

**AIDS DRUG ASSISTANCE PROGRAM
(ADAP)**

Fiscal Year 2020-21

November Estimate



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I. Program Overview

The California Department of Public Health (Public Health), Center for Infectious Diseases, Office of AIDS (OA), AIDS Drug Assistance Program (ADAP) provides access to life-saving medications for eligible California residents living with human immunodeficiency viruses (HIV), and provides assistance with covering costs related to HIV pre-exposure prophylaxis (PrEP) for clients at risk for acquiring HIV. ADAP services, including support for medications, health insurance premiums, and medical out-of-pocket costs, are provided to five groups of clients:

1. **Medication-only clients** are people living with HIV (PLWH) who do not have private insurance and are not enrolled in Medi-Cal or Medicare. ADAP covers the full cost of prescription medications on the ADAP formulary for these individuals. This group only receives services associated with medication costs.
2. **Medi-Cal Share of Cost (SOC) clients** are PLWH enrolled in Medi-Cal who have a SOC for Medi-Cal services. ADAP covers the SOC for medications for these clients. This group only receives services associated with medication costs.
3. **Private insurance clients** are PLWH who have some form of health insurance, including insurance purchased through Covered California, privately purchased health insurance, or employer-based health insurance; therefore, this group is sub-divided into three client sub-groups: Covered California clients, non-Covered California clients, and employer-based insurance clients. These groups receive services associated with medication costs, health insurance premiums, and medical out-of-pocket costs.
4. **Medicare Part D clients** are PLWH who are enrolled in Medicare and have purchased Medicare Part D plans for medication coverage. This group receives services associated with medication co-pays, medical out-of-pocket costs, and Medicare Part D health insurance premiums. Qualifying Medicare Part D clients have the option for premium assistance with Medigap supplemental insurance policies, which cover medical out-of-pocket costs.
5. **PrEP clients** are individuals who are at risk for, but not infected with, HIV and have chosen to take PrEP as a way to prevent infection. For insured clients, the PrEP Assistance Program (PrEP-AP) pays for PrEP-related medical out-of-pocket costs and covers the gap between what the client's insurance plan and the manufacturer's co-payment assistance program pays towards medication costs. For uninsured clients, PrEP-AP only provides assistance with PrEP-related medical costs, as medication is provided free by the manufacturer's medication assistance program.

As a covered entity in the 340B Drug Pricing Program, ADAP collects rebate for a majority of prescriptions purchased for ADAP clients. ADAP does not collect rebate for prescriptions purchased for Medi-Cal SOC, nor PrEP-AP clients. As the primary payer, Medi-Cal has the right to claim mandatory rebate on prescriptions for Medi-Cal SOC clients. In order to ensure duplicate rebate claims are not submitted to manufacturers by both programs, which is prohibited, ADAP does not invoice for rebates on these claims. ADAP also does not collect rebate on medication purchases for PrEP-AP clients because PrEP-AP is separate and distinct from ADAP and is not a 340B covered entity.

Historically, the majority of clients ADAP served were medication-only clients without health insurance because PLWH were unable to purchase affordable health insurance in the private marketplace. However, with the implementation of the Affordable Care Act (ACA), more ADAP clients have been able to access public and private health insurance coverage. ADAP clients are screened for Medi-Cal eligibility, and potential eligible clients must apply. Clients who enroll in full-scope Medi-Cal are dis-enrolled from ADAP because these clients have no SOC, no drug co-pays or deductibles, and no premiums. All clients who obtain health coverage through Covered California or other health plans can remain in ADAP's medication program to receive assistance with their drug deductibles and co-pays for medications on the ADAP formulary.

Eligible clients with health insurance can co-enroll in ADAP's health insurance assistance programs for assistance with their insurance premiums and medical out-of-pocket costs, which can only be paid for if ADAP pays the client's premium. Assisting clients with purchasing health insurance is more cost effective than paying the full cost of medications. In addition, assisting clients with purchasing and maintaining health insurance coverage improves the overall health of Californians living with HIV because clients have comprehensive health insurance and access to the full spectrum of medical care, rather than only HIV outpatient care and medications through the Ryan White system.

II. Estimate Overview

The 2020-21 ADAP November Estimate provides a revised projection of Current Year, Fiscal Year (FY) 2019-20, Local Assistance costs for medication, health insurance, medical out-of-pocket costs, ADAP enrollment sites, and administrative costs, along with projected Local Assistance costs for Budget Year, FY 2020-21.

Table 1, page 4, shows the estimated ADAP Local Assistance budget authority need for the Current Year, and compares it to the amount reflected in the 2019 Budget Act.

- For FY 2019-20, Public Health/OA estimates that the ADAP budget authority need will be \$431.3 million, which is a \$18.2 million decrease in budget authority compared to the 2019 Budget Act. The net decrease is primarily due to a decrease in projected medication expenditures partially offset by a projected increase in private insurance medical out-of-pocket expenditures (see key influences on ADAP expenditures on page 5 for more detail).
- For FY 2020-21, Public Health/OA estimates that the ADAP budget authority need will be \$467.5 million, which is a \$18 million increase in budget authority compared to the 2019 Budget Act. The net increase is primarily due to a projected increase in insurance premium and medical out-of-pocket expenditures partially offset by a projected decrease in medication expenditures (see key influences on ADAP expenditures on page 5 for more detail).

Table 2, page 4, shows the estimated ADAP revenue for Current Year and Budget Year and compares them to the amount reflected in the 2019 Budget Act.

- For FY 2019-20, Public Health/OA estimates ADAP revenue will be \$363.7 million, which is a \$15.2 million decrease compared to the 2019 Budget Act. The decrease is primarily due to a decrease in projected medication expenditures (see revenue on page 7 for more detail).
- For FY 2020-21, Public Health/OA estimates ADAP revenue will be \$370.5 million, which is a \$8.4 million decrease compared to the 2019 Budget Act. The decrease is primarily due to a decrease in projected medication expenditures (see revenue on page 7 for more detail).

California Department of Public Health AIDS Drug Assistance Program 2020-21 November Estimate Table 1: Local Assistance Budget Authority (In Thousands)								
Local Assistance	2019 Budget Act	Current Year FY 2019-20			2019 Budget Act	Budget Year FY 2020-21		
		2020-21 November Estimate	\$ Change from 2019 Budget Act	% Change from 2019 Budget Act		2020-21 November Estimate	\$ Change from 2019 Budget Act	% Change from 2019 Budget Act
Total Funds Requested	\$449,469	\$431,280	-\$18,189	-4.0%	\$449,469	\$467,464	\$17,995	4.0%
Federal Trust Fund - Fund 0890	\$135,138	\$116,571	-\$18,567	-13.7%	\$135,138	\$113,259	-\$21,879	-16.2%
ADAP Rebate Fund - Fund 3080	\$314,331	\$314,709	\$378	0.1%	\$314,331	\$354,205	\$39,874	12.7%
Caseload	34,628	32,623	-2,005	-5.8%	34,628	33,919	-709	-2.0%

Estimate numbers are rounded for presentation purposes; as a result, numbers may not total exactly.

