

**The National  
ADAP  
Working Group**

An AIDS Drug  
Assistance Program  
Advocacy Coalition

1773 "T" Street, NW  
Washington, D.C. 20009

Ph: (202) 588-1775  
FAX: (202) 588-8868  
Email: [weaids@tiicann.org](mailto:weaids@tiicann.org)

aaa+ ADAP Advocacy Association  
Abbott Laboratories  
AIDS Alabama  
AIDS Action Council  
AIDS Alliance for Children,  
Youth & Families  
AIDS Foundation of Chicago  
AIDS Project Los Angeles  
AIDS Treatment Data Network  
American Academy of HIV Medicine  
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National Minority AIDS Council  
Positive Opportunities  
SAVE ADAP Inc.  
Southern AIDS Coalition (SAC)  
The AIDS Institute  
Tibotec Therapeutics  
Title II Community AIDS  
National Network

2/08

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Director  
William E. Arnold

**Ryan White CARE Act, Title II**

**AIDS Drug Assistance Program  
(ADAP)**

**Annual  
Ryan White CARE Act –Part B (Title II)  
ADAP Needs Projection.**

**ADAP Program Year  
(1 April, 2009 – 31 March,2010)**

**Funded by the Federal Budget  
For**

**FY 2009**

**Budget Projection**

**#45**

**Complete Projection, with slides - 27 Pages**

**10 February, 2008**

**Copies of this pharmacoeconomic model projection are  
available electronically on [www.tiicann.org](http://www.tiicann.org) or - contact us.**

## **Introduction to the ADAP Budget Projection Model, Fiscal Year 2009**

The National ADAP Working Group is a unique ad hoc coalition of HIV/AIDS community-based organizations, health care providers, biotechnology and pharmaceutical research companies. Our mission is to ensure adequate access to HIV/AIDS-related therapies through the AIDS Drug Assistance Program (ADAP), funded under Title II of the Ryan White CARE Act.

ADAP has played a key role in the federal and state response to the U.S. domestic AIDS epidemic. Since the advent of Highly Active Anti-Retroviral Therapy (HAART) in 1996, ADAP has provided preventative medications to hundreds of thousands of Americans living with HIV who are uninsured or underinsured, keeping them out of costly hospital care and off Medicaid. With advances in treatment research, managing HIV disease has become a life-long commitment. Combined with new HIV infections at the rate of 60,000 per year, the demand for ADAP continues to grow.

In order to quantify this growing need, the National Alliance of State and Territorial AIDS Directors (NASTAD), working with national ADAP experts, have utilized a pharmacoeconomic model<sup>1</sup> to project the amount of funding needed to adequately treat Americans eligible for ADAP in upcoming fiscal cycles. Using current utilization trends as reported in a June 2007 survey through the National ADAP Monitoring Project<sup>2</sup>, this model computes the increased annual cost of pharmaceuticals to ADAP, based on current program dispensing patterns, increases in new ADAP clients at historical rates and drug cost inflation.

This pharmacoeconomic model enables us to estimate the economic need of the ADAP program for the upcoming fiscal year. This “need” number represents the amount that would allow each state to provide treatment for ADAP clients under the current eligibility rules for each individual state.

For the next fiscal cycle, however, two recent changes to the environment in which ADAP operates suggested the need for a revised approach to estimating the budget need. First, reauthorization of the Ryan White Care Act has resulted in a significant shifting of ADAP Earmark funds between states due to a revised

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<sup>1</sup> J Acquire Immune Defic Syndr. 2000 Apr 1;23(4):302-13. Impact of zidovudine-based triple combination therapy on an AIDS drug assistance program. Mauskopf JA, Tolson JM, Simpson KN, Pham SV, Albright J. Research Triangle Institute, Research Triangle Park, North Carolina, USA.

