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). 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 third in a series of four ADAP technical assistance briefs focusing on cost effectiveness strategies. Other topics include: Eligibility Criteria, Formulary Utilization Management and Coordination of Benefits.

Some ADAPs have implemented waiting lists because of an increased demand for services, heightened by national efforts focused on HIV testing and linkages into care, and new HIV treatment guidelines recommending earlier therapeutic treatments, and high medication costs. State and federal appropriations have not been able to meet this increased need, even with additional emergency relief funding.

What Is A Waiting List?

A waiting list is a strategy used when adequate funding is not available to provide medications to all eligible persons requesting enrollment in the state ADAP after implementing all other feasible cost-effectiveness strategies (e.g., lowering federal poverty level [FPL], reducing formulary, capping costs, etc.). ADAPs verify overall eligibility for the program and place eligible individuals on a waiting list, as necessary, prioritized by a pre-determined criterion (e.g., medical status of need, or date of application). ADAPs manage waiting lists to move clients into the program as funding becomes available. Any program that does institute a waiting list, must work with case managers and other providers to ensure that individuals are receiving their medication through other programs (e.g., pharmaceutical Patient Assistance Programs [PAPs]).

Frequency of ADAP Waiting Lists

According to NASTAD’s bi-monthly ADAP Watch surveys conducted between July 2002 and April 2012 (see Figure One):

- Twenty-seven states had a waiting list at least once during the period.
- Ten states had a waiting list in place as of April 2012.
Waiting List Models

If, after implementing all other feasible cost-effectiveness strategies (e.g., lowering federal poverty level (FPL), reducing formulary, capping costs, etc.), demand for ADAP services continue to outpace available resources, a waiting list may become necessary. From an administrative perspective, creating and managing a waiting list is a challenging process. Among the issues ADAPs face are:

- How to monitor the waiting list?
- How do clients access medications while on the waiting list?
- How will clients be transitioned from the waiting list to the ADAP?
- What ethical principles will be used to develop policies and procedures for the management of the waiting list?
- What other options are available to reduce or eliminate the need for waiting lists?

In order to address each of these issues in an efficient, equitable and effective manner, the state should work closely with its ADAP Advisory Committee. Before creating a waiting list, ADAPs should review models used by other states and their “lessons learned.” Equally important, ADAPs must publish their policy to the community of clients, providers and case managers, and then ensure that these policies are administered consistently across the state.

**First-come, First-served Model**

An ADAP waiting list using a first-come, first-served model is generally structured to place any individual applying to ADAP on the waiting list, in order of receipt of a completed enrollment application and eligibility confirmation. ADAPs may choose to require that all applications be completed through a case manager. This requirement ensures that each applicant has the opportunity to work with a case manager to access HIV medications through other mechanisms, such as pharmaceutical Patient Assistance Programs (PAPs), while on the waiting list.
Hierarchical Criteria Model

Hierarchical criteria are typically established by the state based on recommendations from its ADAP Advisory Committee, which should include HIV/AIDS medical specialists, other service providers, pharmacists and consumers. Examples of waiting list hierarchical criteria include the following:

- Pregnant women (risk of vertical transmission)
- An individual diagnosed with any AIDS-defining condition
- An individual with acute opportunistic infections (e.g., tuberculosis, toxoplasmosis, Pneumocystis jirocevi pneumonia, etc.)
- An individual with a lower CD4 count (e.g., <200 cells/mm3)
- An individual with a rapidly declining CD4 count (e.g., >100 cells/mm3 decrease per year)
- An individual with higher viral loads (e.g., >100,000 copies/mL)
- An individual with HIVAN (HIV-associated nephropathy)
- An individual with hepatitis B and/or hepatitis C co-infection and when treatment is indicated

Ethical Considerations

General ethical considerations for public health, as well as HIV/AIDS treatment-specific guidelines, are relevant to guide the development of ADAP waiting list criteria. While these considerations can conflict and will not apply to every situation, it is important to maintain a consistent and fair process for access to ADAP. There are important ethical principles to consider when developing a waiting list.