2020-21 November Estimate Table 2: ADAP Rebate Fund (Fund 3080) Revenues (In Thousands)								
Local Assistance	2019 Budget Act	Current Year FY 2019-20			2019 Budget Act	Budget Year FY 2020-21		
		2020-21 November Estimate	\$ Change from 2019 Budget Act	% Change from 2019 Budget Act		2020-21 November Estimate	\$ Change from 2019 Budget Act	% Change from 2019 Budget Act
Total Revenue Requested	\$378,909	\$363,719	-\$15,190	-4.0%	\$378,909	\$370,526	-\$8,383	-2.2%
ADAP Rebate Fund - Fund 3080	\$374,909	\$355,719	-\$19,190	-5.1%	\$374,909	\$362,526	-\$12,383	-3.3%
Interest Income	\$4,000	\$8,000	\$4,000	100.0%	\$4,000	\$8,000	\$4,000	100.0%

Estimate numbers are rounded for presentation purposes; as a result, numbers may not total exactly.

III. Overview Projections

A. Key influences on ADAP expenditures

- a) FY 2019-20: Compared to the 2019 Budget Act, Public Health/OA estimates that FY 2019-20 expenditures will net decrease by 4 percent. The net decrease is primarily due to a decrease in projected medication expenditures for all client groups as a result of lower caseloads than previously estimated. For medication-only clients medication expenditures decreased due to transitioning to private insurance, or dis-enrollment from ADAP as a result of full-scope Medi-Cal eligibility. The net decrease is partially offset by a projected increase in private insurance medical out-of-pocket expenditures, which have gone up as a result of higher than projected service utilization. Starting in FY 2019-20 and moving forward, projected Medigap premium expenditures will be displayed as Medicare Part D insurance premiums instead of Medicare Part D medical out-of-pocket costs. This shift is reflected in the tables on page 23 and 24.
- b) FY 2020-21: Compared to the 2019 Budget Act, Public Health/OA estimates that FY 2020-21 expenditures will net increase by 4 percent. The net increase is primarily due to an increase in projected insurance premium expenditures and projected medical out-of-pocket costs that are a result of an increase in private insurance clients utilizing premium assistance and medical out-of-pocket services. The net increase is partially offset by a decrease in projected medication expenditures for medication-only and Medicare Part D clients. The number of medication-only clients is projected to decrease due to transitioning to private insurance, or dis-enrollment from ADAP as a result of full-scope Medi-Cal eligibility (see expenditure detail on page 24).

B. Expenditures

ADAP expenditures are broken out into two types: 1) variable expenditures consisting of health care expenditures and enrollment expenditures and 2) fixed expenditures.

- a) Health Care and Enrollment Expenditures (Variable Expenditures)
- Health care expenditures are estimated based on five client groups. Four of the client groups are PLWH: Medication-only clients, Medi-Cal SOC clients, private insurance clients, and Medicare Part D clients. The fifth client group includes persons at risk for HIV who are receiving PrEP and are referred to as PrEP-AP clients. Services the different client groups receive can include coverage of the following health care expenses: Prescription medication costs for medications on the ADAP formulary (including deductibles, co-pays, and co-insurance), health insurance premiums, and medical out-of-pocket costs (e.g., deductibles and co-pays for physician visits, laboratory tests,

etc.). Estimated expenditures by client group are shown in Table 3. A detailed display of caseload and expenditures by client group and service type is in Section V on page 23.

- Local ADAP enrollment services: Beginning in FY 2016-17, Public Health/OA began allocating funds directly to ADAP enrollment sites based on ADAP services provided at each site. These funds may only be used for costs associated with enrolling and maintaining clients in ADAP. The total amount of funds for ADAP services performed is adjusted annually through the ADAP Estimate based on caseload and estimated services to be performed. Estimated expenditures for enrollment services are shown in Table 3.

TABLE 3: ESTIMATED VARIABLE EXPENDITURES BY CLIENT GROUP		
CLIENT GROUP	EXPENDITURES	
	FY 2019-20	FY 2020-21
Medication-Only	\$304,049,841	\$310,204,641
Medi-Cal SOC	\$1,049,441	\$1,180,878
Private Insurance	\$87,428,538	\$112,917,214
Medicare Part D	\$23,457,664	\$26,910,401
PrEP-AP	\$6,069,446	\$7,868,071
SUBTOTAL	\$422,054,930	\$459,081,205
Enrollment Costs	\$7,875,000	\$8,382,500
TOTAL	\$429,929,930	\$467,463,705
Estimate numbers are rounded for presentation purposes; as a result, numbers may not total exactly.		

b) Fixed Expenditures

- Access, Adherence, and Navigation Program (AAN; formerly ADAP Case Management): In FY 2019-20, Public Health/OA will be allocating funds to ADAP enrollment sites identified as having a large number of medication-only clients to provide navigation services to comprehensive health coverage and to provide assistance with achieving and maintaining viral suppression. Public Health/OA will allocate \$1.35 million for AAN in FY 2019-20.

C. Revenue

a) ADAP Special Funds – ADAP receives both mandatory and voluntary supplemental rebates from drug manufacturers for ADAP medication expenditures. A six-month delay in rebate revenue exists because of the time required for billing the drug manufacturers and receipt of the rebate. FY 2019-20 revenue projections are based on estimated rebates from estimated and actual medication expenditures from January through December 2019. FY 2020-21 revenue projections are based on estimated rebates from estimated drug expenditures from January through December 2020.

- For FY 2019-20, Public Health/OA estimates ADAP rebate revenue will decrease by 4 percent from \$378.9 million in the 2019 Budget Act to \$363.7 million in the revised Current Year forecast. The decrease is primarily due to a decrease in projected medication expenditures from medication-only clients, private insurance clients, and Medicare Part D clients.
- For FY 2020-21, Public Health/OA estimates ADAP rebate revenue will decrease by 2.2 percent from \$378.9 million in the 2019 Budget Act to \$370.5 million in the revised Budget Year forecast. The decrease is primarily due to a decrease in projected medication expenditures from medication-only clients and Medicare Part D clients. Federal Funds – for FY 2019-20, total federal fund budget authority will decrease by \$18.5 million to \$116.6 million compared to the \$135.1 million established in the 2019 Budget Act. Federal fund budget authority includes: the 2019 Ryan White Part B grant (ADAP Earmark) in the amount of \$97.6 million (see New Assumption #1 on page 15), the 2019 Ryan White Part B Supplemental grant in the amount of \$4.7 million (see New Assumption #2 on page 16), the 2019 ADAP Emergency Relief Funds grant (also called ADAP Shortfall Relief grant) in the amount of \$11 million (see Unchanged Assumption #3 on page 21), and the 2018 Ryan White Part B grant carryover in the amount of \$3.3 million (see New Assumption #3 on page 17).

