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NATIONAL ALLIANCE OF STATE & TERRITORIAL AIDS DIRECTORS

FORMULARY MANAGEMENT

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# AIDS Drug Assistance Programs and Cost Containment Strategies: Formulary Management

## INTRODUCTION

Part B of the Ryan White HIV/AIDS Treatment Modernization Act (Ryan White Program) established federally-funded, state-administered AIDS Drug Assistance Programs (ADAPs) to provide HIV medications for low-income, uninsured, and underinsured individuals living with HIV/AIDS in the United States. This is the second in a series of six ADAP technical assistance briefs focusing on cost containment strategies. Other topics include: *Eligibility Criteria, Managing Prescription Utilization, Insurance Purchasing, Client Cost-Sharing, and Waiting List Management.*

ADAPs continually make cost effectiveness and efficiency a priority in their program design and delivery. The increasing client utilization and rising medication costs make fine tuning cost effectiveness challenging. Nationally, the number of clients enrolled in ADAPs increases every year. ADAPs continue to be impacted by Medicaid reform, the disproportionate impact of the epidemic on the poor and uninsured, and amplified efforts to identify new HIV positive clients. Additional federal funding for ADAPs has not accompanied these challenges, rendering cost containment strategies an on-going priority for ADAPs.

ADAPs are allowed to determine what drugs their program will provide as long as the formulary includes at least one drug from each class of antiretroviral medications. As a result, drug 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 containment strategy and each ADAP should investigate the formulary management strategies that are economically feasible and administratively manageable for their program.

This brief discusses four strategies for addressing the ADAP formulary:

- Management in order to contain costs;
- Determining the ADAP formulary;
- Getting the "best" price for drugs; and
- Prior authorization.

For each strategy, there is an overview of important issues to consider before adopting the strategy, and 'how to' implementation steps. Examples of ADAPs using the strategy are included with a brief description of their experience in terms of the benefits and challenges. Finally, there is a checklist ADAP coordinators can use when considering changes in how to manage the ADAP formulary, along with a list of additional available technical assistance resources.

## DETERMINING THE ADAP FORMULARY

Beginning July 15, 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).[1] If an ADAP cannot cover all ARVs in every class or OI medi-

### STRATEGIES FOR ADDRESSING ADAP FORMULARY MANAGEMENT:

Before adding or deleting medications from the ADAP formulary, first determine if any of the medications are available through other programs. As payer of last resort, the ADAP should investigate the availability of other resources such as state Pharmacy Assistance Programs (SPAPs), other state assistance programs for disabled/special populations, and pharmaceutical manufacturers' Patient Assistance Programs (PAPs). It should be noted that manufacturers' PAPs have limitations and varying eligibility criteria. Although a valuable resource, a PAP should not be considered a long-term solution for essential HIV/AIDS medications.

HRSA believes it is critical for Part B grantees to convene an ADAP Advisory Committee to assist with establishing the ADAP formulary, eligibility criteria, an 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 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 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 the ADAP in implementing process or program changes as appropriate.

cations recommended by the CDC's Guidelines for the Prevention and Treatment of Opportunistic Infections,[2] the state's ADAP Advisory Committee (AAC) can recommend drugs for exclusion in the formulary. ***It is important to understand that limiting an ADAP formulary may impact patient care and possibly clinical outcomes.***

A process to prioritize categories of drugs based on clinical indications (e.g., prevention and treatment of *Pneumocystis carinii* 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. The drugs used for each indication may be further ranked using factors such as: FDA approval for indication; efficacy; toxicity; cost; available alternatives; and potential for unintended use. Input from experienced pharmacists can assist in assessing the impact of including or excluding certain drugs.

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

When considering expanding the formulary, the ADAP should also assess the financial impact prior to adding a medication, and utilize their AAC to assist with the assessment. 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 the ADAP provides 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.

## WILL REDUCING THE FORMULARY ACTUALLY SAVE MONEY?

Containing cost through formulary reduction is challenging, as antiretroviral medications make up 89 percent of per capita drug expenditures for the majority of ADAPs.[3] Therefore, removing non-ARV medications typically does not result in a significant cost reduction. The ADAP should review its expenditure data by individual drug to determine whether eliminating individual drugs other than currently covered ARVs or "A1" OIs would achieve significant cost savings.

