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Budget - FY [Fiscal Year] '99 - ADAP [AIDS Drug Assistance Program] - Working Group

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ADAP

Working Group

An AIDS Drug
Assistance Program
Advocacy Coalition

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AIDS Treatment Data Network
Bristol-Myers Squibb
Celgene Corporation
Cities Advocating Emergency
AIDS Relief Coalition
COVANCE Inc.
Du Pont Merck
Gilead Sciences
Glaxo Wellcome
Hoffmann-La Roche
Immune Response Corp.
International Association of
Physicians in AIDS Care
Log Cabin Republicans
Merck & Co.
Mother's Voices
National AIDS Treatment
Advocacy Project
National Association of
People With AIDS
PAREXEL International
Pharmacia and Upjohn, Inc.
Project Connect
Project Inform
Roxane Laboratories, Inc.
San Francisco AIDS Foundation
Serono Laboratories
Stadtlanders Pharmacy
The National Native American
AIDS Prevention Center
Title II Community AIDS
National Network
Treatment Action Group
Triangle Pharmaceuticals

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Ryan White CARE Act, Title II

AIDS Drug Assistance Program (ADAP)

Annual Health Care Costs and Ryan White CARE Act - ADAP Needs.

ADAP Program years Funded by Federal Budgets for FY 1998 & 1999

Budget Projection

3.

15 March, 1998

**Copies, and additional information, available on the
World Wide Web at:
www.aidsinfonyc.org/awg**

March 15, 1998

Introduction to the ADAP Budget Projection Model #3

The ADAP Working Group is a unique ad hoc coalition of HIV/AIDS community-based organizations, biotechnology, pharmacy 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.

The ADAP Working Group believes that the enclosed budget projection provides an accurate representation of the cost of providing a basic standard of HIV/AIDS care to those on ADAP in Fiscal Year 1999, which runs April 1, 1999 - March 31, 2000.

The cost of treating a person with AIDS on Medicaid can be upwards of \$40,000 a year*. In fiscal 1999, adequate treatment per person on ADAP will average little more than \$10,000.00 for the year, including costs for treating and preventing opportunistic infections. Without adequate ADAP funding, uninsured and underinsured people with HIV will have to wait until they are sick and disabled in order to qualify for Medicaid and receive the treatment that could have prevented their illness. This is clearly unsound health care policy.

The impact of multi-drug anti-HIV therapy has been well publicized over the past two years. The many incremental gains in the prevention and treatment of opportunistic infections have also made a significant contribution to extending and improving the lives of people with AIDS. The stunning 44% drop in deaths from AIDS nationally in the first half of 1997 is the most recent testament to these facts. The National Institutes of Health and the Public Health Service have released guidelines on the use of antiretroviral therapy that promise to further improve the standard of care for people with HIV and AIDS.

The ADAP Working Group believes that we cannot afford to deny optimum HIV and AIDS treatment to all those that could benefit from it. The ADAP population is particularly vulnerable, often depending upon a fractured system of care and other vital Ryan White services. They should not have to decline into disability to receive the treatments they need. The following summarizes this ADAP Budget Projection:

FY '98

Projected total ADAP budget "need" for FY 1998:

\$ 554,318,812

Current estimated FY 1998 Budget available:

\$ 532,887,033**

* See footnotes for sources.

Current Projected FY 1998 Shortfall:**(\$21,431,779)******FY '99**

Projected ADAP budget "need" for FY 1999:

\$ 751,820,222

Base budget estimated available for FY 1999:

\$ 532,887,033**

Current Projected ADAP Shortfall for FY 1999: (\$218,933,189)**To address this shortfall we project needs as follows:****Federal Share (80%***): FY 1999 an increase of +\$175,146,551**

N.B. The President's FY '99 budget, request already proposes an increase over the FY '98 \$285.5 Million in "targeted ADAP" funds for the FY '99 Budget of an additional \$100 Million.

State and other sources (20%* nationally): an increase of: +\$43,786,638**

* Source: Connors, Medicaid Working Group (data from Community Medical Alliance, Santa Barbara, CA, January 1993). The 1998 inflation-adjusted annual cost of treating advanced AIDS, based on this data, would be \$53,056.00.

** These totals project a 20% state match of the FY '98 Federal ADAP increase of \$118,500,000 and may change resulting from State Legislative ADAP Budget actions during calendar 1998.

***This estimated projection percentage is derived from referencing Congressional report language. The historical ADAP budget data shows funding ratios of 74% - Federal funds and 26% State funds. The current projection avoids artificially inflating the Federal share by projecting a 20% State match of the additional FY 98 Federal appropriation (see footnote **, above).

