The AIDS Drug Assistance Program Overview

Ryan White Part B
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HAB DSHAP Vision and Mission

- Vision: Optimal HIV AIDS prevention, care and treatment for all.

- Mission: To provide leadership and support to States/Territories for developing and ensuring access to quality HIV prevention, health care and support services.

AIDS Drug Assistance Program Overview

The AIDS Drug Assistance Program (ADAP) is a component of the Ryan White Part B program that provides access to HIV/AIDS medications and medications to prevent the serious deterioration of health resulting from HIV disease.

Ryan White Legislation ADAP Milestones

- Ryan White Legislation was signed into law on August 18,1990
- 1990: AZT Demonstration Project incorporated into Title II of the Ryan White CARE Act.
- 1996: First reauthorization created the Federal ADAP earmark.
- 2000: Second reauthorization allowed insurance purchasing and flexibility for access, adherence and monitoring and created ADAP supplemental grants.

- 2006: Third reauthorization of the Ryan White Program created a new formula incorporating living HIV/AIDS cases in the state award, minimum formulary, ADAP supplemental set aside & eligibility.
- 2009: Currently reauthorized for four years as the Ryan White HIV/AIDS Treatment Extension Act (Ryan White HIV/AIDS Program

ADAP— National Overview

- Each of the 59 States and Territories are provided funding for ADAP.
- There is a wide variation in program characteristics due to individual State administration of each ADAP and HIV/AIDS prevalence in each State.
- Differences most pronounced in areas of funding, eligibility criteria, formulary size, and cost-saving strategies.

ADAP's Impact

- **1 in 4** PLWHA receiving ARVs in USA use ADAP services.
- **211,307** PLWHA served through ADAP in CY 2011.
  - **165,233** ADAP clients received medications
  - **45,814** ADAP clients received insurance assistance (including medications)

ADAP Funding (FY12)

- **Part B (X07)**
- ADAP Earmark: $824,050,153
- ADAP Supplemental: $42,914,950
- **ADAP Emergency Relief Funding (X09)**
- $75 million (including $35 Million World AIDS Day money)
- **Other sources of ADAP Funding:** State match, drug rebates, state general revenue funds, Part A/B contributions

ADAP Funding Distribution

- 95% of the ADAP Earmark is distributed by formula, based on the number of living HIV/AIDS cases in the state in the most recent calendar year.
- 5% of the Earmark is set-aside for the ADAP Supplemental grant, which is distributed based on need:
  - Reduction in eligibility standards, (FPL)
  - Reduction in formulary
  - Initiation of waiting list
  - Unanticipated increase in eligible PLWH/A
- There were 27 ADAP Supplemental grantees in FY10, 42 in FY11.

ADAP Overview

- ADAPs provide access to medications by either:
  1) purchasing medications; or
  2) providing assistance with health insurance premiums, co-pays and deductibles (HAB Policy 07-05)

ADAP Overview (continued)

- Through the ADAP Flex Policy (HAB Policy 07-03), ADAP funds may also be used to assist with
  - adherence support
  - monitoring of drug treatment
  - enhanced access to services

ADAP – Related Legislation

Section 2616. [300ff–26] Provision of Treatments

(a) IN GENERAL.—A State shall use a portion of the amounts provided under a grant awarded under section 2611 to establish a program under section 2612(b)(3)(B) to provide therapeutics to treat HIV/AIDS or prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals, including measures for the prevention and treatment of opportunistic infections.

ADAP- Related Legislation

2616. [300ff–26] (f)(1)

(f) USE OF HEALTH INSURANCE AND PLANS.—

(1)IN GENERAL.—In carrying out subsection (a), a State may expend a grant under section 2611 to provide the therapeutics described in such subsection by paying on behalf of individuals with HIV/AIDS the costs of purchasing or maintaining health insurance or plans whose coverage includes a full range of such therapeutics and appropriate primary care services.

ADAP-Related Legislation

2616. [300ff–26] (f)(2)

(2) LIMITATION.—The authority established in paragraph (1) applies only to the extent that, for the fiscal year involved, the costs of the health insurance or plans to be purchased or maintained under such paragraph do not exceed the costs of otherwise providing therapeutics described in subsection (a).

