

AIDS Drug Assistance Program (ADAP) Advisory Committee Meeting

Notes

October 20, 2014

4pm-5pm

VDH Staff present in meeting: Diana Jordan, Steve Bailey, Lenore Lombardi, Anne Rhodes, Carrie Rhodes, Jennifer Flannagan, Daniela Isayev, Craig Parrish, Dr. Lori Forlano-by phone

ADAP Advisory Committee Members on call: Dr. Robert Brennan, Dr. David Wheeler, Dr. Edward Oldfield, Karen Council, Bob Higginson

Additional participants on call: Dr. Rebecca Dillingham, UVA; Lindsay Wilton, Macaulay & Burtch; Keenan McDonagal, UVA; Paul Spidel and Dan Santos, Optima; Michael Harper and John Lupo, Kaiser; Laura Lee Viergever, VAHP.

Welcome and Introductions – *Robert Brennan*

1. Status Update

- ***Enrollment Update – Carrie Rhodes***

- As of 10/14/2014 the program enrollment numbers are as follows:

Date	Total Clients in ADAP	Direct ADAP	MPAP	ICAP	ACA
10/14/2014	5214	2063	446	401	2304

- ***Funding Update - Steve Bailey***

- ADAP Emergency Relief Funding – received \$11 million award through 3/31/2015. An application has been submitted for GY2015.
- Ryan White Part B Grant Application is currently being prepared. This reward varies from \$27-28 million depending on federal appropriation.
- Part B Supplemental - \$1.8 Million reward through 9/29/2015.
- Virginia will no longer eligible for ADAP supplemental funds in 2015; this is a program loss of \$1.6 million.
- 1115 Waiver/General Assembly (GA) report and cost to pay for uncovered meds
 - 60% of ADAP clients are insured.
 - 40% of ADAP clients are being served by Direct ADAP.
 - The goal is to support the majority of clients through insurance, as this is the more cost effective option.
 - It is possible to have a shortfall of \$14-16 million if other funding sources, including 2015 ADAP ERF, are not received.
 - Link to GA report
<http://leg2.state.va.us/DLS/h&sdocs.nsf/5c7ff392dd0ce64d85256ec400674ecb/2755dece7a3bb81485257d070070b882?OpenDocument&Highlight=0,adap>

2. **University of Virginia- Dr. Rebecca Dillingham**-Update regarding research project to evaluate the health outcome differences between ADAP clients enrolled into ACA insurance and those not. –

- This study was proposed by Kate McManus MD, UVA Infectious Disease Fellow and is supervised by Rebecca Dillingham MD.
- This research project focuses on the differences between ADAP clients enrolled in ACA insurance plans and those who are not in terms of meeting care markers.
- The goal is to quantify whether HIV outcomes improve with ACA insurance enrollment to assess if the ACA has its intended effects for people living with HIV.

3. **Affordable Care Act (ACA) Insurance Plan Review and Enrollment – Lenore Lombardi**

• ***Plan Selection Update***

- VDH has access to preliminary plan information and VDH is reviewing this information to determine which plans can be approved to use ADAP dollars to pay for. However plans can change up to October 22, and have to be approved by the Federal Government by November 5. We do not know if plans will be made public November 5, or November 15th, which is the 1st day of open enrollment.
- Each insurance plan was evaluated to assure that it met HRSA requirement of covering antiretrovirals (ARVs) on ADAP formulary
 - Formularies are currently incomplete, not including all ARVs.
 - New HRSA guidelines allow VDH to purchase insurance plans for clients that meet formulary requirements of offering coverage of at least one ARV from each class.
 - Prescribers will need to submit a formulary exception request to the insurer for any uncovered medications.

• ***Communication Plan*** – clients/providers

- Jennifer Flannagan is working together with the Virginia HIV/AIDS Resource and Consultation Center (VHARCC) to provide ACA related education sessions to stakeholders and clients.

