NASTAD
NATIONAL ALLIANCE OF STATE & TERRITORIAL AIDS DIRECTORS

ADAP TECHNICAL ASSISTANCE BRIEF NO. 2
FORMULARY AND UTILIZATION
NOVEMBER 2012

Introduction

AIDS Drug Assistance Programs (ADAPs) are state administered programs authorized under Part B of Title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Ryan White Program).[1] ADAPs provide Food and Drug Administration (FDA) approved medications to low-income, uninsured or underinsured individuals with HIV who have no other means to obtain these necessary medications. All 50 states, the District of Columbia, American Samoa, the Federated States of Micronesia, Guam, the Marshall Islands, the Northern Mariana Islands, Puerto Rico, the Republic of Palau and the U.S. Virgin Islands are eligible to receive ADAP funding. This is the second in a series of four ADAP technical assistance (TA) briefs focusing on cost effectiveness strategies. Other topics include: Eligibility Criteria, Waiting List Management and Coordination of Benefits.

ADAPs make cost effectiveness and efficiency a priority in program design and delivery. Increasing client utilization and rising medication expenditures make fine tuning cost effectiveness challenging. Nationally, the number of clients enrolled in ADAPs increases every year. Additional federal and state funding for ADAPs has not kept pace with the changing landscape of HIV care, rendering cost effectiveness strategies an on-going priority for ADAPs. ADAPs will continue to be impacted by the implementation of the Affordable Care Act, changes to the Ryan White Program, further economic budget constraints, the disproportionate impact of the epidemic on the poor and uninsured, amplified efforts of the National HIV/AIDS Strategy to identify new HIV positive clients and new treatment guidelines recommending initiation of antiretrovirals (ARV) therapy regardless of CD4 counts.

ADAPs are allowed to determine what medications their program will provide as long as the formulary includes at least one drug from each class of ARV medications, as mandated by Ryan White law. ADAP formularies may also include medications for the prevention and treatment of opportunistic infections related to HIV, vaccines, mental health therapies, hepatitis treatments and other medications for chronic conditions (e.g., diabetes, heart disease, etc.). As a result, formularies across the nation vary widely and are typically determined by available financial resources, additional state pharmaceutical payers and medical prescriber preferences. Making formulary changes can be a useful cost effectiveness strategy and each ADAP should investigate formulary management strategies that are economically feasible and administratively manageable for their program. ADAPs also may structure guidelines on how clients access the medications from the formulary. States may use several mechanisms to manage program access and expenditures to maximize ADAP resources and manage prescription utilization.

Effective Use of an ADAP Advisory Committee

The Health Resources and Services Administration (HRSA) encourages ADAPs to convene an ADAP Advisory Committee to assist with establishing the ADAP formulary, eligibility criteria, the ADAP quality management plan and to help assess potential ADAP cost effectiveness strategies. The state's ADAP Advisory Committee may be comprised of clinicians, pharmacists, service providers, consumers, representatives from other Ryan White parts, the health department and the state Medicaid program. The ADAP Advisory Committee may meet in person, by conference call or electronically as needed from twice a year to once a month and as appropriate for the state process. The ADAP Advisory Committee should review the ADAP program policies or regulations, functions, quality indicators and budget annually. The committee should also make recommendations on formulary management, utilization management or program eligibility to help guide ADAPs in implementing process or program changes, as appropriate.

HRSA Mandates

HRSA expects Part B grantees to include ADAP in their mandated clinical quality management plans to ensure that:

1. Clients receive treatment consistent with current Department of Health and Human Services (HHS) Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents.
2. ADAPs are providing access to, and support for, appropriate medications.
3. ADAPs are including at least one medication on their formulary from new antiretroviral classes within 90 days of inclusion in the HHS Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents.
4. ADAP formularies have at least one medication from each antiretroviral class.

The state's ADAP Advisory Committee, experienced pharmacists and/or HIV/AIDS medical providers can be effective partners in this endeavor by conducting clinical reviews of prescribing patterns, making decisions about changes to the formulary and determining utilization management strategies.