For FY 2020-21, total federal fund budget authority will decrease by \$21.8 million to \$113.3 million compared to the \$135.1 million established in the 2019 Budget Act. Federal fund budget authority includes: estimated 2020 Ryan White Part B grant (ADAP Earmark) in the amount of \$97.6 million, estimated 2020 Ryan White Part B Supplemental grant funding in the amount of \$4.7 million, and estimated 2020 ADAP Emergency Relief Funds grant funding in the amount of \$11 million.

Match – the Health Resources and Services Administration (HRSA) requires grantees to have HIV-related non-HRSA expenditures.

California's HRSA match requirement for the 2019 Ryan White Part B grant year (April 1, 2019 through March 31, 2020) is \$68.8 million. Public Health/OA will meet the match requirement using General Fund State Operations and Local Assistance expenditures from Public Health/OA's HIV Surveillance and Prevention Programs, as well as HIV-related expenditures from the California Department of Corrections and Rehabilitation.

IV. Assumptions

Future Fiscal Issues

New HIV Drugs

Background: The following HIV drugs may receive federal Food and Drug Administration (FDA) approval in the next year:

1. Cabotegravir oral and long-acting (LA)

On April 29, 2019, a New Drug Application (NDA) was submitted to the FDA for oral cabotegravir as an oral lead-in to be taken with oral rilpivirine. Cabotegravir is an HIV integrase strand transfer inhibitor (INSTI) being developed as both an oral tablet and LA injectable formulation. Injectable cabotegravir-LA is being developed as a single drug for HIV PrEP and as a component of a fixed-dose combination (FDC), see #2 below, treatment. Cabotegravir-LA has a very long half-life making intramuscular dosing every four to eight weeks possible. The oral formulation is being developed as a lead-in drug to assess for adverse reactions before patients switch to injections. As of December 21, 2019, it is unknown when the FDA will approve the NDA (please see #2 below on details of the related combo drug cabotegravir/rilpivirine LA).

2. Cabotegravir/rilpivirine LA (Cabenuva®)

On April 29, 2019, the manufacturer submitted an NDA for the approval of Cabotegravir LA/rilpivirine LA as a once-monthly two-drug injectable HIV treatment regimen. Rilpivirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI) and an oral tablet formulation is already FDA approved for HIV treatment. On December 21, 2019, the FDA declined to approve the NDA for cabotegravir/rilpivirine LA and issued a complete response letter. The full details of the complete response letter have not been released and it is unknown when the FDA may approve the NDA.

3. Fostemsavir

Fostemsavir is an oral HIV attachment inhibitor that binds to gp120. It is being studied as a “salvage drug” for use in treatment-experienced people who develop intractable drug resistance to several classes of antiretroviral drugs. On December 5, 2019, the manufacturer submitted an NDA to the FDA seeking approval of fostemsavir. It is unknown at this time when the FDA may approve the NDA.

4. PRO 140 (Leronlimab®)

PRO 140 is a humanized IgG4 monoclonal antibody that blocks HIV entry by binding to CCR5. Phase three clinical trials are evaluating this drug as a weekly injection for use as part of a regimen in people with highly drug resistant virus and limited treatment options and for use as a monotherapy switch option for people with stable viral suppression. The FDA has granted PRO 140 a “fast track” designation. Clinical trial data is still being reviewed, but the manufacturer plans to ask the FDA to give the drug a Breakthrough Therapy designation by the end of January 2020. This designation will

further give priority review for the drug. It is unknown at this time when the FDA will approve this drug.

5. Albuvirtide (Aikening®)

Albuvirtide is an HIV fusion inhibitor that binds to HIV's gp41 envelope protein similar to the mechanism of the FDA-approved enfuvirtide. Albuvirtide is formulated on a weekly intravenous infusion. It was approved for use in China in 2018 and one phase three clinical trial has been completed. Plans for FDA submission are not publically known.

6. UB-421

UB-421 is an investigational CD4 attachment inhibitor being studied for the treatment of HIV infection. UB-421 has recently entered phase three clinical trials for treatment of HIV infected patients experiencing HIV viremia who are not responding to other anti-retroviral drugs. Plans for FDA submission are not publically known.

Description of Change: If any of the above HIV drugs receive FDA approval and the ADAP Medication Advisory Committee (MAC) recommends their addition to the ADAP formulary, Public Health/OA will monitor pricing of each drug and whether the ADAP Crisis Task Force (ACTF) has secured discounted pricing. If Public Health/OA is able to determine that the drugs do not represent a significant cost increase to the program, Public Health/OA will move forward with adding these drugs to the ADAP formulary.

Discretionary: No.

Reason for Adjustment/Change:

- As required by California Health and Safety Code (HSC) Section 120966, Public Health/OA must add an antiretroviral (ARV) drug to the formulary within 30 days of FDA approval if the drug has been recommended for addition by the MAC and its addition does not represent a significant cost increase to the program.
- If the net drug cost (after mandatory and negotiated supplemental rebates) and projected client utilization indicates a significant new cost to the program, the 30-day requirement no longer applies and Public Health/OA must determine whether the program has an adequate budget to fund the addition of the new drug. If not, Public Health/OA may seek additional budgetary authority through the Estimate process.
- Addition of new drugs to the ADAP formulary offers ADAP clients options for drugs that best work to optimize health efficacy.

Fiscal Impact and Fund Sources(s): The fiscal impact is unknown at this time. The funds impacted are the ADAP Rebate Fund (Fund 3080) and Federal Trust Fund (Fund 0890).

New PrEP Drugs

Background: Currently emtricitabine/tenofovir disoproxil fumarate (Truvada®) and the newly approved emtricitabine/tenofovir alafenamide (Descovy®) are the only two drugs approved by the FDA for the prevention of HIV. Additional HIV treatments are being evaluated for potential use for HIV prevention, while new drugs are also in clinical trials for use in HIV prevention.

The following PrEP drugs and devices may receive FDA approval in the next year:

1. Cabotegravir

Cabotegravir is an HIV INSTI being developed as both an oral tablet and LA injectable formulation. Injectable cabotegravir-LA dosed once every eight weeks is being developed as a single drug for HIV PrEP as a potential alternative to the daily oral dose of emtricitabine/tenofovir disoproxil fumarate. Cabotegravir for PrEP is currently in phase three trials. A timeline for FDA submission for a PrEP indication is not publically known.

