

Maximizing Access To Medications Through Efficient Use of Care Act Resources

Health Resources and Services Administration • HIV/AIDS Bureau • May 2005



INTRODUCTION

STUDY 1:

Factors Contributing to Variations in
Per Capita State AIDS Drug
Assistance Program Expenditures

STUDY 2:

ADAP Supplemental Funds

STUDY 3:

The Role of Title I-Funded AIDS
Pharmacy Assistance Programs in
Ensuring Access to HIV Therapeutics

STUDY 4:

Issues Associated With Capped
Enrollment and Waiting Lists

> Methodology/Limitations

> Major Findings/Discussion

> Recommendations

Major Findings and Discussion

ADAPs' decisions to cap enrollment are based on attempts to forecast demand and costs as well as on close monitoring of ongoing expenditures. ADAPs with capped enrollments or waiting lists, however, then rely on "back-of-the-envelope" forecasting approaches, finding other available tools too cumbersome.

All ADAPs reported that the primary factor causing capped enrollment policies was a combination of increased costs and increased demand for services. Administrative and political factors (at the State level) were not seen as significant contributors to the cap. Common factors resulting in capped enrollment included increased applications for ADAP enrollment; increased rates of utilization of medication on the formulary among ADAP clients; lower rates of people enrolling in the Supplemental Security Income (SSI) Program and Medicaid; longer duration of enrollment among ADAP clients; and rising medication costs. Reduced State funding or State funding that did not keep pace with programmatic expenditures of ADAPs aggravated all those factors.

All but three ADAPs reported that their cap applies to the entire ADAP formulary. Three ADAPs have a separate cap on a specific medication (Fuzeon).

All ADAPs reported estimating expenditures per enrollee as a basis for setting the enrollment cap at the beginning of a fiscal year. They use three variables for this forecast: average expenditures, total number of enrollees and applicants, and total available funds. Two ADAPs also estimate future medication costs. ADAPs reported that current tools provided by HAB to forecast expenditures are difficult to use and not more informative than using the simple formula described.

All ADAPs monitor expenditures and utilization to determine when capped enrollment must be enforced. Eleven ADAPs monitor the data monthly, two monitor the data weekly, and one State monitors the data every other month. All ADAPs reported that the determination of the cap and level of the cap is based exclusively on the amount of funds available at the time the determination is made. ADAPs reported keeping data mostly in the form of Excel spreadsheets that are updated by ADAP staff.

All ADAPs reported similar processes in operationalizing capped enrollment. ADAPs begin by disseminating information about the cap to various constituencies. On the government level, States reported requesting additional State funding for the ADAP as a starting point for making State legislators aware of the situation. Only one ADAP reported receiving additional dollars. Several ADAPs have approached their Title I programs and received funding or other support. ADAPs use several avenues (e.g., statewide planning groups, a governor's advisory council, regular meetings with State legislators, and health department administrators) to increase public awareness of the ADAP and its needs.

ADAPs reported consultations with various officials and groups regarding development and implementation of capped enrollment. These include community advisory boards; scientific, clinical, and medical advisory groups; community planning boards; health department directors and administrators; and program and financial staff.

ADAPs define capped enrollment differently; most ADAPs have established a "hard" cap—setting a maximum number of enrollees who can be permitted in the program. Others have created a "rolling" cap that adjusts to demand on a monthly basis.

"Capped enrollment" generally meant that an ADAP had determined a set number of enrollees that could participate in the program; several States reported having "rolling" caps, a limit of enrollees in the program that changes throughout the year based on available funding and program costs. For example, one ADAP caps annual enrollment at 200 clients. This number does not change throughout the year. Another ADAP has a rolling cap, currently set at 135, which changes as program staff evaluate program utilization from the past month and add clients as funding allows. For ADAPs with rolling caps, capped enrollment is based on available funding, so no set number is determined.

Eleven of the interviewed ADAPs reported capping the number of clients that are enrolled in the program. The cap ranged from 70 clients to 1,250 clients. Five ADAPs reported hard caps that had been exceeded. Four ADAPs reported rolling caps that were at capacity. One ADAP reported having set a hard cap but not having reached the number, and one ADAP reported its cap as a monetary cap of \$1,200 per client per month, which had been exceeded. (This ADAP had no cap on the number of clients.)

Given underlying variability in available resources and, thus, variability in eligibility requirements

(Table 4), ADAPs cap enrollment at different levels. Because ADAPs are given flexibility in determining eligibility criteria (including income levels) for the program, an applicant at a certain income level might be waitlisted in one State and not in another.

ADAPs vary in the steps taken to contain costs prior to imposing capped enrollment. All ADAPs have considered a standard set of cost-containment measures (e.g., reduced formulary, change in eligibility rules, use of 340B pricing, use of ADAP Task Force negotiated prices, back-billing third-party payers, and imposition of client co-payments), but no standardized approach to cost-containment yet exists.