Determining the ADAP Formulary

Since July 1, 2007, all ADAPs are required to include at least one drug from each class of antiretroviral medications (ARVs) on their formulary. Most ADAPs also include medications for the treatment and prevention of opportunistic infections (OIs).[2] If an ADAP cannot cover all ARVs in every class or OI medications recommended by the HHS Guidelines for the Use of Antiretroviral Agents in HIV-I-Infected Adults and Adolescents,[3] the state's ADAP Advisory Committee can recommend medications be excluded from the formulary. It is important to understand that limiting an ADAP formulary may impact patient care and clinical outcomes.

A process to prioritize categories of medications based on clinical indications (e.g., prevention and treatment of Pneumocystis jiroveci pneumonia) is helpful in focusing the committee discussion. Severity of the clinical condition and frequency in the HIV population are factors in determining the relative priority of each indication. Medications used for each indication may be further ranked using factors such as: FDA approval for indication, efficacy, toxicity, cost, available alternatives (e.g., availability of generics or alternative combination therapy) and potential for unintended use. Input from experienced pharmacists and medical providers can assist in assessing the impact of including or excluding certain medications.

An ADAP should seek to provide a range of alternative medications for high priority indications to allow physicians flexibility in choosing the most appropriate treatment for individual patients. The cost of medications for initial treatment of HIV is frequently comparable to the cost of medications used when the initial treatment fails or is contra-indicated.

When considering expanding or reducing the formulary, ADAPs should assess the financial impact and utilize their ADAP Advisory Committee to assist with the assessment. The ADAP Crisis Task Force (ACTF), convened by NASTAD, negotiates with the manufacturer to ensure price neutrality of any new medication compared to the other drugs among the same class. After negotiations with a manufacturer have concluded, the ACTF makes a recommendation to all ADAPs about whether it should be added to formularies based on the final negotiations. It is important to review the ACTF agreements prior to making changes to the formulary. Additionally, it is important to consider both cost and potential improvements in adherence when considering reformulations of existing medications that result in combined, reduced daily dosing.

If ADAPs provide medications in addition to ARVs and OI medications, implementing a preferred drug list or step therapy for those classes of medications (e.g., cardiovascular statins or gastrointestinal proton pump inhibitors) can be considered.

For co-infected HIV and viral hepatitis individuals, treatment for viral hepatitis is allowed under the Ryan White Program, however many ADAPs have limited or provide no hepatitis treatment options due to budget constraints that do not allow inclusion, and low demand by providers and consumers. Data on drug safety, efficacy and tolerability, including drug resistance and drug interactions of new HCV drugs (i.e., telaprevir (Incivek) and boceprevir (Victrelis) with current HIV drugs, is currently limited. Treatment with the new medications also requires the use of the current standard of care which includes pegylated interferon and ribavirin. These treatment options are very expensive, require strict adherence of the individual and have serious side effects often needing additional medication.