<sup>2</sup> The National ADAP Monitoring Project is a collaborative project of the Kaiser Family Foundation and the National Alliance of State and Territorial AIDS Directors (NASTAD).

distribution formula and an increased proportion of the allocation set aside for ADAP Supplemental funds to address access disparities in FY07. Waiting lists have been eliminated, and formularies and income eligibility criteria have been increased in states, where access has been limited for years.

The second change that has impacted ADAPs nationally is implementation of Medicare Part D. Many individuals who had previously relied on ADAP for access to medications have enrolled in Part D. Those eligible for the Low Income Subsidy (LIS) have the vast majority of their drug expenses paid by Part D. However, many other individuals with Part D coverage continue to receive assistance from ADAPs to meet their deductibles and co-payments, and receive full coverage from ADAP when they reach the “donut hole”.

Due to both of the environmental changes (Ryan White funding changes and Medicare Part D) and an increase in State appropriations for ADAP and increased rebates from drug companies, ADAPs nationally were in a state of budget “equilibrium” in FY07 and were able not only to reduce formulary and eligibility disparities between states but to provide access to medications to all eligible individuals. This has led to a revised focus of the projection model, to estimate the incremental costs required to provide coverage for new clients enrolled in ADAPs in FY08 and FY09. Total funding is calculating by adding the incremental costs to the inflation-adjusted drug costs for the base population of ADAP clients enrolled in FY07. Additionally, rather than estimating medication costs through modeling, ADAP drug expenditure data are used to calculate the average monthly medication cost per client.

The analyses does not attempt to account for further possible changes in eligibility criteria; drug formularies; changes in state Medicaid or other public health insurance programs; or other possible variables that could impact state ADAPs in the future.

**Projection Summary**

For FY2009, ADAP needs a federal increase of **\$134,845,718** to adequately meet the projected program demand. In addition, the model estimates a federal ADAP shortfall in the amount of **\$39,591,618** for FY2008.

**Summary Table**

	<b>FY 2008</b>	<b>FY 2009</b>
Model Projected Cost for New ADAP clients	\$25,207,129	\$73,810,172
Base Program Drug Inflation Component	+ \$43,282,393	+\$45,257,453
FY08 Revenue Need Remaining		+\$49,489,522
<b>Total ADAP Budget Increase Required</b>	<b>\$68,489,522</b>	<b>\$168,557,147</b>
FY 2007 Federal Appropriation Increase	- \$19,000,000	-\$0
<b>Total Revenue Increase Needed</b>	<b>\$49,489,522</b>	<b>\$168,557,147</b>
<b>80% Federal Share of Increase</b>	<b>\$39,591,618</b>	<b>\$134,845,718</b>
20% State Share of increase	\$9,897,904	\$33,711,429

**Projection Model Details**

**1. Base population and estimated monthly program growth**

Using annual ADAP utilization data (number of clients who have filled at least one prescription), from June 2006-June 2007, the monthly program growth rate is estimated to be approximately 386 clients. The increase in new clients is shown in the accompanying chart, starting at the beginning of FY08 (April 2008). Also shown is the total client population, based on the 101,049 clients utilizing ADAP in June 2007. Monthly client utilization is projected forward from the beginning of ADAP FY2008 (April 1, 2008) to the end of FY2009 (March 31, 2010).

**Population Growth Chart**

<b>Year</b>	<b>Month</b>	<b>Cumulative New Clients</b>	<b>Total Clients</b>	
<b>2008</b>	April	386	104,904	
	May	771	105,290	
	June	1157	105,675	
	July	1542	106,061	
	August	1928	106,446	
	September	2313	106,832	
	October	2699	107,217	
	November	3084	107,603	
	December	3470	107,988	
	<b>2009</b>	January	3855	108,374
		February	4241	108,759
		March	4626	109,145
April		5012	109,530	
May		5397	109,916	
June		5783	110,301	
July		6168	110,687	
August		6554	111,072	
September		6939	111,458	
October		7325	111,843	
November		7710	112,229	
December		8096	112,614	
<b>2010</b>	January	8481	113,000	
	February	8867	113,385	
	March	9252	113,771	