For additional information or technical questions contact:

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• **ADAP** •

The ADAP Working Group

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Current (and previous) versions on this ADAP forecast and Congressional testimony relevant to this issue are available on the internet at:

www.aidsinfonyc.org/awg

Projection Methods

A computer model, developed by respected pharmacoeconomists, was used to estimate the cost of providing the standard of care to these utilizing ADAP clients on a month-by-month basis out to March 2000.

The model uses real world information about the immune system status of ADAP clients to project the need for preventive and acute treatment with outpatient drugs. The expected incidence of illness is based on the Multi-AIDS Center Cohort Study (MACS) by Bacellar et al (Journal of Infectious Disease 1994;170). The same model has predicted individual state ADAP expenditures within 5% of the actual totals and was used by the ADAP Working Group for previous national budget projections.

The model makes assumptions about antiretroviral therapy as described in the new NIH/PHS Guidelines. In addition to their basis in the new NIH/PHS Guidelines, these projections mirror current trends in the state ADAPs.

The model cannot anticipate the changes and refinements in standards of care which may occur within the timeframe of this projection. The ADAP Working Group will update this projection model whenever new and validated information that impacts the model becomes available.

The following slides provide more details on the methodology and the results.

Ryan White Title II ADAP Budget Model

Computes the costs for HIV positive patients
enrolled in Ryan White AIDS Drug
Assistance Programs *and* annual total
health care costs for this population

Formula and Calculations

Number of Clients* on Antiretroviral Therapy	X	Cost of Antiretroviral Therapy
Number of Clients on Prophylaxis for OIs	X	Cost of Prophylaxis for OIs
Number of Cases of Each Type of OI	X	Cost of Treatment for Each Type of OI
SUM	=	TOTAL BUDGET

* Throughout this document, "Clients" refers to the number of ADAP clients utilizing the program, i.e. filling a prescription each month

Determining Costs in the Model

- All drug costs were based on AWP - 20%^{1*}
- Treatment costs for each type of OI were based on treatment algorithms for each opportunistic disease
 - » developed by an expert panel
 - » included all resources used in diagnosis and treatment of each OI
 - » used Medicare fee schedule/RBRVS reimbursement rates from 1997 adjusted by inflation to 1999 dollars to assign monetary value for each unit in the algorithm
 - » cost per algorithm unit was summed to yield a total treatment cost for each OI, weighted to reflect different treatment options
 - » Health care system costs are limited to antiretroviral therapy and the twelve OIs contained in the model

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

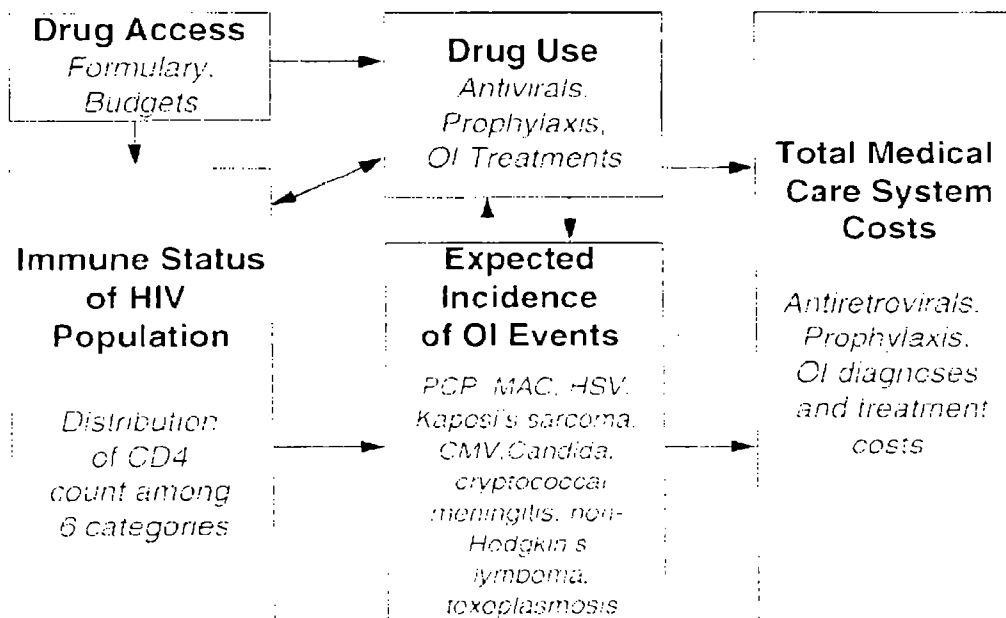
Opportunistic Infection Treatment Costs

Opportunistic Infections	Average Annual Treatment Costs 1999-2000
Cytomegalovirus retinitis	\$67,785
Non-Hodgkin's lymphoma	\$22,911
Tuberculosis	\$18,634
Leukoencephalitis	\$18,321
Toxoplasmosis	\$16,736
Cryptococcal meningitis	\$15,493
Mycobacterium avium complex	\$11,332
Cryptosporidiosis	\$11,112
Pneumocystis carinii pneumonia	\$ 9,195
Kaposi's sarcoma	\$ 3,917
Candida esophagitis	\$ 2,796
Genital herpes (GH) episode	\$ 2,649

