Florida Blue (_no_)
- **PAP availability:** yes

Voriconazole

Note: A provider also submitted an ADAP Formulary addition request for voriconazole.

- **Description:** Azole antifungal agent
- **Potential interaction with ARVs:** Interacts with PIs and cobicistat, dosage adjustments may be necessary
- **Coverage on other formularies:**
  - Florida Medicaid (_no_), Florida Blue (_yes_)
- **PAP availability:** yes

VOTING RESULTS:

Do you approve the Summary of Vote on October Action Items and LPAP High-Use/High-Cost Medication Review Discussion?		
	Response Percent	Response Count
Yes	100.00%	8
No	0.00%	0

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 Percent	Response Count
amylase, lipase, protease	100.00%	8	0.00%	0	0.00%	0
brexpiprazole	87.50%	7	12.50%	1	0.00%	0
carbamazepine (Note: The preliminary recommendation provided for this drug was to NOT add it to the ADAP formulary due to concerns about interactions with most ARVs.)	12.50%	1	62.50%	5	25.00%	2
cefixime	100.00%	8	0.00%	0	0.00%	0
chlorhexidine gluconate	100.00%	8	0.00%	0	0.00%	0
diclofenac	100.00%	8	0.00%	0	0.00%	0
dorzolamide/timolol	100.00%	8	0.00%	0	0.00%	0
doxycycline (Note: A provider also recently submitted an ADAP Formulary addition request for doxycycline.)	100.00%	8	0.00%	0	0.00%	0
fluticasone	100.00%	8	0.00%	0	0.00%	0
hydrocortisone	100.00%	8	0.00%	0	0.00%	0
ivabradine	100.00%	8	0.00%	0	0.00%	0
ivermectin (Note: One or more members brought up concerns about the use of this drug for the treatment of COVID-19 infection since this is NOT a recommended treatment. If added, some members propose having a prior authorization requirement.)	12.50%	1	75.00%	6	12.50%	1
lansoprazole	100.00%	8	0.00%	0	0.00%	0
lidocaine	100.00%	8	0.00%	0	0.00%	0
lurasidone	100.00%	8	0.00%	0	0.00%	0
mesalamine	100.00%	8	0.00%	0	0.00%	0
mometasone	100.00%	7	0.00%	0	0.00%	0

morphine (Note: One or more members brought up concerns about the high abuse potential for morphine and recommended it not be added to the Florida ADAP formulary.)	12.50%	1	75.00%	6	12.50%	1
naloxone	87.50%	7	12.50%	1	0.00%	0
nepafenac	87.50%	7	12.50%	1	0.00%	0
penicillin	100.00%	8	0.00%	0	0.00%	0
polyethylene glycol and electrolyte oral solution	100.00%	8	0.00%	0	0.00%	0
prazosin	75.00%	6	25.00%	2	0.00%	0
sacubitril/valsartan	100.00%	8	0.00%	0	0.00%	0
temazepam	100.00%	8	0.00%	0	0.00%	0
tiotropium	100.00%	8	0.00%	0	0.00%	0
travoprost	100.00%	8	0.00%	0	0.00%	0
tretinoin	87.50%	7	12.50%	1	0.00%	0
vitamin B complex	100.00%	8	0.00%	0	0.00%	0
vitamin C	100.00%	8	0.00%	0	0.00%	0

Please list any drug(s) mentioned above for which you recommend restriction on use (e.g., prior authorization) below:
• Prior authorization for ivermectin • ivermectin • ivermectin and morphine • I would ask for a prior authorization for the morphine and the ivermectin if they are placed on the formulary.

The following drugs were recently recommended by HSMFW for addition to Test and Treat Formulary and are not currently on the Florida ADAP Formulary. Please indicate whether you recommend for addition to the Florida ADAP Formulary as well.						
	Yes		No		Abstain	
	Response Percent	Response Count	Response Percent	Response Count	Response Percent	Response Count
amoxicillin	100.00%	8	0.00%	0	0.00%	0
amoxicillin/clavulanate	100.00%	8	0.00%	0	0.00%	0
ciprofloxacin	100.00%	8	0.00%	0	0.00%	0
famciclovir	87.50%	7	12.50%	1	0.00%	0
levofloxacin	100.00%	8	0.00%	0	0.00%	0
moxifloxacin	87.50%	7	12.50%	1	0.00%	0
rifapentine	75.00%	6	12.50%	1	12.50%	1
voriconazole (Note: A provider also submitted an ADAP Formulary addition request for voriconazole.)	75.00%	6	12.50%	1	12.50%	1

SUMMARY

There are a total of 13 voting members on the HIV/AIDS Section Medication Formulary Workgroup. For a workgroup vote to pass, there must be a 50% +1 majority to pass . At least 50% of voting members must respond in order for a vote to be considered valid. The highlighted items above were not approved by the group. A summary of results follows:

- Summary of Vote on October Action Items and LPAP High-Use/High-Cost Medication Review Discussion was passed.
- All the medications from the LPAP High-Use/High-Cost list proposed for recommended addition to the ADAP Formulary were **approved** except for the following:
    - Carbamazepine
    - Ivermectin
    - Morphine

  It should be noted that all comments regarding the restricted use of medications corresponded to the medications that were not recommended for approval.
- All medications recently recommended for addition to the Test and Treat Formulary were recommended for addition to the ADAP formulary.