All ADAPs reported having used other budget control measures before implementing capped enrollment. Those measures include using a reduced formulary (3 States); changing the eligibility rules (2 States), using 340B pricing (7 States), using ADAP Task Force contracts (11 States), and back-billing Medicaid and other sources (3 States). Several ADAPs specifically mentioned ruling out several of these options, most commonly the reduced formulary, client copays, and lowering the income eligibility as a percentage of Federal Poverty Level (FPL). At least in some cases, the ADAP determined that the cost savings were insufficient to be worth the change in policy. For a full discussion of the policy opportunities in this area, see GWU's earlier report prepared under this Task Order, The AIDS Drug Assistance Program: Assessing the Use and Distribution of Scarce Resources, submitted to HAB in May 2004.

Table 4. ADAP Eligibility Requirements

State	Federal Poverty Level %	Income	Household, Family, or Individual Income	Asset Limits	Require No Insurance	Medicaid Denial Letter, Application, or None
Alabama	250	Gross	H	N	Y	A
Alabama	250	Gross	H	N	Y	A
Arkansas	300	Gross	H	N	N	DL
Idaho	200	Gross	F	N	Y	A
Iowa	200	Gross	F	Y	N	A
Kentucky	300	Gross	H	N	N	DL
Montana	330	Net	F	N	N	DL
North Carolina	125	Net	F	N	N	A
South Dakota	300	Gross	H	N	N	A
West Virginia	250	Gross	F	N	N	DL
Indiana	300	Gross	H	N	N	DL
Oklahoma	200	Gross	F	N	N	DL
Massachusetts	\$50,000/yr and \$2,900/dependent	Gross	I	N	N	DL
Missouri	300	Gross	I	N	N	A
New Mexico	300	Gross	F	N	N	N

Most ADAPs maintain waiting lists. ADAPs, even those not maintaining formal waiting lists, continue to receive and process new applications to determine program eligibility.

In all the ADAPs interviewed, case managers continue to take and forward applications for the program after the cap has been reached. Applications are sent to the ADAP staff where they are either held until a slot becomes available or the person is put on an official waiting list. Case managers trained to provide assistance to clients through other programs, primarily patient assistance programs established by the pharmaceutical companies. Case managers are updated regularly (usually monthly) on the status of clients on waiting lists. Clients are informed by letter regarding their status. All ADAPs provide this letter to clients. A copy of the letter is usually sent to the case manager. Information on the client (e.g., updating of address, current medical status) is maintained by the case managers at the organization level.

All ADAPs that maintain waiting lists determine client eligibility for the ADAP before placing them on the waiting list. The level of review of the applications varies for ADAP enrollment in general. For example, some States do not require proof of Medicaid denial or State residency, only statements to that effect. Variation also occurs in how frequently people on the waiting lists are recertified for eligibility in the program, though this generally follows the program's criteria for recertification.

Data collected vary from State to State. ADAPs reported using the following data to determine eligibility and add the applicant to the waiting list: FPL (12 States), residency requirement (12 States), Medicaid

denial (7 States), no insurance (2 States), and asset limits (1 State). All ADAPs verify eligibility at the ADAP programmatic level after receiving the applications. Providing proof of residency, Medicaid denial, etc., varies. Some ADAPs require documentation, while others do not.

All ADAPs regularly review the status of current clients to determine whether a slot can be opened for someone on the waiting list.

Variability exists in how ADAPs make room for applicants to be moved from the waiting list. All ADAPs use recertification (meeting the criteria set by the ADAP to be eligible for the program) to open slots. Twelve ADAPs reported that they conduct recertification yearly, two ADAPs reported that they recertify every 6 months, and one ADAP reported recertifying every month. Eight ADAPs recertify applicants on the waiting list before they are placed on the program, unless they have been on the list less than 4 months (on average). Several ADAPs move clients off the program if they have not filled prescriptions in 90 days or more (unless documentation of a drug holiday is on file), and a few ADAPs remove applicants from the waiting list who move to a Title I EMA that covers medications.

Coordination between ADAPs and Medicaid programs varies. Some ADAPs have excellent working relationships, including online access to Medicaid eligibility verification systems; other ADAPs have essentially no working relationship with the Medicaid program, even with regard to eligibility determination.

ADAPs reported the following approaches to coordination with State Medicaid programs: access to online eligibility database (five States), access to phone eligibility database (five States), regular meetings with Medicaid staff (three States), and meetings at the case manager level (one State). Four ADAPs reported no coordination or contact. Some ADAPs reported a positive and highly interactive relationship with their Medicaid program, whereas others reported a poor, almost adversarial relationship with their Medicaid counterparts. Personal relationships provide the best hope for strong program coordination, but with strained Medicaid budgets, these relationships were not always helpful in coordinating programs.

No ADAP reported coordination between ADAP staff and the Social Security Administration (SSA) in determining SSI eligibility. Seven ADAPs reported this coordination as taking place at the case management level, although most reported that such coordination depends on personal relationships between case managers and SSA staff.

Clients on waiting lists receive varying levels of support in enrolling in pharmaceutical company patient assistance programs (APAs). Case managers have had a variety of levels of training and experience with this usually complex process, which requires different application forms for each pharmaceutical company.