4. **Molecular HIV Surveillance (MHS) Update – Anne Rhodes**

- Funding to collect data and regulation update
- The objective of Molecular HIV Surveillance is:
 - To collect HIV nucleotide sequence data from laboratories that perform HIV genotype testing;
 - Estimate the prevalence of and monitor trends in HIV drug resistance mutations;
 - Monitor the distribution of HIV genetic subtypes and recombinants;
 - Use molecular HIV data to describe patterns of HIV transmission;
 - Disseminate the results of MHS data analyses to assist HIV treatment, prevention, and program planning and evaluation.
- The Medical Monitoring Project (MMP) will be expanding the sample pool from receiving lists from providers to contacting cases sampled through the surveillance registry. This allows the sample size to include all people living with HIV, not just those in care.

5. ADAP Medication and Formulary Update – Jennifer Flannagan

Removal of the preauthorization (exception) criteria for dolutegravir

- As of September 24th Virginia ADAP no longer requires a medication exception for dolutegravir.
- Dolutegravir has been on the ADAP Formulary since October 25, 2013 and upon review of medication exceptions and the criteria, the medication is being prescribed appropriately.
- It was recommended to implement prior authorization for double-dosing for six months to determine how often this alternative is being used. This allowed Virginia Department of Health (VDH) staff to determine use, financial implications and effectiveness.
- Since the addition of dolutegravir to the formulary, data indicates that four exception forms were received. Only two medication exception forms were received for double-dosing since October 2013. Two additional forms were received for clients involved in a clinical trial before it was added to the formulary.
- Based on the low number of exceptions received and appropriate prescribing of dolutegravir by medical providers, it is reasonable to remove the preauthorization criteria for this medication.

Single pill combination of dolutegravir, abacavir and lamivudine- Triumeq

- Triumeq (dolutegravir/abacavir/lamivudine) is a new fixed drug combination (FDC) for the treatment of HIV. Triumeq is the fourth FDC to be approved by the FDA and contains two nucleoside reverse transcriptase inhibitors (NRTI) and an integrase inhibitor. The single tablet, triple-combination antiretroviral (ARV) is approved as a first-line therapy to treat HIV-1 infection. Triumeq is the only FDC on the market that does not contain Truvada (tenofovir/emtricitabine) thus making it a candidate in patients with impaired renal function. Triumeq was approved by the U.S. Food and Drug Administration (FDA) on 8/22/2014 and is manufactured by ViiV Healthcare.
- If approved, this medication will be added to the existing single-tablet regimens including Atripla, Stribild and Complera.
- VDH has compiled medication information (indication, usage, pricing information and relevant ADAP data including number of clients on single pill regimen and a breakdown of ADAP clients on Atripla, Complera and Stribild). As with all prior additions to the Direct ADAP formulary, the process takes 4-6 weeks of analysis. VDH likes to get feedback from clinicians regarding projected utilization and the impact it may have on regimens. VDH will be sending a request for information to the committee within a week.

6. Questions and Answers/Closing of Call

- Lenore Lombardi requested physician input regarding any changes with the newly insured client population.
 - Dr. Oldfield stated that there have not been issues with ACA insurance plans and clients are typically meeting the Maximum Out of Pocket (MOOP) prior to doctor visits.
 - Dr. Wheeler stated that he sees a minority of patients enrolled in the ACA at his private practice and they tend to be more knowledgeable about insurance.
 - Dr. Wheeler inquired about additional resources for labs and would like to be informed of any resources available for those not being supported by Ryan White funds but do have an ACA plan.
 - VDH will provide additional input regarding this at a later date.

- Dr. Dillingham stated that patients are meeting the MOOP but pointed out the learning curve which effects newly insured clients that have no previous experience with setting up insurance benefits.
- Dan Santos at Optima inquired about VDH's approach to selecting plans when multiple plans are available in a region for a client.
 - Steve Bailey reviewed that clients are able to choose from any plans offered, and may select from a menu of plans that are paid for by ADAP if they want to benefit from that ADAP service. If more than one plan supported by ADAP is offered in a region, a client may choose from those options based on their needs. VDH anticipates being able to support plans from an increased number of insurance carriers during the next open enrollment period.

Call information:

Call Number: 1-866-842-5779

Code: 8036961650