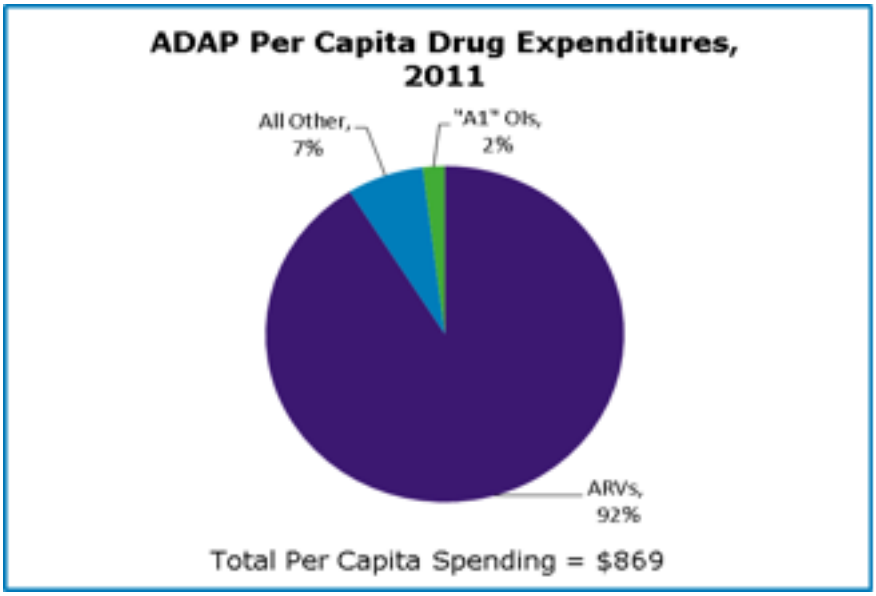
State Spotlight on Formulary

In 2010, **Virginia** ADAP's financial forecasts began to show a potential shortfall of funds by the end of current Ryan White fiscal year. A number of cost effectiveness strategies were considered and forecasts of potential cost savings were performed for each strategy. They were then presented to the ADAP Advisory Committee, comprised of HIV medical providers, a pharmacist and an individual living with HIV. The forecasts demonstrated the removal of certain medications would save approximately 1.2 percent of total ADAP costs per year. With the concurrence of the ADAP Advisory Committee, the Virginia ADAP formulary was reduced. Historically, the Virginia ADAP formulary covered over 100 different medications that were commonly prescribed for HIV treatment, HIV treatment-related conditions and mental health conditions. The formulary currently provides only antiretrovirals (ARVs) to treat HIV, medications to prevent and treat opportunistic infections (OIs) and selected vaccines.

Cost-saving Analysis

Containing cost through formulary reduction is challenging, as antiretroviral medications nationally for ADAPs comprise an average of 92 percent of per capita drug expenditures (see Figure One).[4] Therefore, removing non-ARVs typically does not result in a significant cost reduction. ADAPs should review expenditure data by individual drug to determine whether eliminating individual medications other than currently covered ARVs or "A1" OIs would achieve significant cost-savings. ADAPs are encouraged to discuss prescription utilization, drug data and any possible changes to their formularies with other ADAPs to benefit from previous lessons learned.

Figure One:

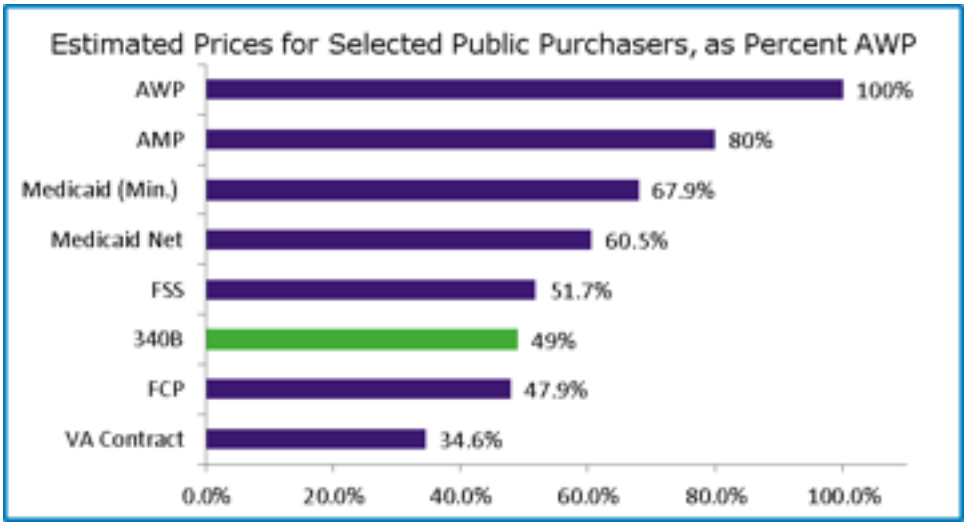


Source: National Alliance of State and Territorial AIDS Directors. (2012). N*ational ADAP Monitoring Project: Annual Report.*

Getting the Best Price

The Ryan White law states ADAPs to use every means at their disposal to secure the best price available for all products on ADAP formularies. Meeting this requirement means that ADAPs are able to serve the most people with the most medications possible. Ryan White Part B grantees must adopt at least one defined cost-saving practice for their ADAP that is equal to or more economical than the 340B drug discount program (see Figure Two). Managing pricing of pharmaceuticals is a complex and multi-layered approach that can require considerable staff time to monitor.