HIV Section Medication Formulary Workgroup (HSMFW)
Email Vote on March 2022 Action Items

On February 8, 2022, HIV Section Medication Formulary Workgroup Co-Chairs, Jeffrey Beal and Joanne Urban, Co-Chair initiated, via email, a discussion and annual review of the ADAP Formulary, PrEP Formulary, and Test and Treat Formulary. Members were asked to participate in a dialogue related to recommended additions and deletions to each formulary.

The following summarizes the medications being considered and feedback that was provided:

ADAP Formulary

Note: ADAP will determine the fiscal and programmatic feasibility of adding any drugs recommended by HSMFW to the ADAP formulary.

Mupirocin

- **Description:** Topical antibacterial agent
- **Indication(s):** Treatment of skin infections, methicillin-resistant S. aureus nasal carriage eradication
- **Place in therapy (including guidelines recommendations if applicable):** https://www.idsociety.org/practice-guideline/skin-and-soft-tissue-infections/
- **Potential interaction with ARVs:** No significant interactions expected
- **Coverage on other formularies:**
  - **Florida Medicaid (Y)**
- **PAP availability:** No

Permethrin

- **Description:** Topical anti-infective, scabicide
- **Indication(s):** Treatment of scabies and pediculosis
- **Place in therapy (including guidelines recommendations if applicable):** https://www.cdc.gov/std/treatment-guidelines/ectoparasitic.htm
- **Potential interaction with ARVs:**
- **Coverage on other formularies:**
  - **Florida Medicaid (_Y_)**
- **PAP availability:** No

Modafinil

- **Description:** Central nervous system stimulant
- **Indication(s):** Treatment of narcolepsy, obstructive sleep apnea, shift work sleep disorder
- **Place in therapy (including guidelines recommendations if applicable):** Guidelines from the American Academy of Sleep Medicine include modafinil as a recommended option for the

treatment of a variety of hypersomnolence disorders including narcolepsy, idiopathic hypersomnia and post-traumatic hypersomnia
https://jcsm.aasm.org/doi/pdf/10.5664/jcsm.9328

- **Potential interaction with ARVs:** Drugs that inhibit CYP3A4 (e.g., protease inhibitors, cobicistat) may increase modafinil levels; however, 3A4 is a minor part of modafinil metabolism.
- **Coverage on other formularies:**
  - **Florida Medicaid** (_Y_)
- **PAP availability:** No

Carboxymethylcellulose sodium

- **Description:** Lubricant eye drops or gel
- **Indication(s):** Relief of dry eyes and irritation
- **Place in therapy (including guidelines recommendations if applicable): N/A**
- **Potential interaction with ARVs:** No significant interactions expected
- **Coverage on other formularies:**
  - **Florida Medicaid (_N_)**
- **PAP availability:** No

Midodrine

- **Description:** Vasopressor
- **Indication(s):** Treatment of orthostatic hypotension, cirrhotic ascites with hypotension, postural tachycardia syndrome.
- **Place in therapy (including guidelines recommendations if applicable):** N/A
- **Potential interaction with ARVs:** No significant interactions expected
- **Coverage on other formularies:**
  - **Florida Medicaid (_Y_)**
- **PAP availability:** No

Carbamide peroxide

- **Description:** Ear wax removal agent
- **Indication(s):** Cerumen (ear wax) removal (Note: there is also an oral formulation uses for gum or mucosal surface irritation.)
- **Place in therapy (including guidelines recommendations if applicable):** N/A
- **Potential interaction with ARVs:** None expected
- **Coverage on other formularies:**
  - **Florida Medicaid (_N_)**
- **PAP availability:** No

Loteprednol etabonate

- **Description:** Ophthalmic corticosteroid
- **Indication(s):** Treatment of steroid responsive ophthalmic conditions such as conjunctivitis, uveitis, post-operative ocular inflammation, allergic rhinitis.
- **Place in therapy (including guidelines recommendations if applicable):** Lower potential to increase intraocular pressure compared to prednisolone. Used as an alternative in treatment of uveitis since not as potent/effective as prednisolone.
- **Potential interaction with ARVs:** No significant interactions expected

- **Coverage on other formularies:**
  - **Florida Medicaid (_Y_)**
- **PAP availability:** No

Prednisolone

- **Description:** Ophthalmic corticosteroid
- **Indication(s):** Treatment of steroid responsive ophthalmic conditions such as conjunctivitis, uveitis, post-operative ocular inflammation, allergic rhinitis.
- **Place in therapy (including guidelines recommendations if applicable):**
- **Potential interaction with ARVs**: No significant interactions expected
- **Coverage on other formularies:**
  - **Florida Medicaid (_Y_)**
- **PAP availability:** No

Avena sativa (Eucerin)

- **Description:** Topical humectant
- **Indication(s):** Treatment of dry skin
- **Place in therapy (including guidelines recommendations if applicable): N/A**
- **Potential interaction with ARVs**: No significant interactions expected
- **Coverage on other formularies:**
  - **Florida Medicaid (_N_)**
- **PAP availability:** No

Cariprazine

- **Description:** Atypical antipsychotic
- **Indication(s):** Treatment of schizophrenia, bipolar disorder
- **Place in therapy (including guidelines recommendations if applicable):**
- **Potential interaction with ARVs:** Levels may be increased by protease inhibitors and cobicistat. Dosage reduction is necessary.
- **Coverage on other formularies:**
  - **Florida Medicaid (_Y_)**
- **PAP availability:** Yes

Note: This drug has identified by the program as high cost. If the drug is added to the Formulary, a prior authorization may be required.