## 2. Cost of therapy per-member-per-month (PMPM)

The cost of providing drugs to ADAP clients (inflation adjusted for the projection period) is based on the weighted average cost (\$997.54) reported by ADAPs in June 2007. This approach takes into account the variability of client needs for ADAP support for both ADAP full pay and “partial pay” (e.g., partial private insurance and Medicare Part D) clients. The cost is adjusted based on the rate (19.1%) of additional “discount” that ADAPs are able to achieve through rebates and cost recoveries to arrive at a net cost of \$807.01 in June 2007. For FY2009 the PMPM for drugs is calculated to be \$862.46.

## 3. Base program drug cost inflation component

In FY2007, the total reported budget of all ADAPs was \$1,502,860,871. Under the Federal 340B Drug Program, in which all ADAPs participate, the increase in drug prices is limited to the Consumer Price Index for All Urban Consumers (CPI-U). An annual inflation rate of 2.88%, the average CPI-U for the past five years, was applied to the total budget to project the cost of maintaining coverage for the ADAP “base” population.

## 4. Health system costs

The model estimates the impact on health care system costs as a function of clients’ health status and their access to antiretrovirals and medicines for the prevention and treatment of opportunistic infections. When individuals are not provided access to these medications their HIV disease continues to progress, resulting in an increased incidence of opportunistic infections, and increased medical treatment and hospitalization costs. The model was used to estimate the FY2009 health system costs that would be incurred if funding is not available to cover new client growth. The disease status of these new clients was modeled using the CD4 count distribution of new clients in 2007 from four large states (CA, FL, NJ and NY) which represent 44.5% of June 2007 clients served. If funding limitations for ADAP in FY2009 were to leave the estimated 386 clients per month without access to medications, it is projected that 7,375 additional cases of opportunistic infections would occur. This includes 5,000 more cases of cancer (Kaposi’s sarcoma and lymphoma) and an additional 1,251 cases of pneumocystis carinii pneumonia (PCP), a fungal infection that is a major cause of death in people with HIV. In this scenario the national health care system would spend \$83,944,327 on medical treatment for opportunistic infections. This represents an increase of \$58,496,443 over what would be spent on such treatment if ADAPs had sufficient funding to enroll and provide medications to these clients.

## 5. Funding needs and clients

The following chart illustrates the number of ADAP clients that could be served by the model’s estimate of needed revenues in FY09:

Funding Source	Need Amount	Number of Clients
Federal Share (80%)	\$134,845,718	13,029
State Share (20%)	\$33,711,429	3,257

Total Need	\$168,557,147	16,286
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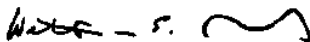
### Conclusions

- ADAPs achieved a measure of stability in FY2007 due to environmental changes and increased revenues, which allows a revision in the model to focus on the future incremental costs to ADAP.
- The revised methodology reduces the number of assumptions required and provides more accurate assessment of actual drug costs.
- There is an estimated need for \$49,489,522 in additional revenue in FY2008 to allow continued growth.
- The Federal Need in FY2009 is estimated to be \$134,845,718 to allow ADAPs to continue to meet the enrollment demands of new clients, as well as pay for the annual inflation costs for drugs to their base population.
- The model estimates that the national health system would avoid costs of \$58,496,443 for medical treatment of opportunistic infections if ADAPs are able to provide access to antiretroviral therapy for new clients in FY2009.

The ADAP Working Group endorses the enclosed budget estimates as an accurate projection of the costs of providing necessary HIV/AIDS treatments to uninsured and underinsured ADAP clients in Fiscal Year 2009, (April 1, 2009 - March 31, 2010).

It is not possible to anticipate changes in the standard of HIV care that may occur within the timeframe of this projection. The projection will be updated whenever new and validated information that impacts the projection becomes available.