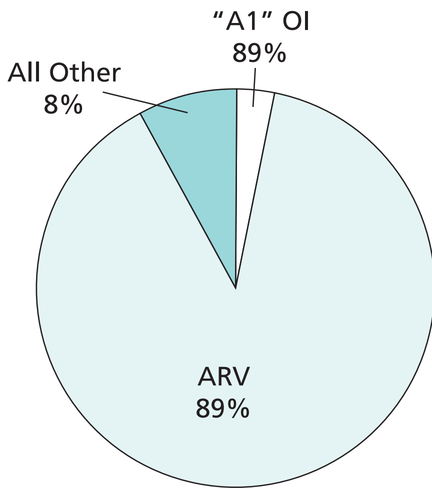
## GETTING THE "BEST" PRICE

Congress and the Department of Health and Human Services expect states to use every means at their disposal to secure the best price available for all products on their 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 program that is equal to or more economical than the 340B drug discount program. Managing pricing for pharmaceuticals is a complex and multi-layered approach that can require considerable staff time to monitor.

When **Michigan** began addressing a fiscal crisis, their ADAP immediately realized that the problems caused to clients by reducing the formulary outweighed any savings for the ADAP. So rather than reducing the number of covered drugs on their formulary, Michigan focused on managing the existing ADAP formulary better.

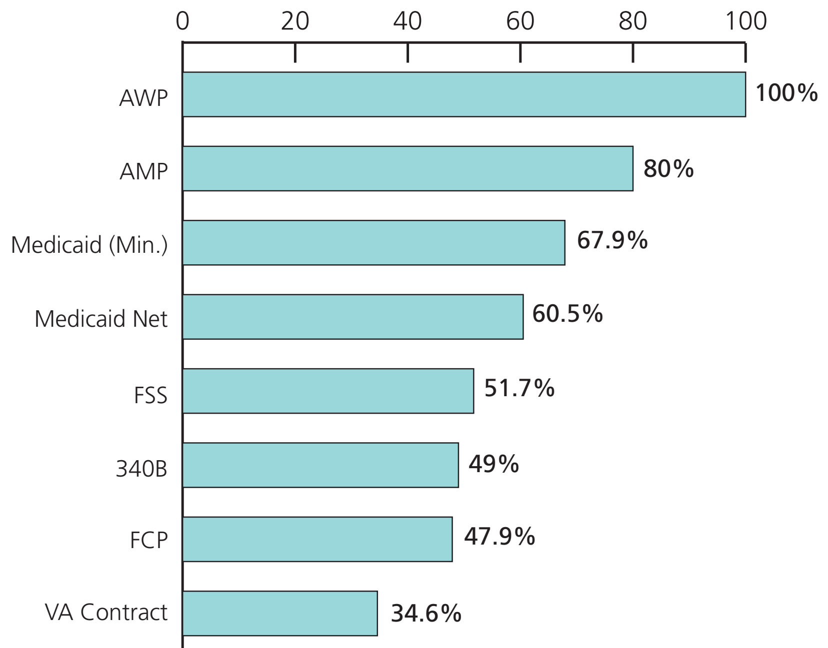
A mandatory generics program and step therapy was instituted. In addition, Michigan's ADAP pursued a contract with a "specialty pharmacy" to achieve reduced cost on particular drugs (Fuzeon, Neupogen, Procrit, Hepatitis C medications). Michigan also placed quantity limits on medications. This is both a cost containment tool as well as a way to discourage abuse on high cost medications. Lastly, Michigan is considering pharmaceutical PAPs for patients in need of medications with low utilization but high cost to ADAP. Michigan is prepared to reduce the formulary as an alternative to starting another ADAP waiting list if these cost containment strategies do not yield enough savings.

**ADAP Per Capita Drug Expenditure, June 2006**




Total Per Capita Spending = $991.43

**Estimated Prices for Selected Public Purchasers, as Percent AWP [7]**




Source: Stephen Schondelmeyer, PRIME Insitute, University of Minnesota (2001).

Beyond the 340B drug discount program pricing, ADAPs also have 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 the ADAP to monitor these prices at least monthly. Any increases beyond small percentages based on the Consumer Price Index (CPI) may indicate that an incorrect price has been charged. Some ADAPs are able to access their wholesaler prices online and monitor any changes this way. Other ADAPs have created customized pricing schedules to be aware of prices being paid and possible fluctuations.[4] 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.

## PRIOR AUTHORIZATION

To avoid more stringent cost containment measures, an ADAP may choose to implement a prior authorization process.[5] 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 drugs.

Thirty one (31) ADAPs currently report having prior authorization processes,[6] and use various models. 1) an ADAP medical provider conducts a full review of an application with clinical information; 2) a limited medical provider and/or non-clinical staff member reviews an application based on objective criteria (e.g. lab test results); 3) or an automated phone system processes the application, requiring no further clinical or administrative review. An ADAP should consider its access to clinical oversight, as review processes can be administratively burdensome.

