

## ADAP Formulary Workgroup

### AGENDA

August 29, 2019 1pm to 2pm (EST)

Please register for the meeting at:

<https://attendee.gotowebinar.com/register/3326196796599385089>

Dial in #: 1-888-670-3525

Conference Code: 633-829-6633

#### Subcommittee-Members:

Jeffrey A. Beal, M.D., AAHIVS Medical Director, HIV/AIDS Section*	Linda Gellatly, APRN, Polk County Health Department
Paul Arons, MD, Medical Consultant*	Ernesto Lamadrid, MD, Primary Care of Gainesville
Michael D'Amico, PharmD, Pharmacy Director, Sarasota CHD	Javier Romero, MD, MPH, ADAP-Miami ADAP Program Manager
Mahesh Amin, Pharmacist, Orange CHD	Elizabeth Sherman, PharmD, Associate Professor, Nova Southeastern University
Ken Bargar, Consumer	Michael Sension, MD, CAN Community Health
David Brakebill, Consumer	Joanne Urban, PharmD, ADAP Clinical Pharmacist*
Jeanette Cancel, MD, Infection Diseases Specialist, AIDS Healthcare Foundation	Daniel T. Wall, Assistant Director Miami-Dade County, Office of Management and Budget
Mike Ehren, PharmD, Pharmacy Director, Broward CHD	Danyelle Williams, PharmD, Pharmacy Director, Bureau of Public Health Pharmacy

\*HIV/AIDS Section, non-voting member

I. Call to order

II. Roll call

III. APPROVAL OF MINUTES FROM NOVEMBER 26, 2018 MEETING

IV. OLD BUSINESS:

a. **Action Items Presented to October 15, 2018 P&T Committee Meeting**

1. Meeting was cancelled due to staff assignments for hurricane Michael relief. Committee planned an email vote.

b. **ADAP Formulary Workgroup Charter**

1. Final charter attached

c. **Drugs recommended for addition to the Formulary during November 26, 2018 meeting**

1. **Drugs added February 15, 2019**

a) Doxazosin (Cardura®, Cardura XL®)

b) Tamsulosin (Flomax®)

c) Finasteride (Proscar®)

d) Doravirine (Pifeltro™)

e) Hepatitis B vaccine, recombinant, adjuvanted (Heplisav-B®)

f) Baloxavir marboxil (Xofluza™)-20 mg 40 mg tablets

g) Ibalizumab (Trogarzo™)-Note: HRSA mandated addition of this drug

1. **Drugs added July 15, 2019**

a) Darunavir 800 mg/cobicistat 150 mg/tenofovir alafenamide 10 mg/  
emtricitabine 200 mg (Symtuza™)

b) Dolutegravir 50 mg/lamivudine 300 mg (Dovato™)

- d. **Drugs recommended for deletion from the Formulary**  
 1. **Removed from the Formulary February 15, 2019**  
 a) Zanamavir (Relenza®)  
 b) Prochlorperazine (Compazine®)

V. **NEW BUSINESS:**

a. **Drugs to consider for addition to the Formulary**

1. Agents for hypercholesterolemia-See 2018 Guidelines on the Management of Blood Cholesterol, A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <https://www.acc.org/latest-in-cardiology/ten-points-to-remember/2018/11/09/14/28/2018-guideline-on-management-of-blood-cholesterol>

- a) Pitavastatin (Zypitamag®, formerly Livalo)-HMG CoA Reductase Inhibitor (aka “statin”)
- Review requested since there is now ADAP negotiated pricing through National Alliance of State and Territorial AIDS Directors (NASTAD)
  - Currently have atorvastatin, pravastatin, rosuvastatin on Formulary.
  - Pitavastatin does not have “high intensity” dosing option. Only atorvastatin and rosuvastatin have
  - Drug interactions: No dosage adjustments needed with ATV, DRV/r, LPV/R. No data with cobicistat boosted PIs or INSTIs (pitavastatin levels may be increased by cobi and decreased by elvitegravir)