It is also important to keep in mind that the Department of Health and Human Services (HHS) Guidelines for the Use of Antiretroviral Agents in HIV-I-Infected Adults and Adolescents have ethical, as well as clinical implications, for ADAPs and clinicians. For example, the “Guidelines:”

- Recognize that there are subgroups of patients or special populations where specific considerations are critical when selecting and monitoring antiretroviral treatment, in order to assure safe and effective treatment, including: patients with acute HIV infection, HIV-infected adolescents, injection drug users, women of child bearing potential and pregnant women, and those with hepatitis B or C, or tuberculosis co-infections.
- Recommend against complete antiretroviral cessation in late treatment failure as this has resulted in rapid progression to AIDS and death.
- Discuss when treatment should be initiated with asymptomatic patients: “Antiretroviral therapy (ART) should be initiated in all patients with a history of an AIDS-defining illness or with a CD4 count <350 cells/mm3,” but also recommend ART for patients with CD4 count between 350 and 500 cells/mm3.” A review of the literature on this issue can be seen in the “Initiating Antiretroviral Therapy in Treatment—Naïve Patients” section.
Waiting List Management

Managing an ADAP waiting list is of crucial importance and has ethical dimensions as well. Patients on waiting lists should be provided with clear and understandable information about:

- Why his/her access to drugs through ADAP is being delayed and the options and alternatives that are available.
- The objective and standardized waiting list criteria that have been established with the guidance of health experts.
- The approximate length of time one can expect to remain on the waiting list before access to drugs through ADAP becomes available.
- Information on how to access needed medications through other sources.

ADAPs work with individuals on the waiting list and their case manager to access HIV/AIDS prescriptions through PAPs or other medication assistance or insurance program options. HRSA/HAB does require that ADAPs with waiting lists ensure that these individuals are able to access their medications through other programs. Keep in mind that PAPs may require people to apply often, sometimes as frequently as every month, and separate applications must be sent to the manufacturer for each prescribed medication needed. For someone on a multiple drug regimen, this process can be quite time-consuming and cumbersome. Medication delivery methods and timing of when a client receives the medications may vary by company as well. For individuals with special needs the process can be completely overwhelming.

Access to Treatment for Individuals on an ADAP Waiting List

Currently, when an individual is placed on an ADAP waiting list, the individual (or with the assistance of a case manager) has to apply for a PAP with each individual pharmaceutical company. This can be tedious and time-consuming and can create delays in receiving necessary medications. NASTAD is working with its partners to streamline this process through the use of one application and screening through a clearinghouse or online portal. Additional information on individual manufacturer’s co-payment assistance programs and PAPs is available on the Positively Aware website and the Fair Pricing Coalition’s website.

In 2010, Welvista, a non-profit mail-order pharmacy based in South Carolina, began to provide HIV medications to individuals on ADAP waiting lists, rather than use individual PAPs. ADAPs are able to refer clients directly to Welvista with a simple certification form and to ensure that all ARV medications are received at once and that there is easy transition and no delays in receiving life-saving medications. Welvista is supported by pharmaceutical partners, such as Abbott Pharmaceuticals, Bristol-Myers Squibb, Boehringer Ingelheim, Gilead Sciences, Janssen Therapeutics, Merck and Company, and Viiv Healthcare. Welvista is currently licensed to dispense medications in 20 states and is seeking licensure in seven more. Visit Welvista’s website for more information.

In order to effectively monitor the status of ADAP eligible individuals on the waiting list, case managers may be responsible for providing a monthly update to ADAP on the status of their clients’ access to medications and any changes in the applicants’ eligibility status. All monthly updates should be documented on a waiting list log.

