

AIDS Drug Assistance Program (ADAP) Advisory Committee Meeting Agenda

November 25, 2019

4:00pm-6:00pm, Room 639 for VDH staff

Description & Teleconference Details

Dial In Number: 866-845-1266

Participant Code: 29147038

- **Welcome and Introductions (Dr. Brennan)**

- **Long Acting Antiretrovirals (LA ARVs):**

Background information:

The Antiretroviral Therapy as Long Acting Suppression (ATLAS) study is researching whether HIV type-1 adult subjects who are currently on a viral suppression regimen can remain suppressed when switched to a 2-drug, intramuscular, long-acting regimen of **cabotegravir** and **rilpivirine (Cabenuva)**. Presently, Virginia has 18 clients in the Southwest and Northern regions who are participating in the study. HCS is conducting outreach to providers in the Commonwealth to determine if (and how) many patients they have on Cabenuva.

Cabenuva Presentation (Stephanie Wheawill)

Discussion and issues for consideration (Committee Members):

1. Currently there are clients participating in the ATLAS study. It is our understanding that the pharmaceutical company will continue to provide the medication until it becomes available to clients. What questions do committee members have about continuity of medication access for these patients and the role you think the VA Medication Assistance Program (VA MAP) will need to play?
2. What is the possible future utilization of Long Acting ARVs under VA MAP?
 - Role of Affordable Care Act (ACA) and Medicaid Medallion 4.0 carriers
 - Ryan White coverage of the drug and other services for access and administration
 - Clinical parameters for new patients who will access through VA MAP
 - What would change if VA MAP resources were limited?
 - Medication additions to VA MAP formulary to address side effects of LA ARVs
 - Exploration of provider and patient needs for LA ARVs:
 - Medication Storage and Inventory
 - Who can administer the drugs in clinics and practices?
 - Models for medication delivery to provider sites and procurement issues
 - Provider and patient training needs for Cabenuva

- **Formulary Parameters and Exceptions (Review)**

The following medications have an Exception Form requirement. Do we need to continue to have this requirement?

1. etravirine (Intelence) - NRTI and first line NNRTI (delavirdine, efavirenz, or nevirapine) experienced or contraindicated, with either a detectable viral load or intolerance to current regimen.

2. rilpivirine (Edurant) - Indicated in combination with other ARV agents for the treatment of HIV-1 infection in treatment-naïve patients 12 years of age and older with HIV-1 RNA less than or equal to 100,000 copies/ml. Edurant should not be used in combination with NNRTIs.

Note: rilpivirine (RPV) is in several combo products such as Juluca, Complera, and Odefsey, which do not require an exception.

3. enfuvirtide (Fuzeon) - NRTI and NNRTI experienced or contraindicated, with either a detectable viral load or intolerance to current regimen, and prior experience with one or more PIs.

Note: There has been no utilization by our clients in 5 years. However, this is the only drug in this class on the formulary. Per the Health Resources and Sources Administration (HRSA) guidance, "An ADAP formulary must include at least one drug from each class of HIV ARV medications" (ADAP Manual, 2016 pg. 32).

4. maraviroc (Selzentry) - Requires a blood test that identifies HIV tropism type as CCR5 within 3 months of request

5. voriconazole (VFEND) - Only authorized for fluconazole resistant candidiasis, treatment failure of candidiasis after utilizing itraconazole, and for the treatment of invasive aspergillus.

Note: Parameter originally established due to cost, which is no longer relevant.

6. Human papillomavirus (HPV) - Only authorized for clients with a CD4 count of 200 or more and used as indicated in males and females up to age 45.

- **Options for next ADAP Advisory Committee meeting in March 2020:**

- Monday, March 2nd
- Wednesday, March 4th
- Wednesday, March 18
- Thursday, March 19th
- Monday, March 30th

Note: March 2nd and March 4th: The Virginia General Assembly will still in session, so some members of the VDH team may be unavailable.

- **Topics for the next meeting:**

- Delstrigo on formulary
- Topics requested by the committee members?