Sildenafil, tadalafil, vardenafil

- **Description:** Phophodiesterase inhibitor
- **Indication(s):** Treatment of erectile dysfunction or pulmonary hypertension
- **Place in therapy (including guidelines recommendations if applicable):**
  https://www.auanet.org/guidelines/guidelines/erectile-dysfunction-(ed)-guideline
- **Potential interaction with ARVs:** Levels may be increased by protease inhibitors or cobicistat; dosage reduction is necessary.
- **Coverage on other formularies:**
  - **Florida Medicaid (_Y_)-For pulmonary hypertension (PA required)**
- **PAP availability:** No

NOTE: We received notice that there is no restriction from HRSA on adding agents for treatment of erectile dysfunction.

Contraceptives Currently on the Department of Health Family Planning Formulary(including tablets, subcutaneous implants, intrauterine devices, vaginal insert)

norethindrone/ethinyl estradiol	norethindrone
copper IUD	norethindrone/ethinyl estradiol
desogestrel/ethinyl estradiol	norethindrone/ethinyl estradiol
etonogesterol/ethinyl estradiol	norethindrone/ethinyl estradiol/ferrous fumarate
etonogestrel	norgestimate/ethinyl estradiol
levonorgestrel	norgestrel/ethinyl estradiol
levonorgestrel/ethinyl estradiol	

Note: Some of these products are not available to order through the wholesaler (e.g., copper IUD, etonogestrel implant). If these are recommended for addition, the program will need to determine how/if the products can be made available through ADAP.

Pneumococcal conjugate vaccine 15-valent and Pneumococcal conjugate vaccine 20-valent

Feedback
I do think PPV 15 followed by PPV 23 is a better option for HIV+ individuals over single dose PPV 20. Perhaps that can come as guidance/suggestion. (Sension)
Regarding the pneumococcal vaccine—after careful reading of the CDC guidance, the article in this month's Annals of Internal Medicine, and playing around with the CDC pneumonia vaccine app, it looks like either PCV 15 followed by PPSV23 **OR** PCV20 is recommended for PWH. However, we can expect that this may change with more clinical data. We should probably authorize both PCV15 and PCV20. This is going to be really confusing for providers and patients alike until there is more data. (Appelbaum)
As far as the pneumonia vaccines, I feel both should be approved while I would likely recommend the 15 and then the 20 today, ACIP does recommend both, so I feel both are appropriate. (Levin)

- **Description:** Bacterial vaccine (conjugate)
- **Indication(s):** Prevention of pneumococcal disease
- **Place in therapy (including guidelines recommendations if applicable):** The Advisory Committee on Immunization Practices of the CDC recommends either the use of PCV 15 followed by pneumococcal polysaccharide 23 valent (PPSV 23) or PCV 20. **https://www.cdc.gov/mmwr/volumes/71/wr/mm7104a1.htm?s_cid=mm7104a1_w**
    - No data for PCV 20 in immunocompromised patients but offers 1 dose vaccine option
    - PCV 15 followed by PPSV 23 increasing coverage (12% more of the serotypes causing invasive pneumococcal disease in immunocompromised adults)

  - See slide 48 in https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/02-Pneumococcal-Kobayashi-508.pdf

Potential interaction with ARVs: None expected.

- **Coverage on other formularies:**
  - **Florida Medicaid (_?_)-Medicaid formulary does not list covered vaccines**
- **PAP availability:** No

Pioglitazone

Feedback
Pioglitazone is definitely not my first choice for diabetes as it causes weight gain/fluid retention as well as impacting bones and exacerbating already existing HF so with other agents such as GLP 1 RA and SGLT2i that were approved previously, I definitely wouldn't go this route for diabetes. However, Joanne and I had spoken that a provider was requesting it for NAFLD, which it can be used for so I suppose it light of that, it's ok; however, I would not recommend it to my providers for diabetes. (Levin)

- **Description:** Thiazolidinedione (glitazone, TZD) antidiabetic agent
- **Indication(s):** Treatment of type 2 diabetes, also studied for management of nonalcoholic fatty liver disease.
- **Place in therapy (including guidelines recommendations if applicable):** Primarily only used in Type 2 diabetes when cost or access to other agents is an issue. Use with caution in patients with cardiac disease as TZDs may increase risk of congestive heart failure. https://diabetesjournals.org/care/article/44/Supplement_1/S111/31020/9-Pharmacologic-Approaches-to-Glycemic-Treatment
- **Potential interaction with ARVs:**
- **Coverage on other formularies:**
  - **Florida Medicaid (_Y_)**
- **PAP availability:** No