Determining Incidence Rates in the Model

- **Number of clients on Prophylactic Therapy**
 - » Based on standard treatment for PCP, MAC, fungal infections and HSV
- **Number of clients on Antiretroviral Therapy**
 - » NIH/PHS Guidelines²
 - » 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

Modeled Program Costs



Population Distribution by CD4 Count* and Prophylaxis Rates

CD4 Count (Cells/mm ³)	% of Enrollees	Prophylaxis Assumptions
< 50	30.4	PCP, MAC, limited fungal ³
51-99	9.4	PCP and MAC
100-149	8.3	PCP
150-199	9.6	PCP
200-299	16.7	
>=300	25.6	

* Average from ADAP⁶ members in TN, TX, NY & NC

Assumptions of the Model

- The number of clients utilizing ADAP will increase at a rate of 1,000 per month from a baseline of 43,494 utilizing clients in July 1997. ⁴
- All assumptions are conservative, so as not to overestimate costs.
- Triple combination therapy includes two nucleoside analogues and a protease inhibitor*. ⁵

* zidovudine, lamivudine, indinavir

Additional Assumptions

- The CD4 cell levels of RW enrollees do not differ by state.
- Triple combination antiretroviral therapy results in a shift upwards of 50-100 CD4 cells.⁶
- The NIH/PHS Guidelines will become accepted as the standard of care for ADAP clients.

Projection of the Ryan White ADAP and Total Health Care Costs for FY 1999 - ADAP Working Group

1999

<u>Ryan White Drug Costs</u>	\$751,820,222
Total Health Care Costs	\$1,060,922,395

Conclusions

- This model estimates the cost of providing the new NIH/PHS standard of care to ADAP clients nationally
- Ryan White costs increase as additions are made to the formulary but those increases are offset by savings to the health care system

Conclusions

- In addition to health care system savings, increasing access to drug therapy results in improved health states and fewer opportunistic infections
- Higher health states maintained for longer periods of time will likely result in increased membership and higher costs for the ADAP program

Endnotes

1. 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.

Previous analyses uses a range of pricing, maximum (Average Wholesale Price) and minimum (Public Health Service price), and identified the average cost of eight antiretroviral therapies. The average price identified by this method was AWP - 15.8%. In the current projection, a rebate/discount of 20% below Average Wholesale Price is applied to all pharmaceutical costs in the model, to take into account potentially broader ADAP access to the Public Health Service pricing schedule through a rebate mechanism.

Endnotes

2. Based upon the NIH/PHS Guidelines on the use of antiretroviral therapy and the known CD4 cell distribution of ADAP clients, triple combination therapy would be recommended for close to 100% of ADAP clients. The more conservative assumption used in this projection is that 90% of ADAP clients will receive triple combination therapy and 10% will receive prophylaxis only at any given time due to the necessity of changes in regimens or client choice.

3. As fungal prophylaxis is not generally recommended for all people with less than 50 CD4 cells, the model uses recent data from the New York ADAP to assign fungal prophylaxis to 24% of this population.

4. Monthly ADAP utilization figures were available from all programs (100% reporting) for July 1996 and most recent month, July 1997. The average increase in utilizing ADAP clients was calculated using these timepoints, for a result of 1010 new utilizing clients per month nationally. The baseline number of clients utilizing ADAP in July 1997 was established at 43,494. The monthly costs to ADAP nationally were projected forward on a month-by-month basis to March 1999 adding a rounded figure of 1,000 new utilizing clients for each month.

5. The modeled response to triple therapy is based upon a clinical trial of this antiretroviral combination, conducted by R. Gulick et al. It is not possible to accurately predict the distribution of various potential antiretroviral drug combinations in FY 1999. The cost of this triple combination is used as a conservative placeholder, acknowledging that antiretroviral therapy may consist of both more and less costly combinations (including 2 - 4 or more drugs).

6. This CD4 cell response to triple therapy is based upon the clinical study cited in footnote #5.