It is not possible to anticipate all potential Medicare and Medicaid actions which have the potential to change access to drugs for thousands of HIV+ patients in state level Medicaid “cutback” actions or all possible impacts of the evolution of Medicare Part D in FY2008 & 2009. What we can say is ADAP history clearly indicates that “normal conditions” have produced a net monthly increase in the number of HIV+ Americans who will need ADAP services in every state, territory and political jurisdiction. With adequate ADAP resources we will be able to treat them. If resources to ADAP are inadequate – ADAPs will NOT be able to treat them, but health care costs will increase in other areas as medical providers seek to treat opportunistic infections resulting from disease progression.



William E. Arnold  
Director, The National ADAP Working Group

This is the 11<sup>th</sup> consecutive year that this ADAP projection has been generated using data reported by ADAPs and the same basic pharmacoeconomic modeling.

**The following set of 20 slides illustrate the methods utilized, the results projected (in additional detail) and provides additional information.. Contact [weaids@tiicann.org](mailto:weaids@tiicann.org) if you need additional copies of this complete document.**

These documents are all available electronically – contact us for electronic copies or web site locations.

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# Ryan White CARE Act Part B - ADAP Budget Model FY 2009

**10 February, 2008**

Computes the increased funding required to allow for  
continued enrollment of HIV positive patients in the AIDS  
Drug Assistance Programs

**A SERIES OF DESCRIPTIVE SLIDES FOLLOWS**

**The National ADAP Working Group, 1775 T Street NW, Washington,  
DC 20009 (202) 588-1775**

## Revised Focus of Model Projection

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- **Ryan White funding changes and implementation of Medicare Part D have impacted ADAPs nationally.**
- **In FY07, a state of budget “equilibrium” was achieved: formulary and eligibility disparities between states were reduced and all eligible individuals were able to obtain ADAP coverage.**
- **Consequently, the focus of the FY09 projection is on estimating the funding needed to keep pace with anticipated population growth.**
- **Additionally, it is assumed that the cost of covering the base population can be estimated as FY07 funding, inflation-adjusted to future dollars.**

# Formula and Calculations

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$$\begin{aligned} & \text{Number of New Clients} && \times && \text{Weighted Average Cost of} \\ & \text{In ADAP} && && \text{Providing Drugs} \\ \\ & \text{ADAP FY2007 Budget} && \times && \text{Annual Inflation (CPI-U) in} \\ & && && \text{Cost of Drugs} \\ \\ & \text{New Clients cost +} && = && \text{Total Increase Required} \\ & \text{Inflation cost} && && \end{aligned}$$

# Assumptions of the Model

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- **The number of clients utilizing ADAP in June 2007 was 101,049.<sup>1\*</sup>**
- **The number of clients utilizing ADAP will increase at a rate of 386 per month, from a baseline of 109,530 utilizing clients in April 2009 increasing to 113,771 in March 2010.<sup>2</sup>**

\*For all numbered references, see the Endnotes section on the last pages of these slides.

# Determining Costs in the Model

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- **Drug costs were based on ADAPs' reported expenditures and clients served in June 2007.<sup>3</sup>**
- **Drug costs were discounted by 19.1%, based on rebates and recoveries as a portion of the total ADAP budget in FY2007.**

## **Impact of Coverage on Health System Costs**

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**The full model was used to evaluate how the costs of medical treatment for Opportunistic Infections (OI's) would change if funding limitations were to leave the estimated 386 new clients/month without access to HIV medications.**

# Modeled Program Costs

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**Drug Access  
through ADAPs**

**Drug Use**

*Antivirals,  
Prophylaxis,  
OI Treatments,  
Drug Side Effects  
& HIV Related  
Treatments*