Also see HAB Policy 07-05

ADAP Eligibility

- Eligibility Criteria is determined by each State or Territory (through an ADAP Advisory Body or in collaboration with their respective State Legislature or Health Department)

- Eligibility criteria include proof of HIV/AIDS status, financial eligibility, residency and uninsured or underinsured status

- Income eligibility is determined as a percentage of the Federal Poverty Level (FPL)

ADAP-Related Legislation: Eligibility

2616. [300ff–26](b)

(b) ELIGIBLE INDIVIDUAL.—To be eligible to receive assistance from a State under this section an individual shall—

(1) have a medical diagnosis of HIV/AIDS; and

(2) be a low-income individual, as defined by the State.

Payer of Last Resort requirement is in Section 2617(b)(7)(F)

ADAP Eligibility Criteria

- Financial eligibility:
- Income limit (as percentage of Federal Poverty Level); may also include asset limit.
- Medical eligibility:
- Diagnosis of HIV infection
- Residency:
- Proof of current State residency
- Uninsured or Underinsured:
- Proof of no other insurance coverage or that the client's insurance coverage does not cover all their medication costs.

Affordable Care Act and ADAPs

Key impacts of the ACA on ADAPs include:

- Creation of Pre-Existing Conditions Insurance Plans (PCIPs)
- ADAP expenditures counting towards Medicare Part D True Out of Pocket (TrOOP) Costs
- Medicaid Expansions
- Access to insurance for those with pre-existing conditions

ADAP Recertification

- ADAPs are required to recertify the clients' eligibility at least every six months (per NGA since 2005) and at least once a year (whether defined as a 12-month period or calendar year)
- With HAB's approval, instead of a formal 6 month recertification, states may have a **system** of processes that provide assurance of Payer of Last Resort and cover recertification activities such as income eligibility, uninsured and/or underinsured status and residency. (see HAB Policy Clarification Notice #13-02)

ADAP Formulary

- ADAP Formulary must contain at least one medication from each class of PHS approved Antiretroviral classes
- Most States have an ADAP Advisory Body that provides the State guidance on clinical, fiscal and ADAP formulary recommendations
- Most State's ADAP Advisory Body's include physicians, consumers and providers.

ADAP- Related Legislation

- **Section 2616. [300ff–26](e)**
- **(e) List of Classes of Core Antiretroviral Therapeutics—**
- For purposes of subsection (c)(1), the Secretary shall develop and maintain a list of classes of core antiretroviral therapeutics, which list shall be based on the therapeutics included in the guidelines of the Secretary known as the Clinical Practice Guidelines for Use of HIV/AIDS Drugs, relating to drugs needed to manage symptoms associated with HIV.
- **Public Health Service ARV Drug Classes**
- FDA-approved antiretroviral drug classes currently available include: Entry and Fusion Inhibitor, Non-nucleoside Reverse Transcriptase Inhibitor, Nucleoside Reverse Transcriptase Inhibitor, and Protease Inhibitor.

ADAP Flexibility

- ADAPS must ensure that clients receive medication therapies consistent with current HHS HIV/AIDS treatment guidelines.
- States may request to redirect up to 5% of their ADAP earmark under the Flexibility policy (10% in extraordinary circumstances) for expenditures that:
  - improve access to medications,
  - increase adherence to medication regimens, and
  - help clients monitor their progress in taking HIV-related medications

ADAP-Related Legislation

Section 2616. [300ff–26] (c)(6)

(6) encourage, support, and enhance adherence to and compliance with treatment regimens, including related medical monitoring.

Of the amount reserved by a State for a fiscal year for use under this section, the State may not use more than 5 percent to carry out services under paragraph (6), except that the percentage applicable with respect to such paragraph is 10 percent if the State demonstrates to the Secretary that such additional services are essential and in no way diminish access to the therapeutics described in subsection (a).

Also see HAB Policy 07-03

ADAP Costs

The average cost per ADAP client is approximately $11,500/year

- Vary significantly by state depending on formulary and program costs
- Vary depending on ADAP's adoption of cost saving's strategies

ADAP 340B Program

- ADAPs have access to discounted drug prices through the 340B program. 340B discounts are required by the Veterans Health Care Act of 1992 (Section 602).

- ADAPs can access the 340B price through a discount at their drug wholesaler when purchasing medications, or by way of a rebate from the manufacturers after the fact (or a combination of these mechanisms)

ADAP-Related Legislation

2616. [300ff–26](g)

(g) DRUG REBATE PROGRAM.—A State shall ensure that any drug rebates received on drugs purchased from funds provided pursuant to this section are applied to activities supported under this subpart, with priority given to activities described under this section.

