## 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 first in a series of four ADAP technical assistance (TA) briefs focusing on cost effectiveness strategies. Other topics include: Formulary and Utilization Management, Waiting List Management and Coordination of Benefits.

ADAP funds are intended to provide "therapeutics to treat HIV disease or prevent serious deterioration of health arising from HIV disease in eligible individuals."[2] Only individuals living with HIV and residing inside the particular jurisdiction can access ADAP services. Additionally, ADAP funds are intended for individuals who are low income and have limited or no prescription coverage through insurance, by either purchasing medications directly, by purchasing insurance coverage (e.g., paying premiums) or by providing wrap-around assistance (e.g., paying co-pays and deductibles). Beyond these mandated eligibility criteria, ADAPs can institute additional criteria that may limit ADAP services to a more restricted client population (e.g., income level, asset limits and clinical indicators of disease status). This brief provides information to ADAPs considering a change in eligibility requirements as a way to contain or reduce program costs.

Eligibility Criteria

Income Criteria

As of June 2011, ADAP income eligibility requirements vary from 200 to 500 percent of the federal poverty level (FPL). ADAPs considering a reduction of income eligibility criteria should review existing client income data to determine if a reduction will be cost effective. If the majority of clients fall within the low ranges of FPL, such a reduction may not result in significant cost savings (see Figure One). As a requirement in the grantee's Notice of Award, the Health Resources and Services Administration (HRSA) states that ADAPs must semi-annually (i.e., every six months) recertify all ADAP clients and review income data to ensure that clients eligible for other state programs (e.g. Medicaid, Medicare Part D, state high risk pools and pre-existing condition insurance plans (PCIPs)) have been appropriately referred to and enrolled. Looking ahead, determining client eligiblity after the implementation of health care reform will be critical as many clients will be transitioning to Medicaid or private insurance offered through health exchanges.

Figure One:

ADAP Clients Served, by Income Level, June 2011
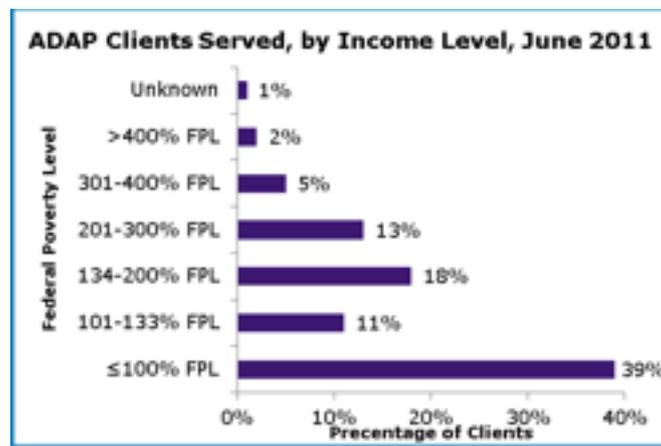
Source: National Alliance of State & Territorial AIDS Directors. (2012). *National ADAP Monitoring Project: Annual Report.*

State Spotlight on Income Criteria

South Carolina experienced significant decreases in federal and state funding in 2010 resulting in a waiting list for its direct dispensing services. After careful consideration, it was deemed that the program would be unable to sustain operations at its current growth rate without additional cost-containment strategies.

The South Carolina ADAP formed an exploratory committee of Ryan White and ADAP staff and several senior management personnel from within the health department to evaluate the effectiveness of various cost-containment options. A proposal was drafted and approved, recommending lowering the financial eligibility from 550 to 300 percent FPL for the direct dispensing program. Insurance clients were not affected by this change because the program was deemed cost-neutral.

South Carolina ADAP staff notified case managers and providers statewide of the upcoming changes in eligibility requirements through on-site trainings and electronic communication. Support was provided to ensure that the newly ineligible clients continued to receive medications through other appropriate means (e.g., pharmaceutical patient assistance programs) without any drug therapy interruptions.

Asset Limits

ADAPs may also consider a client's liquid asset information (e.g. property, bank accounts and/or pensions) as eligibility criteria. As of June 2011, 13 ADAPs had asset limits in place as part of their eligibility criteria. These limits range from $4,000 to $25,000 in annual household or individual income. Inclusion of a home, a vehicle or federally recognized retirement account as part of the asset limits is unique to each ADAP by state policy.[3] As payer of last resort, ADAPs may require that a client expend a portion of liquid assets prior to receiving assistance. ADAPs may also need to know client asset information in order to determine Medicare Part D prescription coverage assistance levels. The Medicaid expansion within the Affordable Care Act will not use asset limits to determine eligibility for states that expand beginning in January 2014. The new expanded Medicaid will use Modified Adjusted Gross Income (MAGI) which is defined by the Internal Revenue Code of 1986. ADAPs should familiarize themselves with the MAGI in order to adequately screen clients for this new option. Current Medicaid programs may continue to have asset limits for eligibility.

Clinical Criteria

ADAPs may employ one or more clinical criteria to qualify individuals for enrollment. Examples include using laboratory results showing a specified CD4 count, viral load and/or other medical test results, either as part of the application process or to access specific medications or classes of medications. As of June 30, 2011, all ADAPs required individuals to provide clinical documentation of HIV infection, while six ADAPs required additional

clinical laboratory criteria (e.g., specific CD4 count).[4]

ADAPs should involve their state's ADAP Advisory Committee in developing clinical eligibility criteria and determine exceptions to clinical criteria (e.g., pregnancy or active opportunistic infection). Once implemented, ADAPs should also have a review process in place to assure that the criteria are being met. In addition to developing a review process, ADAPs should consider clinical oversight of applications either by a medical provider or trained non-clinical staff member to monitor clinical data received. Clinical eligibility criteria are most often implemented for specific medications or classes of medications, such as fusion inhibitors and entry inhibitors.

State Residency

All ADAPs require enrollees to be residents of the state in which they are seeking medications. Many ADAPs require documentation of residency and a few have specific residency requirements (e.g., must be a resident for 30 days). Residency reviews help to maintain and monitor ADAP rosters during enrollment and recertification audits, which help limit fraud and ensure eligible clients are getting necessary support, especially in states that have waiting lists.

Eligibility Criteria Checklist

When considering changes to eligibility criteria as a cost effectiveness strategy, ADAPs should:

- Collaborate with or consider the eligibility criteria of other state programs that may assist people living with HIV (e.g. Medicaid, Medicare Part D, high risk pools, PCIPs, and health exchanges).

- Be familiar with any state legislation and administrative regulations that may impact the program's ability to make changes to ADAP.

- Determine if changes are economically feasible and administratively manageable for the program based on the current staff capacity and internal processes.

- Follow the internal state agency process for review and approval of changes to ADAP policies and regulations.

- Involve the state's ADAP Advisory Committee in reviewing and recommending eligibility criteria.

- Communicate with the community about the reasons for changes and how they will be operationalized.

- 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 eligibility criteria, when and if significant challenges arise, and when any changes are 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
  - 340B 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] Human Resources and Services Administration. "ADAP Manual – 2003 Version." Available at http://hab.hrsa.gov/Resources/adap/section1part2.html
[3] National Alliance of State & Territorial AIDS Directors. (2012). National ADAP Monitoring Project Annual Report.
[4] National Alliance of State & Territorial AIDS Directors. (2012). National ADAP Monitoring Project Annual Report.