Figure Two:



Beyond the 340B drug discount program pricing, ADAPs also have access to additional savings as a result of negotiations on their behalf by NASTAD's ADAP Crisis Task Force. For ADAPs using a central pharmacy, it is necessary for the appropriate reduced prices to be loaded by the wholesaler and for ADAPs to monitor these prices monthly. Any increases beyond small percentages based on the Consumer Price Index (CPI) may indicate that an incorrect price has been charged. As well, most agreements include price freezes so increases in costs might indicate errors in wholesaler pricing. Some ADAPs are able to access their wholesaler prices online and monitor changes.

paid and possible fluctuations.[5] Technical assistance is available from NASTAD to help ensure that ADAPs pay the correct prices for pharmaceuticals under the ADAP Crisis Task Force negotiated agreements.

Strategies for Managing Prescription Utilization

Annual or Monthly Cost Caps

Given resource limitations, some ADAPs have set a limit or "cap" (monthly or annual) what ADAP will spend on prescriptions for each individual client. ADAPs that experience fluctuating month-to-month expenditures may find it useful to establish a monthly cap on per client expenditures for certain drug classes or types of prescriptions.

One way to determine a reasonable annual limit on per client expenditures is to calculate the annual average cost per client for the most recent three year period. Previous experience has shown that the majority of ADAP clients will utilize program resources within the annual average. Clients with more intensive resource needs—including clients requiring salvage therapies or co-infected with viral hepatitis—may exceed the cap. It will be important to reassess the cost cap periodically as client enrollment and utilization changes, new ARVs become available and ADAP pricing fluctuates. Once a maximum cap is established, ADAPs must maintain on-going communication with the medication distribution network and monitor monthly client expenditures. ADAPs using a Pharmacy Benefits Manager (PBM) should receive monthly expenditure reports from the contractor. In the event that the ADAP does not have a PBM, the ADAP coordinator or other staff member would pay all bills and enter and monitor all expenses.

Restricting Prescription Supply or Refills

Prescription supply given to a client: ADAPs may choose to cover a 30-day versus a 90-day supply of ARVs. This reduces the possibility of paying for obsolete medications when a client's regimen or eligibility status changes.

Number of refills without a new prescription: Similarly, ADAPs may limit the number of refills before requiring a new prescription in order to reduce the likelihood of unnecessary, costly refills due to regimen changes or changes in eligibility status. The number of refill limits (e.g., 2-6) may differ for 30-day versus 90-day prescriptions. ADAPs may also limit the total number of refills in a given year for the same reasons.

Refills on medications prior to the end of the month: ADAPs may choose not to authorize refills prior to 21 days after the most recent prescription to limit the possibility of clients receiving extra weeks of medications that may not be needed.

Refills of lost medications without significant justification: ADAPs may limit the number of times it allows refills of 'lost' prescriptions.

Number of medications provided each month: ADAPs may choose to limit the number of ARV prescriptions per month. For example, it may allow four ARVs and two medications for the treatment/prevention of OIs per client per month. Other resources and PAPs must cover any other medication needs.

Prior Authorization

To avoid more stringent cost containment measures, an ADAP may choose to implement a prior authorization process.[6] The most common examples of medications requiring prior authorization are fusion inhibitors and hepatitis C treatments as well as classes of medications such as pain management and mental health medications. An ADAP should consider its access to clinical oversight, as review processes can be administratively burdensome.

How to Implement Prior Authorization

In implementing a prior authorization process, ADAPs should:

- Involve their state's ADAP Advisory Committee in developing the medical criteria for accessing the medication or class of medications.
- Develop an accessible application process (e.g., faxing/mailing a form, by phone, and/or applying online).
- Create a review process for adherence to clinical eligibility criteria and specify the approval/disapproval process and format by which the ADAP responds to the application.
- Establish a response timeline and tracking process similar to the state's ADAP application process.
- Monitor utilization of the medication(s) once approved, especially if there is a waiting list for additional clients to access the medication.
- Monitor the process to determine the number of, and reasons for, denial. This may point to the need for revisions.
- Inform providers and medical case managers of the review process in order to better assist clients.