**Total Health  
Care System  
Costs**

**Immune Status  
of HIV**

**Population  
Distribution  
of CD4  
count among  
6 categories**

**Expected  
Incidence  
of OI Events**

*PCP, MAC, HSV,  
Kaposi's sarcoma,  
CMV, Candida,  
cryptococcal  
meningitis, non-  
Hodgkin's  
lympoma,  
toxoplasmosis*

*Antiretrovirals,  
Prophylaxis,  
OI diagnoses  
and treatment  
costs*

# Opportunistic Infection Treatment Costs

Opportunistic Infections	Average Annual Total Health System Cost Per Case FY2009*	Average Annual Health System Medical Costs Per Case FY2009
Cytomegalovirus retinitis	\$156,774	\$122,764
Non-Hodgkin's lymphoma	\$43,713	\$31,737
Tuberculosis	\$108,757	\$28,824
Leukoencephalitis	\$28,100	\$28,100
Toxoplasmosis	\$39,250	\$31,665
Cryptococcal meningitis	\$35,892	\$27,888
Mycobacterium avium complex	\$34,563	\$25,401
Cryptosporidiosis	\$28,983	\$22,008
Pneumocystis carinii pneumonia	\$16,750	\$16,545
Kaposi's sarcoma	\$11,780	\$5,757
Candida esophagitis	\$6,215	\$4,096
Genital herpes (GH) episode	\$4,279	\$2,547

\*OI treatment costs were derived from Medicaid reimbursement rates, Medicare physician fee schedules and MediSpan. Health System costs for OIs include both drug costs paid by ADAPs and costs for medical treatment of OIs.

# Determining Incidence Rates in the Model

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- **Number of clients on Prophylactic Therapy**
  - » Based on PHS/IDSA Guidelines for the Prevention of Opportunistic Infections
- **Number of clients on Antiretroviral Therapy**
  - » NIH/PHS Guidelines
  - » ADAP Monitoring Report
- **Number of cases for each type of OI**
  - » Based on CD4 cell distribution, drug therapies, and incidence rates from the MACS cohort data

# Population Distribution by CD4 Count\* for New Clients

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CD4 Count (Cells/mm <sup>3</sup> )	% of Enrollees
<50	21.60
51-99	6.11
100-149	6.19
150-199	6.10
200-299	14.31
>=300	45.68

\* Distribution based on CD-4 counts of new clients in 2007 from CA, FL, NJ and NY ADAPs

# Additional Assumptions

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- **All assumptions are conservative, so as not to overestimate costs.**
- **The CD4 cell levels of new ADAP enrollees are represented by the 2007 data from CA, FL, NJ and NY.**
- **Triple combination antiretroviral therapy results in a shift upwards of 100 CD4 cells.<sup>4</sup>**

# Results: Model Projected Costs for New ADAP Clients FY 2008 & FY 2009

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Parameter Estimate	FY 2008	FY 2009
<b><i>ADAP Total</i></b>	\$25,207,129	\$73,810,172
<b><i>ADAP PMPM</i></b>	\$838.31	\$862.46

# Estimated OI Cases for New Clients in FY09

Opportunistic Infection	Estimated Number of OI Cases Assuming No Program Coverage	Estimated Number of OI Cases Assuming Complete Program Coverage	Estimated Number of OI Cases Averted by Providing Coverage to New Clients
PCP	1,350	99	1,251
MAC	193	54	139
Gen. HSV Acute	7,312	2,313	4,999
Kaposi's	661	289	373
Cryptococcal	101	5	96
CMV Retinitis	155	92	63
Candida	202	25	177
Lymphoma	72	14	58
Toxoplasma	111	68	43
Cryptosporidiosis	20	12	8
Leukoencephalitis	28	6	22
Pulmonary TB	158	12	146
<b>TOTALS</b>	<b>10,364</b>	<b>2,989</b>	<b>7,375</b>