**TABLE 3** High-, Moderate-, and Low-Intensity Statin Therapy\*

	High Intensity	Moderate Intensity	Low Intensity
LDL-C lowering†	≥50%	30%–49%	<30%
Statins	Atorvastatin (40 mg‡) 80 mg Rosuvastatin 20 mg (40 mg)	Atorvastatin 10 mg (20 mg) Rosuvastatin (5 mg) 10 mg Simvastatin 20–40 mg§	Simvastatin 10 mg
	...	Pravastatin 40 mg (80 mg) Lovastatin 40 mg (80 mg) Fluvastatin XL 80 mg Fluvastatin 40 mg BID Pitavastatin 1–4 mg	Pravastatin 10–20 mg Lovastatin 20 mg Fluvastatin 20–40 mg

- b) Ezetimibe (Zetia®)-cholesterol absorption inhibitor
- Guidelines recommend ezetimibe be considered for addition to statin therapy if ≥ 50% reduction in LDL is not achieved with statin therapy in patients with atherosclerotic cardiovascular disease (ASCVD) or in very high risk patients whose LDL remains ≥ 70 mg/dL: despite statin therapy.
  - Drug interactions: No significant drug interactions identified with ARVs.

2. Hormonal agents for transgender health

**Guidelines**

1. **UCSF Center of Excellence for Transgender Health**

- **Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People**
  - <http://www.transhealth.ucsf.edu/trans?page=guidelines-feminizing-therapy>
  - <http://www.transhealth.ucsf.edu/trans?page=guidelines-masculinizing-therapy>

2. **Fenway Health**

- **The Medical Care of Transgender Persons**

- <http://www.lgbthealtheducation.org/wp-content/uploads/COM-2245-The-Medical-Care-of-Transgender-Persons.pdf>
- Pages 11-16
- 3. World Professional Association for Transgender Health (WPATH)**
- **Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People**
  - [https://www.wpath.org/media/cms/Documents/SOC%20v7/Standards%20of%20Care\\_V7%20Full%20Book\\_English.pdf](https://www.wpath.org/media/cms/Documents/SOC%20v7/Standards%20of%20Care_V7%20Full%20Book_English.pdf)
  - **Hormone Therapy-pages 33-39**
- 4. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV**
- 5. Considerations for Antiretroviral Use in Special Populations-Transgender People with HIV**
  - <https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf>
- a) Male to Female
  - Estrogen
    - Estradiol (patch, oral)
    - Estradiol cypionate (injection, Depo-estradiol®)
    - Estradiol valerate (injection, Delestrogen®)
  - Anti-androgen
    - Spironolactone (note: also used for hypertension and CHF)
    - Finasteride (note: also used for enlarged prostate, on Florida ADAP Formulary)
  - Progestin
    - Medroxyprogesterone acetate (note: recommended by some to enhance breast enlargement. Injectable only is on Florida ADAP)
- b) Female to Male
  - Testosterone
    - Testosterone topical (gel, patch, solution, e.g., Androgel, Androderm), all are on Florida ADAP Formulary)
    - Testosterone cypionate injection (Depo-testosterone); note: injectable testosterone was removed from ADAP Formulary in January 2017.
      - Providers who gave input stated they use the injectable form.
    - Medroxyprogesterone acetate (note: used to stop menses) oral, Provera; injection, Depo-Provera)

**b. ADAP Formulary Change Request Form (draft attached)**

**VI. PUBLIC COMMENTS**

**VII. ANNOUNCEMENTS:**

- **Next scheduled Statewide P&T Meeting:**
  - **October 21, 2019 (Action items due September 23, 2019)**
  - **January 27, 2020 (Action items due December 30, 2019)**
- **Next meeting AFW will be scheduled for October or November 2019. A poll will be sent out to determine best date/time.**