2. Dapivirine vaginal ring

The dapivirine vaginal ring is a NNRTI that is made of silicone. The ring is LA and is worn for one month at a time. The ring releases dapivirine over the course of a month to protect against HIV. Two phase three clinical trials have been completed demonstrating a 30 percent reduction in HIV infection. The manufacturer has announced plans to submit to the FDA for approval; however, a timeline for FDA submission is not publically known.

3. Emtricitabine/tenofovir disoproxil fumarate (generic Truvada®)

Generic emtricitabine/tenofovir disoproxil fumarate received FDA approval on June 9, 2017 for PrEP. However, the availability of generic emtricitabine/tenofovir disoproxil fumarate is delayed due the fact that a component of the drug; emtricitabine, is still on patent. Generic emtricitabine/tenofovir disoproxil fumarate is expected to become available in Fall 2020.

Description of Change: If these HIV prevention drugs or devices receive FDA approval and the ADAP MAC recommends their addition to the ADAP formulary, Public Health/OA will monitor pricing of the new drugs. If Public Health/OA is able to determine that the drugs do not represent a significant cost to the program, Public Health/OA will move forward with adding these drugs to the ADAP and PrEP-AP formularies.

Discretionary: Yes.

Reason for Adjustment/Change:

- As provided by HSC 120972, eligible PrEP-AP persons have access to drugs listed on the ADAP drug formulary.

Fiscal Impact and Fund Source(s): The fiscal impact is unknown at this time. The fund impacted is the ADAP Rebate Fund (Fund 3080).

Expansion of PrEP Assistance Program (PrEP-AP)

Background: The 2018 Budget Act included \$2 million ongoing to support proposals to modify the PrEP-AP by expanding eligibility and accessibility to the PrEP-AP pursuant to HSC 120972 and authorized through Assembly Bill 1810 (Chapter 34, Statutes of 2018). Approved enhancements include: 1) PrEP medication for insured clients without requiring use of the manufacturer's assistance program if it is not accepted by the client's health plan or pharmacy contracted by the health plan, 2) payment of post-exposure prophylaxis (PEP) and related medical costs, 3) payment for PEP and PrEP starter packs, regardless of whether PrEP-AP eligibility requirements are met, 4) PrEP-AP access for individuals 12 years of age or older, 5) the ability to consider insured individuals as uninsured for confidentiality or safety reasons, 6) up to 28 days of PEP medication for victims of sexual assault regardless of whether PrEP-AP eligibility requirements are met, and 7) payment of insurance premiums for clients enrolled in the PrEP-AP if it will result in cost-savings to the state. Public Health/OA is pursuing a phased implementation strategy and has worked with stakeholders to prioritize implementation of enhancements to the PrEP-AP approved in the 2018 Budget Act. Public Health/OA projects implementation of all enhancements will take place over the next few years, and is dependent on timely execution of contracts, and on the ability of vendors to meet critical milestones.

Description of Change: Enhancements one and two have already been implemented and enhancements four and five are projected to be implemented in late FY 2019-20. Enhancement six is projected to be implemented in 2021 and enhancement seven we are still assessing for feasibility of implementation.

Public Health/OA encountered several barriers during the discovery phase of enhancement three impeding the ability to repackage bottles of PrEP and PEP into starter packs. Truvada[®], one of two, FDA approved drugs for PrEP and is a component in the preferred first-line regimen for PEP. The shelf life of Truvada[®] is drastically reduced to six-weeks once opened and most drug-repackaging companies are not able to extend the shelf life beyond six weeks once repackaged, leading to risk of waste from spoilage or risk of dispensing expired medication. Additionally, Truvada[®] is bottled with a product insert provided by the drug manufacturer, which expressly instructs to only dispense from the original bottle. To this end, some repackaging companies have recently been contacted by the manufacturer to cease repackaging activities. As a result, some repackaging companies that Public Health/OA was in discussion with to potentially provide these services are no longer repackaging Truvada[®]. Lastly, during discovery it was identified that providing PrEP and PEP starter packs without providing the remaining dosage needed to complete the regimen for clients who are not eligible for the PrEP-AP may lead to situations where clients fail to complete their regimen. In order to mitigate against these barriers, Public Health/OA is proposing trailer bill language to augment current statute to allow for an initial dispensing of a full-month supply of PrEP or PEP.

Discretionary: No.

Reason for Adjustment/Change:

- Change to HSC Section 120972.

Fiscal Impact and Fund Source(s): Public Health/OA does not project a need for additional budget authority beyond the \$2 million for FY 2019-20 or FY 2020-21 at this time. Public Health/OA is continually monitoring costs for the PrEP-AP expansion and will provide future updates if projected costs cannot be absorbed within the existing \$2 million budget authority. The fund impacted is the ADAP Rebate Fund (Fund 3080).

U.S. Preventive Services Task Force’s “A” Grade Recommendation on PrEP for Persons at High Risk of HIV Acquisition

Background: On June 11, 2019, the United States Preventive Services Task Force (USPSTF) issued a final recommendation of an “A” grade for PrEP for persons who are at high risk of HIV acquisition. The USPSTF makes recommendations about the effectiveness of specific preventive care services for patients without obvious related signs or symptoms. The Patient Protection and Affordable Care Act (PPACA) states a medical insurer must cover, and may not impose any cost sharing requirement for, any evidence-based preventive items or services that have a grade of “A” or “B” in the current USPSTF recommendations. Federal regulations require plans and issuers to provide coverage for new recommended preventive services for plan/policy years beginning on or after the date that is one year after the date the relevant recommendation or guideline is issued. For most insurers, this will be January 2021.

With exceptions for certain religious employers, coverage requirements apply to all private plans – including individual, small group, large group, and self-insured plans in which employers contract administrative services to a third party payer – with the exception of those plans that maintain “grandfathered” status. In order to have been classified as “grandfathered,” plans must have been in existence prior to March 23, 2010 and cannot make significant changes to their coverage (for example, increasing patient cost-sharing, cutting benefits, or reducing employer contributions).

Currently, PrEP-AP clients with private health insurance are eligible for PrEP medication co-payment assistance of \$7,200 per calendar year through Gilead's Co-Payment Assistance Program. After this threshold has been met, the PrEP-AP provides wrap-around coverage for any remaining PrEP medication co-payments for the remainder of the calendar year. Additionally, PrEP-AP provides assistance with PrEP-related medical cost, including testing for sexually transmitted infections, HIV screening, and other lab costs.