2622. Timeframe for Obligation and Expenditure of Grant Funds

(d) Treatment of Drug Rebates

ADAP Challenges

- Increased Demand for services in an environment of few new/declining resources:

  ADAPs experienced 18% growth since 2010

- Contributory Factors:
  - Economic downturn
  - Increased HIV testing
  - Push for earlier HIV treatment
  - More effective medications
  - Increased HIV prevalence
  - HIV is a chronic disease and PLWHA are living with HIV longer and aging

Cost Containment

- Throughout their history, ADAPs have devised and implemented a variety of cost-containment strategies to maximize scarce resources.

- There are **two** categories of cost containment:
  - Cost Saving Strategies
  - Cost Cutting Strategies

Cost Containment

Cost Saving Strategies:

Measures taken to improve the cost-effectiveness of ADAP operations, which are required to achieve, improve, and/or maximize ADAP resources.

Cost Containment

Cost Saving Strategies:

Examples of “cost-saving” measures:

- Improved systems and procedures for back billing Medicaid,
- Improved client recertification processes,
- Part B Program structural or operational changes
- Expanding insurance assistance
- Collection of 340B rebates for insurance co-pays, deductibles, co-insurance
- CMS data-sharing agreements to allow ADAP expenditures to count towards TrOOP
- Controlling ADAP administrative costs

Cost Containment

Cost Cutting Strategies:

Measures taken that restrict/reduce ADAP Services or enrollment. These activities are instituted out of necessity due to insufficient resources and/or to avoid starting a waiting list.

Cost Containment

Cost Cutting Strategies:

Examples include:

- Lowering of financial eligibility (FPL)
- Capping enrollment
- Reducing benefits (formulary reductions with respect to antiretroviral medications and medications to treat opportunistic infections or complications of HIV disease)
- Starting an ADAP Waiting List

ADAP Waitlist

- An ADAP waiting list is a mechanism used to limit access to the ADAP when funding is not available to provide medications to all eligible persons requesting enrollment in that State.
- The ADAP verifies overall eligibility for the program and places eligible individuals on a waiting list, as necessary, prioritized by a pre-determined criterion.

ADAP Waitlist

- The ADAP manages the waiting list to bring clients into the program as funding becomes available.
- ADAPs are expected to provide training, education and continual feedback to providers, consumers and case managers on how to access the Pharmaceutical Manufacturer's Patient Assistance Programs (PAP).

Common Patient Assistance Program Application

- The Common Patient Assistance Program Application (CPAPA) was announced at the International AIDS Conference in July, 2012.
- This single common application allows uninsured individuals living with HIV to use one application to apply for multiple assistance programs that together provide an entire course of antiretroviral therapy.
- A copy of the application can be found at:
  - http://hab.hrsa.gov/patientassistance/index.html
  - http://www.nastad.org/Docs/110312_CPAPA.pdf

ADAP Waitlist- HAB Expectations

- NASTAD releases a monthly report regarding the ADAP Waiting List known as the ADAP Watch Report
- Internally, DSHAP releases a monthly ADAP Waiting List Report to DSHAP staff and key stakeholders in HAB
- The ADAP Waiting List report may return to a weekly report if the number of PLWHA on ADAP Waiting list rise.

ADAP Waitlist

Through the efforts of on-going HRSA, NASTAD and Peer TA, implementation of cost cutting and cost saving's measures and the availability of ADAP ERF funding, the ADAP Waiting List has seen a **99%** decrease in the number of clients on ADAP waiting lists which at its peak in September 2011 was **9,310**.

ADAP Reports

ADAP-related allocations and expenditures are reported to HAB through a variety of reports, including:

- ADAP Quarterly Report (AQR)
- ADAP Data Report (ADR)
- Regular Part B reports
- ERF-specific reports

ADAP Performance Measures

HAB has developed recommended performance measures for ADAPs, including:

- Percent of ADAP applications approved or denied for new ADAP enrollment within 14 days (two weeks) of ADAP receiving a complete application in the measurement year
- Percentage of ADAP enrollees who are reviewed for continued ADAP eligibility two or more times in the measurement year

ADAP Performance Measures (continued)

- Percentage of new anti-retroviral classes that are included in the ADAP formulary within 90 days of the date of inclusion of new anti-retroviral classes in the PHS Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents1 during the measurement year.
- Percent of identified inappropriate antiretroviral (ARV) regimen components prescriptions that are resolved by the ADAP program during the measurement year.

Resources

- ADAP Manual
  - https://careacttarget.org/content/adap-manual
- HAB and TARGET Center Websites
  - http://hab.hrsa.gov/index.html
  - https://careacttarget.org/
- NASTAD
  - http://www.nastad.org/
- Technical Assistance
- Project Officer

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