When an ADAP slot becomes available, the eligibility status of the person next-in-line on the waiting list should be confirmed prior to moving that person from the waiting list to active enrollment in ADAP. Once confirmed, ADAPs should notify the applicant, the case manager and the appropriate ADAP pharmacy or pharmacy benefits manager.
ADAPs should employ an objective, fair process that will provide legitimacy to the decisions made. A fair process should include:

- Being public and transparent about why, what and how
- Having an appropriate and ethical rationale for the ADAP waiting list model and process
- Appropriate stakeholders’ involvement in developing and implementing the process
- A revisions and appeals mechanism

### State Spotlight on Waiting Lists

**Iowa** ADAP started a waiting list twice, in 2004 and 2009, and used a hierarchical medical criteria model. The options for implementing new cost effectiveness strategies were limited as Iowa has always operated with a very modest formulary, strict eligibility requirements set at 200 percent FPL, and until 2005, no additional financial contributions to the program by the state. Both periods with a waiting list required educating all case managers about the tools necessary to ensure ADAP as payer of last resort, and the requirement that only completed applications could be processed to ensure qualified individuals were enrolled.

In 2005, Iowa ADAP added a resource limit of $10,000 for added assurance that the most in-need had access. But, more importantly, in 2005, the Iowa legislature learned of the situation and allocated enough funding to not only eliminate the waiting list, but to open the program to new enrollees. This was in large part thanks to the formation and organization of a group of advocates as well as the identification of legislative champions.

In 2009, the state funding that Iowa ADAP had received was declining due to the economic downturn. All other cost effectiveness strategies had been thoroughly examined and deemed to already be in place and a waiting list was reestablished. Elimination of the waiting list in 2010 was a result of the new federal funding available through the ADAP Emergency Relief Funding. Since 2010, the program has remained open to new enrollees through the collection of rebates and monitoring expenditures, enrollment and program utilization.

**North Carolina** ADAP initiated a waiting list in January 2010 as a result of a budget shortfall. Implementation of a waiting list ensured current enrollees would not be disenrolled and would be served through the North Carolina ADAP. North Carolina has used a first-come, first-served model for prioritization for enrollment into ADAP.

North Carolina ADAP began an aggressive education campaign to provide information about PAPs to clinicians, case managers and clients prior to establishing the waiting list. When Welvista became available in North Carolina, ADAP also provided information about that program to clinicians, case managers and clients.

On July 12, 2010, due to a substantial increase in the state budget, 654 individuals were moved off the waiting list and enrolled in the North Carolina ADAP. The funding increase came from strong support from the governor, state legislators and advocates. The program was reopened to individuals with the greatest need; for applicants whose net income is equal to or less than 125 percent FPL level, as mandated by the General Assembly in 2006. New applicants whose income is between 126 and 300 percent FPL continue to be placed on the waiting list and are referred to PAPs and Welvista.
Waiting List Management Checklist

When considering instituting or changing waiting list procedures, ADAPs should:

- Be familiar with state legislation and administrative regulations that may impact the ability to make changes in ADAP or establish a waiting list.
- Consult other ADAPs that have investigated and/or adopted a waiting list to find out how they approached it, the results and lessons learned.
- Determine if they are economically feasible and administratively manageable for the ADAP in light of current staff capacity and internal administrative processes.
- Follow the internal state agency process for review and approval of changes to the ADAP.
- Communicate with your HRSA Project Officer and NASTAD when the state is considering implementing a waiting list, when and if significant challenges arise, and when any changes are actually implemented.
- Participate in NASTAD’s monthly conference call with all ADAPs managing a waiting list and those considering implementing a waiting list to openly discuss the challenges and strategies to carefully manage a waiting list.
- Anticipate problems with client participation on the waiting list that may occur with implementation and develop procedures to respond rapidly to address unintended consequences.
- Communicate with the community about why and when the ADAP will introduce a waiting list.
- Educate clients and case managers about the waiting list, including how long a client can anticipate being on a waiting list and other options for receiving medications.
- Train case managers on how to maintain a client on the waiting list and how to enroll clients through PAPs and other medication access programs.
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.

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