Formulary and Utilization Management Checklist

- When considering changes to the formulary and utilization criteria as a cost effectiveness strategy, ADAPs should:
- Determine if any medications on the formulary are available to ADAP clients through any other payer source.
- Thoroughly review drug utilization patterns for the previous year.
- Forecast program costs for new medications coming to the market.
- Determine if NASTAD's ADAP Crisis Task Force has negotiated additional rebates/ discounts on medications considered for change.
- Determine if a formulary reduction will save the ADAP necessary funds.
- Consult the state's ADAP Advisory Committee for guidance on formulary and utilization changes.
- Consider any impact on patient adherence based on formulary and utilization changes.
- Develop procedures to rapidly address unintended consequences of patient access to medications.
- Follow HHS Guidelines for the Use of Antiretroviral Agents in HIV-I-Infected Adults and Adolescents.
- Be familiar with any state legislation and administrative regulations which may impact the program's ability to make changes to its formulary and utilization.
- Follow the internal agency process for review and approval of changes to the ADAP formulary and utilization.
- Consider the value of prior authorization to ensure appropriate use of the most expensive medications.
- Develop a process for applicants to request authorization to restricted medications on the formulary.
- Communicate effectively and in a timely manner with the community about why and when the formulary and utilization criteria will change.
- Establish contract requirements with the ADAP pharmacy network or direct purchase administrative agency for any client or financial data tracking and reporting needs.
- Notify the ADAP pharmacy network or direct purchase administrative agency of formulary and utilization changes.
- Consult other ADAPs that have investigated and/or changed their formulary and utilization, to find out how they approached it, the results and lessons learned.
- Communicate with your HRSA Project Officer and NASTAD when the state is considering changing the criteria, when and if significant challenges arise, and when any changes are actually implemented.

Resources

- National Alliance of State and Territorial AIDS Directors (NASTAD) – www.NASTAD.org
  - National ADAP Monitoring Project Annual Report
  - ADAP Glossary
  - ADAP Frequently Asked Questions
  - 340 B Drug Pricing and ADAP
  - Financial Forecasting
  - ADAP Crisis Task Force
  - Coordination of Benefits
  - Medicaid and Medicare
- HRSA HIV/AIDS Bureau – www.hab.hrsa.gov
- HRSA 340B Prime Vendor Program – www.340bpvp.com
- HRSA Target Center – Technical Assistance for the Ryan White Community - http://careacttarget.org
- HRSA Office of Pharmacy Affairs – www.hrsa.gov/opa
- Kaiser Family Foundation – www.kff.org/hivaids/index.cfm
- Pharmacy Services Support Center – http://pssc.aphanet.org
- ADAP listserv sponsored by NASTAD – NASTADTA@NASTAD.org
- Ryan White HIV/AIDS Treatment Extension Act, Pub. L. No 111-87, October 30, 2009. – www.gpo.gov/fdsys/pkg/PLAW-111publ87/html/PLAW-111publ87.htm
- Current treatment guidelines – http://aidsinfo.nih.gov
- Comprehensive information on ARVs and OI medications – www.aidsmeds.com

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[1] Ryan White HIV/AIDS Treatment Extension Act, Pub. L. No 111-87, October 30, 2009. Available at http://www.gpo.gov/fdsys/pkg/PLAW-111publ87/html/PLAW-111publ87.htm

[2] National Alliance of State and Territorial AIDS Directors. (2012). National ADAP Monitoring Project Annual Report.

[3] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. October 14, 2011; 1–167. Available at http://www.aidsinfo.nih.gov/ContentFiles/

[4] National Alliance of State and Territorial AIDS Directors. (2012) National ADAP Monitoring Project Annual Report.

[5] NASTAD, Issue Brief: AIDS Drug Assistance Programs – Getting the Best Price? April 2002.

[6] It should be noted that some ADAPs implement prior authorization for clinical purposes and quality assurance, rather than cost containment.

The National Alliance of State and Territorial AIDS Directors (NASTAD) strengthens state and territory-based leadership, expertise, and advocacy and brings them to bear on reducing the incidence of HIV and viral hepatitis infections on providing care and support to all who live with HIV/AIDS and viral hepatitis. NASTAD's vision is a world free of HIV/AIDS and viral hepatitis

NASTAD is funded under HRSA Cooperative Agreement U69HA22733 to provide technical assistance to states on ADAP program administration. States interested in investigating cost effectiveness strategies may contact NASTAD at NASTADTA@NASTAD.org to discuss specific technical assistance needs. Part B grantees and ADAPs may also request technical assistance through their HRSA project officer.

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