All ADAPs reported having processes (although not written policies) for assisting clients in finding other sources of medications while on the waiting list. All reported that case managers are trained to assist clients in accessing APAs and are responsible for helping the client fill out the applications. Two ADAPs reported that clinics provide assistance in filling out applications for the programs. All reported that the APA application process is cumbersome because each pharmaceutical company has its own application process and most clients must apply to more than one company to cover their drug regimen.

Most waiting list policies and procedures are not in writing, and the process for their development is not always transparent. Many ADAPs acknowledged that the lack of written policies and procedures for the management of waiting lists, including criteria for transitioning applicants off waiting lists to enrollment, has created challenges in terms of "institutional memory." Given ADAP staff turnover, the absence of documentation diminishes continuity of programmatic operations. Although all ADAPs consult with outside experts in determining capped enrollment and waiting list protocols, it is unclear that consistent consumer involvement is part of their development.

ADAPs reported enacting caps as early as December 1997 and as late as May 2004. Most States enacted their caps in late FY 2002 and FY 2003. Several ADAPs reported seeing a spike in utilization and enrollment in late FY 2003 but were unable to determine the reason for the spike.

ADAPs were asked how providers, pharmacies, case managers, and clients are informed about the existence of a cap for their ADAP. The strongest link is between providers and ADAP staff: Most ADAPs reported that providers are contacted by telephone. Some ADAPs also use letters and emails or faxes to provide information. All ADAPs inform the providers (i.e., individual providers, agencies, organizations) of the cap. Several ADAPs have a centralized pharmacy, so they provide the information in person or by telephone, email, or fax. ADAPs that have reimbursement programs (through various pharmacies) reported that they provide a letter or, in the case of five ADAPs, that they do not inform the pharmacy that they have a cap on ADAP enrollment.

All ADAPs inform the case managers, primarily by telephone (but also by letter, fax, or email), that a cap is in place. Most ADAPs inform the case managers about the ceiling number of ADAP clients, the status of the cap, and the likelihood that the cap will be exceeded and that clients will have to wait for services. ADAPs indicated that this is the most important relationship of the three—relying on the case managers to provide information directly to clients. Because ADAPs are aware of the names of ADAP clients' case managers and because the number of case managers is relatively small, information about the status of the ADAP is

usually accurate and up-to-date.

All ADAPs rely on case managers to provide information to clients regarding capped enrollment. However, most clients are not informed unless they are placed on a waiting list. Most communities have consumer groups that are informed of issues, including capped enrollment and waiting lists, through regular meetings or other correspondence. But ADAPs reported that this information does not always get disseminated in a way that informs potential applicants. ADAPs reported that the same communication mechanisms that are used to announce the cap are used to inform providers, pharmacies, case managers, and clients when the cap has been lifted.

Two ADAPs reported that they have written policies and procedures on program caps (rationale, design, implementation, operationalizing, and maintenance). Two ADAPs reported written policies and procedures in development. All other ADAPs reported that they have no written policies and procedures, although program staff had developed internal protocols and procedures. Some ADAPs recognized this as problematic because loss of staff could cause loss of institutional knowledge about how the cap was developed and is operationalized.

Four ADAPs reported that they have written guidelines for their waiting list. Six ADAPs reported that they have no written guidelines, and four reported that they are in process of writing guidelines. These guidelines cover the process of managing the list, determining how applicants are placed on the list and removed from it, and providing assistance to applicants while they are on the list.

Eleven ADAPs reported relying on case managers to gather information about applicants being placed on the waiting list (completing the application and maintaining contact information). The case managers fill out the information and keep the client informed about movement of applicants on the list. Six ADAPs reported that ADAP staff also collect information on the applicants. No ADAPs reported that providers are involved in collecting information.

Criteria for moving applicants off waiting lists vary by ADAP. Some ADAPs use a strict “first come, first served” approach; others use a medical need approach (e.g., pregnant women, those with severely compromised immune systems) or a combination of the two. Most ADAPs move applicants from the waiting list to ADAP enrollment as slots become available, although at least one ADAP reported waits for enough slots to open up to move the entire waiting list at one time.

All ADAPs with waiting lists reported that they manage the waiting list at the ADAP programmatic level. Priority for placement on the list was reported as follows: first come, first served (nine States); medical need (six States); pregnant women (two States); those already on medications (two States) and, those that are non- EMA clients (two States). A few ADAPs list first come, first served as their priority, but actually bump clients with medical need to the top then prioritize by first come, first served.

Priority determination was developed in various ways: Program staff developed the guidelines; ADAP staff talked to each other to determine the best priority list; medical advisory boards were convened to determine the priority list; standing clinical care committees or ethics committees were used to determine the priority list; clinical advisory boards were used to set medical eligibility criteria for priority; and other methods were used. Most ADAPs did not include consumers in determining priority lists.

ADAPs reported simple policies and procedures for moving applicants off the waiting list. For example, when a space (or spaces) become available, the person (or group) of persons is moved off the list. However, some ADAPs wait until they have enough slots available to move all applicants off the waiting list at one time. Other ADAPs move applicants off the waiting list one at a time. Both clients and case managers are notified by letter.

[<< STUDY 4: METHODOLOGY/LIMITATIONS • STUDY 4: RECOMMENDATIONS >>](#)