****Option: Pioglitazone use in ADAP can be restricted to HIV associated NAFLD.**

<u>Cardiovascular agents</u>

Feedback
I think having additional ARBs (irbesartan, valsartan, Olmesartan) are good options as losartan has been on back order and is the least potent ARB. Whether or not they all need to be on there is a different story. All are equipotent, dosed once daily, and indicated in hypertension and heart failure but for options, we can include them. Clonidine and hydralazine are also good options to have. While they are generally last line for hypertension, sometimes they are needed (especially hydralazine in dialysis patients) so I do recommend them both as well as the vasodilators. (Levin)

Clonidine

- **Description:** Centrally acting alpha 2 agonist
- **Indication(s):** Hypertension (also has been used to treat ADHD in children)

- **Place in therapy (including guidelines recommendations if applicable):** Usually used to treat hypertension that is refractory to treatment with other medications. https://www.ahajournals.org/doi/10.1161/HYP.0000000000000065
- **Potential interaction with ARVs:** No significant interactions expected
- **Coverage on other formularies:**
  - **Florida Medicaid (_Y_)**
- **PAP availability:** No

Hydralazine

- **Description:** Peripheral vasodilator
- **Indication(s):** Hypertension, congestive heart failure
- **Place in therapy (including guidelines recommendations if applicable):** Not used first-line. For heart failure, can be used in combination with nitrates if patients cannot take ACE inhibitor or angiotensin receptor blocker. https://www.ahajournals.org/doi/10.1161/HYP.0000000000000065 https://www.ahajournals.org/doi/epub/10.1161/CIR.0000000000000509
- **Potential interaction with ARVs:** No significant interactions expected
- **Coverage on other formularies:**
  - **Florida Medicaid (_Y_)**
- **PAP availability:** No

Irbesartan, olmesartan, valsartan

- **Description:** Angiotensin receptor II blockers (ARBs)
- **Indication(s):** Hypertension, heart failure
- **Place in therapy (including guidelines recommendations if applicable):** First-line option for treatment of hypertension (renal protective in patients with microalbuminuria), part of first-line therapy in patients with heart failure. https://www.ahajournals.org/doi/10.1161/HYP.0000000000000065 https://www.ahajournals.org/doi/epub/10.1161/CIR.0000000000000509
- **Potential interaction with ARVs:** Cobicistat may increase levels of valsartan, start with low dose and monitor; no significant interactions expected with other ARVs or with other ARBs
- **Coverage on other formularies:**
  - **Florida Medicaid (_Y_)**
- **PAP availability:** No

NOTE: If these drugs are recommended for addition, we will also request to add the combination products of irbesartan/hydrochlorothiazide, olmesartan/hydrochlorothiazide, valsartan/hydrochlorothiazide if fiscally feasible.

Isosorbide dinitrate, isosorbide mononitrate, nitroglycerin

- **Description: Vasodilators**
- **Indication(s):** Treatment of acute (nasal and sublingual) and chronic angina pectoris
- **Place in therapy (including guidelines recommendations if applicable):** Sublingual and intranasal formulations are used in treatment of acute angina and other formulations can be used in chronic angina, usually in combination with beta-blockers in patients who have exertional angina
- **Potential interaction with ARVs:** No significant interactions expected

- **Coverage on other formularies:**
  - **Florida Medicaid (_Y_)**
- **PAP availability:** No

Phentermine/topiramate

Feedback
I understand that ART can cause metabolic syndrome and weight gain, but I have reservations about adding weight loss medications to the formulary when diet and exercise would generally fix this. As a clinician, I worry that we are sending the wrong message about "quick fixes" rather than taking personal responsibility for one's health. (Carscallen)
I am also opposed to adding phertermine when there are better drugs for weight loss (such as GLP1 agonist). What position do we as an advisory group take on some of these medications? (Appelbaum)
I agree with Dr. Applebaum regarding the phentermine/topiramate combo as we have approved GLP 1 RA that are safer and effective. (Levin)

- **Description**: Sympathomimetic amine (phentermine) and anti-epileptic (topiramate)
- **Indication(s):** Treatment of obesity and chronic weight management
- **Place in therapy (including guidelines recommendations if applicable):** The American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity include naltrexone/bupropion, orlistat, phentermine/topiramate, and liraglutide as pharmacologic options for the treatment of obesity. The choice among the agents depends on patient characteristics and co-morbid conditions. See Table 11 in https://www.sciencedirect.com/science/article/pii/S1530891X20446300?via%3Dihub.
- **Potential interaction with ARVs:** No significant interactions expected
- **Coverage on other formularies:**
  - **Florida Medicaid (_N_)**
- **PAP availability:** No

Note: Provider requested phentermine, but guidelines recommend use of combination product with topiramate as this product can be used longer term and has less potential for side effects and abuse. We reviewed this drug last year and did not recommend addition at that time but there no longer appears to be a PAP available and with this new request and increasing concern for obesity in our patients, this drug is being considered again. This is a viable additional option for patients in need who will not take an injectable medication.