Description of Change: The elimination of a cost-sharing requirement for PrEP because of the USPSTF’s “A” grade recommendation will alleviate some of the financial burden on the PrEP-AP for insured clients enrolled in the PrEP-AP; however, there is ambiguity regarding the scope of PrEP-related medical services that health plans would be

required to classify as preventative. Public Health/OA is working with the National Alliance of State and Territorial AIDS Directors to fully understand the potential impact to the PrEP-AP as a result of the USPSTF's "A" grade and is participating in a workgroup to discuss state-level considerations.

Discretionary: No.

Reason for Adjustment/Change:

- USPSTF "A" grade recommendation.
- Federal and State legislative requirements.

Fiscal Impact and Fund Source(s): The fiscal impact is unknown at this time; however, it is expected that this will result in cost-savings. The fund impacted is the ADAP Rebate Fund (Fund 3080).

Proposed Recalculation of Federal Poverty Level/Official Poverty Measure

Background: To produce its inflation measures, the Bureau of Labor Statistics (BLS) tracks the change in price of a collection of consumer goods and services over time. Those items are then weighted using survey data to represent the experience of consumers in their day-to-day living expenses, with each of the Consumer Price Index (CPI) measures reflecting different item substitution rates, consumer populations, or other attributes. The federal Office of Management and Budget (OMB) is seeking comment on a proposal to recalculate the federal poverty level (FPL) by reducing growth rate in five indexes produced by the BLS, one of which - the CPI for All Urban Consumers (CPI-U) - is used to derive the official poverty measures for many federally-funded California programs, including Medi-Cal and ADAP.

Description of Change: The proposed change would likely lower the income-eligibility cutoffs for the programs mentioned above, cutting or eliminating assistance for many low income individuals and families including those with, or at risk for, HIV. By changing the method by which the FPL is calculated, millions of PPACA marketplace consumers are projected to receive lower premium tax credits, meaning they would pay higher premiums, and would get less help with cost sharing, leading to an increase in their deductibles.

Discretionary: No.

Reason for Adjustment/Change:

- On May 7, 2019, the OMB posted a proposal to the U.S. Federal Register requesting comments on updating the Census Bureau's poverty thresholds using an alternative, lower measure of inflation than the traditional CPI. Changing that calculation is anticipated to lower the poverty line by growing amounts each year relative to the current approach.

Fiscal Impact and Fund Source(s): The fiscal impact is unknown at this time. The funds impacted are the Federal Trust Fund (Fund 0890) and ADAP Rebate Fund (Fund 3080).

California's Individual Mandate

Background: Historically, the majority of clients enrolled in ADAP were medication-only clients without health insurance; clients for whom ADAP pays the full cost of medication, because people living with HIV were unable to purchase affordable health insurance in the private marketplace. However, with the implementation of the ACA more ADAP clients have been able to access public and private health insurance coverage. A component of the ACA, which has since been repealed, called the federal "Individual Mandate", required most individuals to have health insurance and enforced a tax penalty for those who didn't.

Description of Change: As part of the 2019 Budget Act, the California State Legislature voted to pass Senate Bill 78, which creates an "Individual Mandate" requiring Californians to purchase health insurance beginning January 1, 2020, and imposes a fine for failure to do so. The impact of a statewide "Individual Mandate" to ADAP is unknown.

Discretionary: No.

Reason for Adjustment/Change:

- Statutory requirement

Fiscal Impact and Fund Source(s): The fiscal impact is unknown at this time; however, any impact will be in the form of cost-savings. The funds impacted are the Federal Trust Fund (Fund 0890) and ADAP Rebate Fund (Fund 3080).

New Assumptions

Decrease in Federal Funds: 2019 Ryan White Part B Grant

Background: The Ryan White Part B grant is the largest of the three federal grants that ADAP receives funding for and unlike the other two grants is a non-competitive grant. Grant funding is appropriated in five, 12-month budget periods that run from April 1st to March 31st. Within the five-year funding cycle, funding from year to year is provided as long as the program remains eligible and submits timely all reporting requirements. The grant is shared between Public Health/OA's HIV Care Branch and ADAP Branch, and is broken into three main sub-components: Base, MAI, and ADAP Earmark. Funding for Base and MAI is utilized by the HIV Care Branch and ADAP Earmark funding is utilized by the ADAP Branch.

In November 2018, Public Health/OA applied for the 2019 Ryan White Part B grant, the third year of the latest five-year funding cycle. The funding requested in the grant application totaled \$140.2 million, of which \$105.7 million was requested for the ADAP Branch, and \$34.5 million was requested for the HIV Care Branch.

Description of Change: In April 2019, Public Health/OA received the notice of award for the 2019 Ryan White Part B grant. The total award received was \$139 million or \$1.2 million below what Public Health/OA applied for. The ADAP Branch received \$104.1 million, \$1.6 million less in funding, and the HIV Care Branch received \$34.9 million, \$400,000 more in funding.

Discretionary: Yes.

Reason for Adjustment/Change:

- Unanticipated funding change.

Fiscal Impact and Fund Source(s): Decrease of \$1.6 million Local Assistance for FYs 2019-20 and 2020-21. The fund impacted is the Federal Trust Fund (Fund 0890).

Decrease in Federal Funds: 2019 Ryan White Part B Supplemental Grant

Background: In March 2019, HRSA released a notice of funding opportunity for the 2019 Ryan White Part B Supplemental Grant. HRSA anticipates approximately \$86.2 million will be available nationwide through the 2019 Ryan White Part B Supplemental grant, but the ceiling amount that each applicant can apply for is \$15 million. The purpose of the Ryan White Part B Supplemental grant is to develop and/or enhance access to a comprehensive continuum of high quality care and treatment services for low-income individuals living with HIV. The amount of each award is based on submitted data demonstrating the severity of the HIV epidemic in the applicant’s state/territory, co-morbidities, cost of care, and service needs of emerging populations. The grant is shared between Public Health/OA’s HIV Care Branch and ADAP Branch.

In May 2019, Public Health/OA applied for the competitive 2019 Ryan White Part B Supplemental grant. Public Health/OA requested the maximum amount of \$15 million, with \$11.3 million specifically for ADAP to be used in FY 2019-20. The table below shows Ryan White Part B Supplemental grant funds applied for and funds received, by grant budget period.