## Effect on Health System Costs

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- **In FY09, the model projects that \$83,944,327 would be spent on medical treatment of OIs if limited ADAP funds prevent new clients from having access to ARVs and OI prophylaxis.**
- **This represents an incremental cost of \$58,496,443 for medical treatment of OIs compared with the scenario in which ADAP funding is sufficient to cover new clients.**
- **Hence adequate ADAP funding results in \$58 million in cost avoidance for medical treatment of OIs in other parts of the Health System.**

# Final Projection Summary

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	FY 2008	FY 2009
Model Projected Cost for New ADAP clients	\$25,207,129	\$73,810,172
Base Program Drug Inflation Component	+ \$43,282,393	+\$45,257,453
FY08 Revenue Need Remaining		+\$49,489,522
<b>Total ADAP Budget Increase Required</b>	<b>\$68,489,522</b>	<b>\$168,557,147</b>
FY 2007 Federal Appropriation Increase	- \$19,000,000	-\$0
<b>Total Revenue Increase Needed</b>	<b>\$49,489,522</b>	<b>\$168,557,147</b>
<b>80% Federal Share of Increase</b>	<b>\$39,591,618</b>	<b>\$134,845,718</b>
20% State Share of increase	\$9,897,904	\$33,711,429

## Number of Clients Served

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**Over the 12-month period from April 2009-March 2010 (FY09) the number of additional clients that could be served by the required new funds (Need) is shown below:**

<b>Funding Source</b>	<b>Need Amount</b>	<b>Number of Clients</b>
Total Need	\$168,557,147	16,286
Federal Share (80%)	\$134,845,718	13,029
State Share (20%)	\$33,711,429	3,257

# Conclusions

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- **ADAPs achieved a measure of stability in FY2007 due to environmental changes and increased revenues, which allows a revision in the model to focus on the future incremental costs to ADAP.**
- **The revised methodology reduces the number of assumptions required and provides more accurate assessment of actual drug costs.**
- **There is an estimated need for \$49,489,522 in additional revenue in FY2008 to allow continued growth.**

# Conclusions

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- **The Federal Need in FY2009 is estimated to be \$134,845,718 to allow ADAPs to continue to meet the enrollment demand of 4,626 new clients, as well as pay for the annual inflation costs for drugs to their base population.**
- **Increasing access to drug therapy results in improved health states and fewer opportunistic infections.**
- **The model estimates that the national health system would avoid \$58M for medical treatment of opportunistic infections if ADAPs are able to provide access to antiretroviral therapy for new clients in FY2009.**

# Endnotes

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1. Monthly ADAP utilization figures were available for June 2007 from the National 2008 ADAP Monitoring Project Report, which is produced by the Kaiser Family Foundation and the National Alliance of State and Territorial AIDS Directors (NASTAD).
2. The average increase in utilizing ADAP clients was calculated as the average annual program growth rate from June 2006 to June 2007, for a result of 386 new utilizing clients per month nationally. This is less than historical trends and reflects the impact of Medicare Part D on ADAP enrollment. The baseline number of clients utilizing ADAP in April 2009 was established at 109,530. The monthly costs to ADAP nationally were projected forward on a month-by-month basis through March 2010 by adding 386 new utilizing clients for each month.

# Endnotes

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3. State ADAP programs utilize a variety of drug distribution systems resulting in a range of costs for the purchase of drugs. Distribution systems are the result of a variety of state factors, including:
  - Available infrastructure and other state systems for drug purchasing.
  - Geographic distribution of clients.
  - Access issues.
  - Scope of drug coverage (maintenance vs. acute care drugs).
  - Availability of rebates vs. discount purchasing.
  - Ability to leverage other funding sources through local distribution.

The cost of drugs used in the model is based on the weighted average monthly cost per client reported by ADAPs nationally in June 2007. It is discounted by 19.1% based on the estimated level of rebates and cost recoveries as a percentage of total budget for ADAPs in FY2007.

4. The modeled response to antiretroviral therapy is based on published clinical trial results.