Drugs for Hyperlipidemia

Feedback
The addition of the PCSK9i (evolocumab, alirocumab) are definitely great options; however, as was stated in a previous email, there is a PAP available, and these are costly medications. They are, however, very effective in LDL reduction and have outcomes benefits so on a medication standpoint, I think they are great and would recommend their use. I personally don't feel like incliseran is necessary since other agents have more

outcomes data and results are still pending for this medication and it will also be costly. Bempedoic acid is a tricky one. I feel that ezetimibe is definitely a better option if I were to choose one because it has outcomes data; however, there is definitely substantial lowering with the combination of ezetimibe and bempedoic acid so it could be an option for statin intolerant patients…we are just awaiting outcomes data, but I think it's a good option. (Levin)
alirocumab, evolocumab, inclisiran : These are injectable lipid lowering agents. There is Patient Assistance Program (PAP) availability. B There shouldn't be a need to add to the ADAP Formulary.
At our last HRSA visit, during the ADAP review I specifically asked if we should be putting medications on ADAP that can be obtained through Patient Assistance Programs (PAP). The response was that we needed to consider when directing patients to a PAP the delay in obtaining the needed medication and the additional burden placed on the patient to provide documentation for PAP and appointments with case managers/medical staff to finalize the PAP process, etc. And they advised we consider the additional burden it would place on case managers and/or medical staffs were the process to be access to PAP versus ADAP. I believe all of us can agree PAPs are time consuming for both patients and clinical support staffs. Providing access to as many medications as ADAP can afford, helps to keep patients in care and certainly improves their quality of life. Related to the issue of "HIV relatedness", HRSA did release a clarification basically stating we are expected to use Ryan White funds to provide the primary care needs of our patients. This underinsured population is aging and has a multitude of comorbid conditions which if left unaddressed will certainly increase cost of care down the road. (Beal)

Alirocumab, Evolocumab, Inclisiran

- **Description:** Injectable lipid lowering agents, inhibit proprotein convertase subtilisin/kexin type 9 (PCSK9)
- **Indication(s):** Treatment of heterozygous or homozygous familial hypercholesterolemia or myocardial infarction prophylaxis, stroke prophylaxis, and to reduce risk of unstable angina requiring hospitalization in patients with established cardiovascular disease
- **Place in therapy (including guidelines recommendations if applicable):** Can be considered in combination with maximally tolerated statin therapy in patients who require additional LDL lowering. Ezetimibe is usually added to statin therapy first. See the 2018 ACC/AHA Guideline on Management of Blood Cholesterol at **https://www.jacc.org/guidelines/cholesterol**
- **Potential interaction with ARVs:** No interactions expected
- **Coverage on other formularies:**
  - **Florida Medicaid (_N_)**
- **PAP availability:** Yes

Bempedoic acid

- **Description:** Lipid lowering agent, adenosine triphosphate-citrate lyase (ACL) inhibitor

- **Indication(s):** Treatment of heterozygous familial hypercholesterolemia or established atherosclerosis to reduce LDL cholesterol
- **Place in therapy (including guidelines recommendations if applicable):** Used in combination with maximally tolerated stating therapy. This drug was not available when the ACC/AHA lipid guidelines were last published in 2018 but is listed as an option in the European Society of Cardiology (ESC) and the European Atherosclerosis Society (EAS) Guidelines for management of dyslipidemia. https://www.escardio.org/static-file/Escardio/Guidelines/publications/DYSLIPguidelines-dyslipidemias-FT.pdf
- **Potential interaction with ARVs:** None expected but can interact with pravastatin (max dose 40 mg) and simvastatin (max dose of 20 mg)-increased risk of rhabdomyolysis
- **Coverage on other formularies:**
    - **Florida Medicaid (_N_)**
- **PAP availability:** No

Note: If this drug is recommended for addition, we will also request the addition of the combination product bempedoic acid/ezetimibe if fiscally feasible.

Muscle Relaxants

Feedback
This month we are asked to approve several muscle relaxers. This is a group of medications that again have little clinical data to support their chronic use. Perhaps they are effective in the short term but many of them are prescribed chronically. If we approve them, do we put limits on the duration of use? (Appelbaum)
I would agree that the muscle relaxants should be ordered for short term therapy, but it seems that some Pain Management specialists keep patients on for extended periods of time. My concern is the balance of maintaining the highest quality of life vs inadvertently putting people in harm's way. (Carscallen)
Methocarbamol and metaxalone This is a muscle relaxant. Cyclobenzaprine (muscle relaxant) is already on the ADAP formulary. Is there a need to add another option? Add only if this is a cost effective, better, or necessary treatment option. (Wall/Miami area pharmacists)
Tizanidine (from Krichbaum, Pain Management pharmacy specialist) **Recommendation: Add to Formulary** Reasoning: Currently on formulary there is only 1 agent for muscle spasticity, baclofen. Baclofen is often indicated 1st line for muscle spasticity; however, it requires renal dose adjustment at CrCl <80ml/min, and therefore therapeutic benefit may be unable to achieve in a patient with reduced kidney function. Tizanidine is indicated for muscle spasticity and while primarily renally eliminated, it is not renally dose adjusted until CrCl <25 mL/min. Early comparison studies between tizanidine and baclofen showed less muscle weakness with tizanidine.[1,2] Tizanidine has a different mechanism of action than baclofen for spasticity and therefore can be used as an adjunct in refractory spasticity. Notes: Tizanidine is an alpha 2 agonist and a structural analogue to clonidine so use caution in hypotensive or bradycardic patients. Tizanidine also causes more sedation than baclofen, so use with caution in the elderly or with other CNS depressants. 1. Bass, B., et al. "Tizanidine versus baclofen in the treatment of spasticity in patients with multiple sclerosis." *Canadian journal of neurological sciences* 15.1 (1988): 15-19.