Grant Budget Period	Application(s)	Funds Received
2015 (09/30/2015 – 09/29/2016)	\$10,000,000	\$10,000,000
2016 (09/30/2016 – 09/29/2017)	\$18,700,000	\$18,700,000*

2017 (09/30/2017 – 09/29/2018)	\$35,000,000	\$35,000,000**
2018 (09/30/2018 – 09/29/2019)	\$35,000,000	\$23,766,000***
2019 (09/30/2019 – 09/29/2020)	\$15,000,000	\$6,376,000****
<p>*Includes \$8.7 million for HIV Care Branch and \$10 million for ADAP. **Includes \$10 million for HIV Care Branch and \$25 million for ADAP. ***Includes \$6.8 million for HIV Care Branch and \$17 million for ADAP. ****Includes \$1.7 million for HIV Care Branch and \$4.7 million for ADAP.</p>		

Description of Change: On September 3, 2019, Public Health/OA received a notice of award for \$6.4 million, which is \$8.6 million less than applied for. Of the amount awarded \$4.7 million will be utilized by ADAP for medication expenditures.

Discretionary: Yes.

Reason for Adjustment/Change:

- The Ryan White Part B Supplemental grant is a competitive funding opportunity.
- Prior funding does not guarantee that funding will be provided in the future.

Fiscal Impact and Fund Source(s): Decrease of \$6.6 million Local Assistance in FY 2019-20 and 2020-21. The fund impacted is the Federal Trust Fund (Fund 0890).

Increase in Federal Funds: 2018 Ryan White Part B Grant Carryover

Background: The Ryan White Part B grant is the largest of the three federal grants that ADAP receives funding for and unlike the other two grants is a non-competitive grant. Grant funding is appropriated in five, 12-month budget periods that run from April 1st to March 31st. Within the five-year funding cycle, funding from year to year is provided as long as the program remains eligible and submits timely all reporting requirements. The grant is shared between Public Health/OA's HIV Care Branch and ADAP Branch, and is broken into three main sub-components: Base, Minority AIDS Initiative (MAI), and ADAP Earmark. Funding for Base and MAI is utilized by the HIV Care Branch and ADAP Earmark funding is utilized by the ADAP Branch.

Funding from the Ryan White Part B grant that is not fully expended by the end of the budget period can be carried over to the next budget period with approval from HRSA. Public Health/OA can generally determine how carryover funding is utilized, with the exception of MAI funding, which must be utilized solely by the HIV Care Branch. Carryover funding from the Base and the ADAP Earmark are always utilized by the ADAP Branch due to administrative limitations that prevent the HIV Care Branch from timely utilization of carryover funds, as carryover funding must be expended by March 31 of any given year.

On August 27, 2019, Public Health/OA finalized closing the 2018 Ryan White Part B grant with HRSA and applied for carryover funding. Upon closure of the grant there remained \$3.4 million in unspent funding, of which ADAP Branch will get \$3.3 million

and the HIV Care Branch will get \$101,000. Broken down by sub-component, Base had \$2.4 million, MAI had \$101,000, and the ADAP Earmark had \$940,000, in carryover funding.

Description of Change: On October 17, 2019, Public Health/OA received a notice of award for the full \$3.4 million that was requested in unspent funding. ADAP Branch's portion of this award is \$3.3 million.

Discretionary: Yes.

Reason for Adjustment/Change:

- Fully leverage federal funding.

Fiscal Impact and Fund Source(s): The \$3.3 million in funding received will be spent in FY 2019-20. No additional budget authority is needed for the \$3.3 million as the net budget authority for the Federal Trust Fund is decreasing in FY 2019-20. The fund impacted is the Federal Trust Fund (Fund 0890).

Existing Assumptions

Access, Adherence, and Navigation (AAN) Program

Background: Beginning in FY 2017-18, Public Health/OA began allocating funds to a select number of ADAP enrollment sites with the highest uninsured client caseloads to navigate uninsured individuals to comprehensive health coverage and to support ADAP clients with achieving and maintaining viral suppression. Public Health/OA initially selected the top 19 sites with the largest ADAP medication-only client population to participate in the AAN Program. Of the 19 ADAP enrollment sites invited to participate, ten enrollment sites declined due to a variety of reasons. These reasons include lack of capacity and lack of infrastructure to bill for clients with private insurance. Additionally, financial disincentive due to reduced reimbursement rates from private insurance plans compared to higher reimbursement rates received for some Ryan White Part A funded ambulatory health services contributed to declining enrollment.

To align with the federal grant year and allow for the program to operate during an additional open enrollment period, Public Health/OA amended program contracts to extend the contract end date from June 30, 2019 to March 31, 2020.

Also, because of lower than anticipated enrollment site participation, Public Health/OA allocated an additional \$120,000 in FY 2018-19 and \$90,000 in FY 2019-20 to five of the nine participating enrollment sites identified as having the highest number of medication-only clients. The increased funding is being leveraged to add additional resources at these sites to navigate more clients to comprehensive health coverage.

Description of Change: The AAN program has been valuable in helping to understand the unique barriers clients face by county in accessing health care coverage. Since

contract inception, navigators have navigated 629 clients to comprehensive health coverage out of 2,217 outreach attempts to unique clients. The current AAN contracts with the nine participating enrollment sites expire on March 31, 2020, after which Public Health/OA plans to use information learned during the program to expand the geographic scope of navigation services statewide by centralizing these functions in-house. Public Health/OA plans to have approximately 18 existing state staff funded through the Ryan White Part B grant absorb this work and conduct outreach to clients and provide linkage to certified Covered California enrollment sites. Public Health/OA staff maintain collaborative workgroups with insurance plans during the open enrollment period and will be able to provide specialized assistance to uninsured clients. Approximately 9,000 ADAP clients or one-third of all ADAP clients statewide are uninsured, with more than half of uninsured clients receiving ADAP services in Los Angeles County where six of the nine AAN sites are located and where a majority of the enrollment barriers have been identified. By widening the geographic scope, Public Health/OA is increasing the pool of clients that can be engaged and anticipates being able to increase the number of client interactions that lead to successful navigation outcomes.

Discretionary: Yes.

Reason for Adjustment/Change:

- To expand navigation services statewide and maximize outreach and enrollment into comprehensive health coverage. Increase overall health coverage enrollment among all ADAP clients.

Fiscal Impact and Fund Source(s): Estimated net savings for FY 2019-20, \$1.3 million from navigating an estimated 242 clients to comprehensive health insurance. Estimated net savings for FY 2020-21, \$4.7 million from navigating an estimated 362 clients to comprehensive health insurance. No additional budget authority is needed. The funds impacted are the Federal Trust Fund (Fund 0890) and ADAP Rebate Fund (Fund 3080).

Unchanged Assumptions/Premises

ADAP Special Fund State Operations Cost Adjustment - Interim ADAP Enrollment System (AES)/Project Approval Lifecycle (PAL)

Background: The interim AES was built as a basic solution while a permanent Information Technology (IT) solution could be identified through the PAL process. In July 2018, during Stage 2 of the PAL process, the California Department of Technology (CDT) provided Public Health/OA with an approval and delegated authority for the project back to Public Health/OA. Public Health/OA is now beginning the project that will complete PAL process-identified enhancements that will finalize the establishment of a permanent IT ADAP Enrollment System.