## HOW TO:

In implementing a prior authorization process, an ADAP should do the following:

- Involve their state's AAC 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 pro-

The **New Jersey** ADAP does not use prior authorization (PA) criteria as a mechanism to contain costs. PA criteria in New Jersey are driven solely by clinical criteria to ensure that medications are used according to labeler indications. This is especially important in situations where a medication is not indicated as a first line therapy.

The **Utah** ADAP utilizes prior authorization (PA) for Aptivus and Fuzeon. To process a prescription for either Aptivus or Fuzeon, the Client Services Coordinator contacts the prescribing physician's office to let them know the PA form along with the algorithm is being faxed to them. The form must be filled out and faxed back to the Client Services Coordinator. Following receipt of the completed form, a medication override in the RX America System is processed, allowing access to the PA drug.

cess 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 wait 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 in the process.

## FORMULARY MANAGEMENT CHECKLIST

When considering changes to the formulary as a cost containment strategy, the ADAP should:
- Determine if any drugs 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 drugs coming to the market.
- Determine if NASTAD's ADAP Crisis Task Force has negotiated additional rebates/discounts on drugs considered for change.
- Determine if formulary reduction will save the ADAP necessary funds.
- Consult the state's AAC for guidance on formulary changes.
- Consider any impact on patient adherence based on formulary changes.
- Follow Public Health Service guidelines for providing HIV-related medications.
- Be familiar with any state legislation and administrative regulations which may impact the program's ability to make changes to its formulary.
- Follow the internal agency process for review and approval of changes to the ADAP formulary.
- Consider the value of a prior authorization to ensure appropriate use of the most expensive drugs.
- Communicate to the community about why and when the formulary will change.
- Develop a process for applicants to request authorization to restricted drugs on the formulary.
- Notify the ADAP pharmacy network or direct purchase administrative agency of formulary changes.
- Consult other ADAPs that have investigated and/or changed their eligibility criteria, 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
- HRSA HIV/AIDS Bureau – www.hab.hrsa.gov
- HRSA 340B Prime Vendor Program – www.340bpvp.com/public/
- HRSA Target Center – Technical Assistance for the Ryan White Community - http://careacttarget.org/
- Kaiser Family Foundation – www.kff.org/hivaids/us.cfm
- Office of Pharmacy Affairs – www.hrsa.gov/opa
- Pharmacy Services Support Center – http://pssc.aphanet.org
- ADAP listserv sponsored by NASTAD – NASTADTA@NASTAD.org
- Kaiser Family Foundation and National Alliance of State and Territorial AIDS Directors, National ADAP Monitoring Project Annual Report. April 2007.
- Ryan White HIV/AIDS Treatment Modernization Act, Pub. L. No 109-415, (2006).
- Current treatment guidelines – http://aidsinfo.nih.gov
- Comprehensive information on ARVs and OI medications – www.aidsmeds.com

**Endnotes**

1. Kaiser Family Foundation and National Alliance of State and Territorial AIDS Directors, *National ADAP Monitoring Project Annual Report.* April 2007.
2. CDC, "Guidelines for the Prevention of Opportunistic infections in Persons Infected with Human Immunodeficiency Virus." *MMWR 2002;* 51(No. RR08):1-46; CDC, "Treating Opportunistic Infections Among HIV-Infected Adults and Adolescents." *MMWR 2004;* 53(No. RR15):1-112. Available at: http://aidsinfo.nih.gov/Guidelines/GuidelinesDetail.aspx?MenuItem=Guidelines&Search=Off&GuidelineID=14&ClassID=4.
3. Kaiser Family Foundation and National Alliance of State and Territorial AIDS Directors, *National ADAP Monitoring Project Annual Report.* April 2007.
4. NASTAD, Issue Brief: *AIDS Drug Assistance Programs – Getting the Best Price?* April 2002.
5. It should be noted that some ADAPs implement Prior authorization for clinical purposes and quality assurance, rather than cost containment.
6. NASTAD, ADAP Watch. April 10, 2007.
7. The definitions of these pricing acronyms can be found at the HRSA TARGET Center TA Library (ADAP Glossary: Definitions and Acronyms).

NASTAD is funded under HRSA Cooperative Agreement U69HA05543 to provide states with technical assistance on ADAP program administration. States interested in investigating cost containment strategies may contact NASTAD at NASTADTA@nastad.org to discuss specific technical assistance needs. Part B grantees and ADAPs may also obtain technical assistance through their HRSA project officer.

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