2. Groves, L., M. K. Shellenberger, and C. S. Davis. "Tizanidine treatment of spasticity: a meta-analysis of controlled, double-blind, comparative studies with baclofen and diazepam." *Advances in therapy* 15.4 (1998): 241-251.

Methocarbamol & Metaxalone (from Krichbaum, Pain Management pharmacy specialist)
Recommendation: Do not add to formulary
Reasoning: Systematic literature reviews for methocarbamol and metaxalone demonstrate minimal to no benefit vs placebo or other pharmacologic agents such as tizanidine or cyclobenzaprine for skeletal muscle spasms and/or pain.[3] The mechanism of actions for both drugs is unknown but has been shown to have NO direct effect on contractile mechanism of striated muscle, the nerve fiber, or the motor end plate.[4]

3. Chou, Roger, Kim Peterson, and Mark Helfand. "Comparative efficacy and safety of skeletal muscle relaxants for spasticity and musculoskeletal conditions: a systematic review." *Journal of pain and symptom management* 28.2 (2004): 140-175.
4. Metaxalone. In: Lexi-drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed March 2, 2022. Last updated Feb 12, 2022. http://online.lexi.com

Tizanidine

- **Description:** Muscle relaxant
- **Indication(s):** Acute and intermittent management of increased muscle tone associated with spasticity
- **Place in therapy (including guidelines recommendations if applicable):** Option for short-term (e.g., 2 to 3 days) treatment of pain/muscle spasm. Used in combination with other agents such as non-steroidal anti-inflammatory drugs (NSAIDS).
- **Potential interaction with ARVs:** No significant interactions expected
- **Coverage on other formularies:**
    - **Florida Medicaid (_Y_)**
- **PAP availability:** No

Methocarbamol

- **Description:** Muscle relaxant
- **Indication(s):** Treatment of musculoskeletal spasm and/or pain
- **Place in therapy (including guidelines recommendations if applicable):** Option for short-term (e.g., 2 to 3 days) treatment of pain/muscle spasm. Used in combination with other agents such as non-steroidal anti-inflammatory drugs (NSAIDS).
- **Potential interaction with ARVs:** No significant interactions expected
- **Coverage on other formularies:**
    - **Florida Medicaid (_Y_)**
- **PAP availability:** No

Metaxalone

- **Description:** Muscle relaxant
- **Indication(s):** Treatment of muscle pain/spasm
- **Place in therapy (including guidelines recommendations if applicable):** Option for short-term (e.g., 2 to 3 days) treatment of pain/muscle spasm. Used in combination with other agents such as non-steroidal anti-inflammatory drugs (NSAIDS).
- **Potential interaction with ARVs:** No significant interactions expected
- **Coverage on other formularies:**

- **Florida Medicaid (_N_)**

- **PAP availability:** Yes

Opioid Analgesics

Feedback
I also have concerns about the potential issues that can come with the addition of oxycodone. (Sension)
Looks like there are two Schedule II opioid analgesics on the list, oxycodone and tapentadol. I got a bit lost in the CDC guidelines, but did find this interesting article with useful comparisons of clinical and cost factors https://www.aafp.org/afp/2012/0501/p910.html. Looks like Medicaid covers oxy but not tap, which also costs more. For the sake of discussion: What is the current status of this class of drugs on the formulary? Is PA or ongoing usage review programmatically indicated for current sched. II meds or any to be added? If to be added, are both on this list needed on the formulary? (Arons)
Question to you and others; I recently learned of a colleague's metastatic cancer requiring fentanyl patches in addition to other opioids for pain management. Should we be considering additional products to address the specifics of intractable pain? (Arons)
I worry about the opioids and the potential of misuse, redirection for financial profit, and overdose. I would agree that the muscle relaxants should be ordered for short term therapy, but it seems that some Pain Management specialists keep patients on for extended periods of time. My concern is the balance of maintaining the highest quality of life vs inadvertently putting people in harm's way. (Carscallen)
Do share concerns with addition of schedule II opioid analgesics to the formulary (Oxycodone, Tapentadol). Would there be any added restrictions for the use of this class of drugs (pain management specialist)? Would a PA be needed? (Cancel)
Requiring on-going opioid prescriptions be written by pain management specialists would be reasonable. Any exceptions (outside of a malignancy diagnosis) should require a prior authorization. (Appelbaum)
Tramadol: Recommend adding it to the ADAP Formulary for pain. (Wall/Miami area pharmacists)
Tapentadol: This is an opioid analgesic. What is the utilization of this drug? This is not very commonly prescribed. Tapentadol ER is generally not recommended as first or second line therapy due to a high risk for addiction and safety concerns compared to modest pain reduction (Pop-Busui 2017). (Wall/Miami area pharmacists)
I did want to provide some feedback regarding the concern for having CII opioids on the formulary. There are laws that restrict the prescribing and dispensing of these medications (e.g., limitations on days' supply, limitations on who can prescribe). These laws will still apply if the drugs are added to the ADAP formulary. https://flhealthsource.gov/FloridaTakeControl/controlled-substances-bill/ Other formularies such as Medicaid do include some CII medications (e.g., oxycodone, morphine). I recently had an uninsured patient who was being treated for metastatic urethral cancer. He was prescribed oxycodone by his oncologist, but he did not get the medication as it was not on the