For FY 2019-20 the total costs for the AES and PAL include: 1) \$37,800 for adjustments in CDT staff costs for Independent Project Oversight Consulting, 2) \$150,324 for Public Health/Information Technology Services Division (ITSD) staffing costs for PAL project management, 3) \$40,000 for the newly identified costs for a consultant to assist Public Health/ITSD with independent verification and validation, 4) \$233,333 for Project Development Cost – Enhancements completion, and 5) \$2,800,000 for Maintenance and Operations costs for AES.

By the end of FY 2019-20, the enhancements identified via the PAL process are expected to be completed, making the interim AES the permanent IT solution. A budget change proposal is being proposed for FY 2020-21 to request ongoing budget authority for ongoing Maintenance and Operations.

Description of Change: No change from the 2019-20 ADAP May Revision Estimate.

Discretionary: Yes.

Reason for Adjustment/Change: N/A.

Fiscal Impact and Fund Source(s): No additional budget authority is needed for FY 2019-20 beyond the \$3.3 million included in the 2019 Budget Act. The fund impacted is the ADAP Rebate Fund (Fund 3080).

New HIV Drug

Background: The following HIV drug has received federal FDA approval:

1. Ibalizumab (Trogarzo®)

On March 6, 2018, the FDA approved ibalizumab (Trogarzo®), an HIV-1 inhibitor and long-acting monoclonal antibody for multi-drug resistant HIV-1 infection. Ibalizumab is administered intravenously once every 14 days by a trained medical professional and is used in combination with other ARV medications. The drug is indicated for adult patients who have tried multiple treatment options with current available therapies, but whose HIV infections cannot otherwise be successfully treated, including those with multidrug-resistant HIV.

On May 22, 2018, the ACTF announced that an agreement with the manufacturer of ibalizumab was reached for discounted pricing for this medication. Although Public Health/OA will be receiving reduced pricing, this new injectable is not cost neutral, and is projected to have a minor fiscal impact. Additionally, Public Health/OA is consulting with other Ryan White programs to determine how administration costs of this new injectable treatment can be covered.

On October 26, 2018, Public Health/OA was notified by HRSA that per the U.S Department of Health and Human Services' guidelines, ibalizumab has been deemed a new classification of ARV known as a CD4 Post-Attachment Inhibitor, which according

to federal statute makes addition to the ADAP formulary compulsory for ADAPs nationwide.

Description of Change: No change from the 2019-20 ADAP May Revision Estimate.

Discretionary: No.

Reason for Adjustment/Change: N/A.

Fiscal Impact and Fund Source(s): No additional budget authority is needed for FY 2019-20 beyond the \$1 million for 16 clients. The funds impacted are the ADAP Rebate Fund (Fund 3080) and Federal Trust Fund (Fund 0890).

Federal Funds: 2019 ADAP Emergency Relief Funds Grant (ADAP Shortfall Relief Grant)

Background: On June 25, 2018, HRSA released the funding opportunity announcement for the 2019 ADAP Emergency Relief Funds grant (ADAP Shortfall Relief grant). This award is intended for states/territories that demonstrate the need for additional resources to prevent, reduce, and/or eliminate ADAP waiting lists, including through implementation of cost-containment measures. Public Health/OA’s cost-containment measures include maintaining data match agreements to ensure ADAP is the payer of last resort. On October 23, 2018, ADAP applied to HRSA for the maximum amount of \$11 million for the competitive 2019 ADAP Emergency Relief Funds grant. Public Health/OA received the notice of award on March 20, 2019, for the full \$11 million. The table below shows historically how much Public Health/OA applied for through the ADAP Emergency Relief Funds grant and how much was received:

Grant Budget Period	Application(s)	Funds Received
2015 (04/01/2015 – 03/31/2016)	\$11,000,000	\$6,441,447
2016 (04/01/2016 – 03/31/2017)	\$11,000,000	\$10,991,645
2017 (04/01/2017 – 03/31/2018)	\$9,000,000	\$9,000,000
2018 (04/01/2018 – 03/31/2019)	\$11,000,000	\$11,000,000
2019 (04/01/2019 – 03/31/2020)	\$11,000,000	\$11,000,000

Description of Change: No change from the 2019-20 ADAP May Revision Estimate.

Discretionary: Yes.

Reason for Adjustment/Change: N/A.

Fiscal Impact and Fund Source(s): The \$11 million in funding received will be spent in FY 2019-20. Budget authority in the amount of \$11 million has already been built into the baseline for FY 2019-20 and will not change. The fund impacted is the Federal Trust Fund (Fund 0890).

Discontinued Assumptions/Premises

Increase in Federal Funds: 2018 Ryan White Part B Grant

Why is Change Needed/Reason for Adjustment: Previously approved in the FY 2019-20 ADAP November Estimate for use in FY 2018-19. Since FY 2018-19 has ended and the funding has already been expended, this assumption will be discontinued.

Decrease in Federal Funds: 2018 Ryan White Part B Supplemental Grant

Why is Change Needed/Reason for Adjustment: Previously approved in the FY 2019-20 ADAP November Estimate for use in FY 2018-19. Since FY 2018-19 has ended and the funding has already been expended, this assumption will be discontinued.

Increase in Federal Funds: 2017 Ryan White Part B Grant Carryover

Why is Change Needed/Reason for Adjustment: Previously approved in the FY 2019-20 ADAP November Estimate for use in FY 2018-19. Since FY 2018-19 has ended and the funding has already been expended, this assumption will be discontinued.

V. Expenditure Details

A. A detailed breakdown of caseload and expenditures by client group and service type is shown below in Tables 6 through 11.

TABLE 6: FY 2019-20 - November Estimate Caseload and Variable Expenditures							
CLIENT GROUP	CASELOAD		SERVICE TYPE EXPENDITURE				
	NUMBER	PERCENT	MEDICATIONS	INSURANCE PREMIUMS	MED OUT-OF-POCKET COST	ADDITIONAL ADMIN COSTS	TOTAL EXPENDITURE
Medication-Only	12,307	37.7%	\$303,638,408	\$0	\$0	\$411,434	\$304,049,841
Medi-Cal SOC	107	0.3%	\$1,045,875	\$0	\$0	\$3,566	\$1,049,441
Private insurance*	10,170	31.2%	\$22,784,302	\$57,773,711	\$5,316,239	\$1,554,286	\$87,428,538
Medicare Part D*	7,627	23.4%	\$17,382,365	\$4,141,549	\$768,036	\$1,165,714	\$23,457,664
PrEP-AP	2,412	7.4%	\$1,690,297	\$0	\$1,255,149	\$3,124,000	\$6,069,446
SUBTOTAL	32,623	100.0%	\$346,541,246	\$61,915,261	\$7,339,424	\$6,259,000	\$422,054,930
Enrollment Site Costs	0	0.0%	\$0	\$0	\$0	\$7,875,000	\$7,875,000
TOTAL	32,623	100.0%	\$346,541,246	\$61,915,261	\$7,339,424	\$14,134,000	\$429,929,930

* Subgroup of 10,239 clients receiving assistance for premium payments and medical-out-of-pocket costs.
Estimate numbers are rounded for presentation purposes; as a result, numbers may not total exactly.