ADAP formulary, and he could not afford it. He was new to the RW program and did not understand that there were other resources to help him get this medication. Certainly, the abuse potential for opioids is a concern but we also don't want patients who need them to go without them. (Urban)
Oxycodone (from Krichbaum, Pain Management pharmacy specialist) **Recommendation: Add to Formulary** Reasoning: Opioids are a mainstay of treatment for moderate to severe pain when other options have failed. They are recommended first line in sickle cell disease and pain secondary to cancer. As no opioids exist on the current ADAP formulary, it is reasonable to have an opioid option for patients with moderate to severe pain that have failed multiple analgesic regimens.
Tapentadol (from Krichbaum, Pain Management pharmacy specialist) **Recommendation: Add to Formulary** Reasoning: Tapentadol is a multi-modal opioid. It is a mu opioid receptor agonist providing benefit for moderate to severe nociceptive pain, as well as a norepinephrine reuptake inhibitor providing benefit for neuropathic pain. It has FDA approval for both nociceptive and neuropathic pain and can be an excellent choice in a patient with mixed, refractory pain. Neuropathic pain is especially prevalent in patients living with HIV/AIDS secondary to the pathology of the disease as well as some of the treatments used in its management. Gabapentin is an excellent 1st line option for neuropathic pain, but if patients experience severe, refractory neuropathic pain, tapentadol is a reasonable medication option to add on.
Currently if a PWH has insurance, they can get services of Pain Management inclusive of support for medications prescribed within the formulary of their insurance plan. If they are supported only by Ryan White, Pain Management can be covered by Part A or B and medication payment is out of pocket or supported through a patient assistance program or through Part A or Part B formularies or emergency financial assistance line item. Medication availability on ADAP provides an immediate access for those in need versus patient assistance program or Part A/B support. The discussion so far shows concerns which I feel we all have. Outside of pain management clinics narcotic prescriptions can be for 3 or 7 days. We would expect any prescriptions for chronic pain to come from Pain Management Specialists. Monitoring within the ADAP program is a recommendation HSMFW can make. What monitoring would you advise if these drugs are added? Are there other drugs for pain management not on formulary you would like added? I just checked and realize that Tramadol is not on the ADAP formulary. Make other recommendations please for which you may have a greater comfort level. (Beal)

Oxycodone

- **Description:** Opioid analgesic
- **Indication(s):** Treatment of acute and chronic pain
- **Place in therapy (including guidelines recommendations if applicable):** Short acting formulation can be used for short-term (e.g., usually < 3 days) acute pain that is severe enough to require an opiate. Use of nonopioid analgesics should be maximized. Extended-release formulations should be reserved for patients who experience continuous pain despite the use of immediate release formulation for at least 1 week.
- **Potential interaction with ARVs:** Levels may be increased by protease inhibitors and cobicistat.

- **Coverage on other formularies:**
  - **Florida Medicaid (_Y_)**
- **PAP availability:** No

Tapentadol

- **Description: Opioid analgesic**
- **Indication(s):** Treatment of severe pain
- **Place in therapy (including guidelines recommendations if applicable):** Various guidelines exists regarding use of opioid analgesics in management of chronic non-cancer pain due to opioid epidemic and risk of abuse, overdose, and death. See https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
- **Potential interaction with ARVs: Levels may be increased by atazanavir due to UGT inhibition**
- **Coverage on other formularies:**
  - **Florida Medicaid (_N_)**
- **PAP availability:** No

Tramadol

- **Description: Opioid analgesic**
- **Indication(s):** Treatment of severe pain
- **Place in therapy (including guidelines recommendations if applicable):** Various guidelines exists regarding use of opioid analgesics in management of chronic non-cancer pain due to opioid epidemic and risk of abuse, overdose, and death. See https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
- **Potential interaction with ARVs: Levels may be increased by PIs and cobicistat**
  - **Florida Medicaid (_Y_)**
- **PAP availability:** No

Fentanyl

- **Description: Opioid analgesic**
- **Indication(s):** Treatment of severe pain
- **Place in therapy (including guidelines recommendations if applicable):** Various guidelines exists regarding use of opioid analgesics in management of chronic non-cancer pain due to opioid epidemic and risk of abuse, overdose, and death. See https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
- **Potential interaction with ARVs: Levels may be increased by PIs and cobicistat**
  - **Florida Medicaid (_Y_)**
- **PAP availability:** No

On Friday, March 11, 2022, another email was distributed to HSMFW members. Members were asked to vote on the following items by close of business, Friday, March 18, 2022:

- Approval of the meeting summary from the February 8, 2022, meeting
- Additions to ADAP formulary (based on the discussion above)
- Addition of cabotegravir to the PrEP formulary
- Whether Florida ADAP should consider adopting the Florida Medicaid formulary in the future (if this is recommended, feasibility will be determined and if the program decides to move forward, HSMFW will be called upon to provide feedback on which drugs will need to require a PA)

A summary of votes was shared with the Co-Chairs on March 22, 2022, and are as follows:

Do you approve the Meeting Summary for the HSMFW meeting that took place on February 8, 2022?			
	Response Percent	Response Count	
Yes	100.00%	9	
No	0.00%	0	

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 Percent	Response Count
mupirocin	100.00%	9	0.00%	0	0.00%	0
permethrin	100.00%	9	0.00%	0	0.00%	0
modafinil	77.78%	7	11.11%	1	11.11%	1
carboxymethylcellulose sodium	88.89%	8	0.00%	0	11.11%	1
midodrine	88.89%	8	0.00%	0	11.11%	1
carbamide peroxide	88.89%	8	0.00%	0	11.11%	1

loteprednol etabonate	88.89%	8	0.00%	0	11.11%	1
prednisolone	100.00%	9	0.00%	0	0.00%	0
avena sativa (Eucerin)	88.89%	8	11.11%	1	0.00%	0
cariprazine	77.78%	7	11.11%	1	11.11%	1
sildenafil	88.89%	8	11.11%	1	0.00%	0
tadalafil	88.89%	8	11.11%	1	0.00%	0
vardenafil	77.78%	7	22.22%	2	0.00%	0
Contraceptives currently on the Department of Health Family Planning Formulary (including tablets, subcutaneous implants, intrauterine devices, and vaginal inserts)	77.78%	7	22.22%	2	0.00%	0
Pneumococcal conjugate vaccine 15-valent	100.00%	9	0.00%	0	0.00%	0
Pneumococcal conjugate vaccine 20-valent	100.00%	9	0.00%	0	0.00%	0
pioglitazone	66.67%	6	33.33%	3	0.00%	0
phentermine/topiramate	44.44%	4	44.44%	4	11.11%	1

Cardiovascular Agents						
	Yes		No		Abstain	
	Response Percent	Response Count	Response Percent	Response Count	Response Percent	Response Count
clonidine	88.89%	8	11.11%	1	0.00%	0
hydralazine	88.89%	8	11.11%	1	0.00%	0
irbesartan	88.89%	8	11.11%	1	0.00%	0
olmesartan	88.89%	8	11.11%	1	0.00%	0
valsartan	88.89%	8	11.11%	1	0.00%	0
isosorbide dinitrate	88.89%	8	11.11%	1	0.00%	0
isosorbide mononitrate	88.89%	8	11.11%	1	0.00%	0
nitroglycerin	88.89%	8	11.11%	1	0.00%	0

Please list any drug(s) mentioned above for which you recommend restriction on use (e.g., prior authorization) below:

- Phentermine/topiramate- would suggest requiring a GI recommendation prior to authorization. Would also look for documentation that patient was counseled about a healthy diet (low carb, high protein, vegetables) and exercise. Maybe a dietician consult.

Drugs for Hyperlipidemia						
	Yes		No		Abstain	
	Response Percent	Response Count	Response Percent	Response Count	Response Percent	Response Count
alirocumab	66.67%	6	22.22%	2	11.11%	1
evolocumab	66.67%	6	22.22%	2	11.11%	1
inclisiran	55.56%	5	33.33%	3	11.11%	1
bempedoic acid	66.67%	6	22.22%	2	11.11%	1
Muscle Relaxants						
	Yes		No		Abstain	
	Response Percent	Response Count	Response Percent	Response Count	Response Percent	Response Count
tizanidine	77.78%	7	22.22%	2	0.00%	0
methocarbamol	66.67%	6	33.33%	3	0.00%	0
metaxalone	55.56%	5	33.33%	3	11.11%	1

Opioid Analgesics						
	Yes		No		Abstain	
	Response Percent	Response Count	Response Percent	Response Count	Response Percent	Response Count
oxycodone	44.44%	4	55.56%	5	0.00%	0
tapentadol	55.56%	5	44.44%	4	0.00%	0
tramadol	66.67%	6	33.33%	3	0.00%	0
fentanyl	33.33%	3	55.56%	5	11.11%	1

Please list any drug(s) mentioned above for which you recommend restriction on use (e.g., prior authorization) below:

- all of the new hyperlipidemia drugs, all opioids unless 1. for acute pain (3 days' supply) or 2. malignancy diagnosis"
- I would recommend restriction of the Opioid Analgesic medications to Pain Management or Oncology specialists. As for the muscle relaxants I have seen where several pain management doctors in my area leave patients on the muscle relaxants in conjunction with opioid therapies for chronic pain issues for longer periods of time. There is also substantial literature to suggest that the majority of people living with HIV suffer from myalgias and that this is related to the disease process itself.

Do you recommend the addition of cabotegravir to the PrEP Formulary?		
	Response Percent	Response Count
Yes	88.89%	8
No	11.11%	1
Abstain	0.00%	0

Do you recommend that ADAP mirror the Medicaid Formulary medications applicable to outpatient care?		
	Response Percent	Response Count
Yes	88.89%	8
No	11.11%	1
Abstain	0.00%	0

In summary:

- The meeting summary from the February 8, 2022, HIV Section Medication Formulary Workgroup (HSMFW) was approved
- All recommended additions to the ADAP Formulary were approved with the exception of phentermine/topiramate, oxycodone, and fentanyl
- Cabotegravir was recommended for addition to the PrEP Formulary
- The workgroup voted to recommend that ADAP mirror the Medicaid Formulary medications applicable to outpatient care