TABLE 7: 2019 Budget Act Caseload and Variable Expenditures							
CLIENT GROUP	CASELOAD		SERVICE TYPE EXPENDITURE				
	NUMBER	PERCENT	MEDICATIONS	INSURANCE PREMIUMS	MED OUT-OF-POCKET COST	ADDITIONAL ADMIN COSTS	TOTAL EXPENDITURE
Medication-Only	12,580	36.3%	\$315,378,783	\$0	\$0	\$593,586	\$315,972,368
Medi-Cal SOC	136	0.4%	\$1,471,091	\$0	\$0	\$6,414	\$1,477,505
Private insurance*	10,687	30.9%	\$25,839,557	\$58,584,847	\$2,011,467	\$1,546,913	\$87,982,784
Medicare Part D*	7,683	22.2%	\$21,370,782	\$1,717,372	\$3,431,095	\$1,112,087	\$27,631,337
PrEP-AP	3,542	10.2%	\$2,564,143	\$0	\$1,651,215	\$3,094,000	\$7,309,358
SUBTOTAL	34,628	100.0%	\$366,624,356	\$60,302,219	\$7,093,777	\$6,353,000	\$440,373,352
Enrollment Site Costs	0	0.0%	\$0	\$0	\$0	\$7,745,000	\$7,745,000
TOTAL	34,628	100.0%	\$366,624,356	\$60,302,219	\$7,093,777	\$14,098,000	\$448,118,352

* Subgroup of 11,373 clients receiving assistance for premium payments and medical-out-of-pocket costs.
Estimate numbers are rounded for presentation purposes; as a result, numbers may not total exactly.

TABLE 8: FY 2019-20 - Difference Between November Estimate and 2019 Budget Act							
CLIENT GROUP	CASELOAD		SERVICE TYPE EXPENDITURE				
	NUMBER	PERCENT	MEDICATIONS	INSURANCE PREMIUMS	MED OUT-OF-POCKET COST	ADDITIONAL ADMIN COSTS	TOTAL EXPENDITURE
Medication-Only	-273	13.6%	-\$11,740,375	\$0	\$0	-\$182,152	-\$11,922,527
Medi-Cal SOC	-29	1.5%	-\$425,216	\$0	\$0	-\$2,848	-\$428,065
Private insurance*	-517	25.8%	-\$3,055,255	-\$811,136	\$3,304,772	\$7,373	-\$554,246
Medicare Part D*	-55	2.8%	-\$3,988,417	\$2,424,177	-\$2,663,059	\$53,627	-\$4,173,673
PrEP-AP	-1,130	56.4%	-\$873,846	\$0	-\$396,067	\$30,000	-\$1,239,913
SUBTOTAL	-2,004	100.0%	-\$20,083,110	\$1,613,041	\$245,646	-\$94,000	-\$18,318,422
Enrollment Site Costs	0	0.0%	\$0	\$0	\$0	\$130,000	\$130,000
TOTAL	-2,004	100.0%	-\$20,083,110	\$1,613,041	\$245,646	\$36,000	-\$18,188,422

* Subgroup decreased 1,134 clients receiving assistance for premium payments and medical-out-of-pocket costs.
Estimate numbers are rounded for presentation purposes; as a result, numbers may not total exactly.

TABLE 9: FY 2020-21 - November Estimate Caseload and Variable Expenditures							
CLIENT GROUP	CASELOAD		SERVICE TYPE EXPENDITURE				
	NUMBER	PERCENT	MEDICATIONS	INSURANCE PREMIUMS	MED OUT-OF-POCKET COST	ADDITIONAL ADMIN COSTS	TOTAL EXPENDITURE
Medication-Only	11,984	35.3%	\$309,793,091	\$0	\$0	\$411,550	\$310,204,641
Medi-Cal SOC	100	0.3%	\$1,177,428	\$0	\$0	\$3,450	\$1,180,878
Private insurance*	10,814	31.9%	\$27,474,253	\$76,678,264	\$7,169,669	\$1,595,028	\$112,917,214
Medicare Part D*	7,627	22.5%	\$17,886,453	\$6,634,112	\$1,264,864	\$1,124,972	\$26,910,401
PrEP-AP	3,392	10.0%	\$2,884,833	\$0	\$1,859,238	\$3,124,000	\$7,868,071
SUBTOTAL	33,919	100.0%	\$359,216,058	\$83,312,375	\$10,293,772	\$6,259,000	\$459,081,205
Enrollment Site Costs	0	0.0%	\$0	\$0	\$0	\$8,382,500	\$8,382,500
TOTAL	33,919	100.0%	\$359,216,058	\$83,312,375	\$10,293,772	\$14,641,500	\$467,463,705

* Subgroup of 12,676 clients receiving assistance for premium payments and medical-out-of-pocket costs.
Estimate numbers are rounded for presentation purposes; as a result, numbers may not total exactly.

TABLE 10: 2019 Budget Act Caseload and Variable Expenditures							
CLIENT GROUP	CASELOAD		SERVICE TYPE EXPENDITURE				
	NUMBER	PERCENT	MEDICATIONS	INSURANCE PREMIUMS	MED OUT-OF-POCKET COST	ADDITIONAL ADMIN COSTS	TOTAL EXPENDITURE
Medication-Only	12,580	36.3%	\$315,378,783	\$0	\$0	\$593,586	\$315,972,368
Medi-Cal SOC	136	0.4%	\$1,471,091	\$0	\$0	\$6,414	\$1,477,505
Private insurance*	10,687	30.9%	\$25,839,557	\$58,584,847	\$2,011,467	\$1,546,913	\$87,982,784
Medicare Part D*	7,683	22.2%	\$21,370,782	\$1,717,372	\$3,431,095	\$1,112,087	\$27,631,337
PrEP-AP	3,542	10.2%	\$2,564,143	\$0	\$1,651,215	\$3,094,000	\$7,309,358
SUBTOTAL	34,628	100.0%	\$366,624,356	\$60,302,219	\$7,093,777	\$6,353,000	\$440,373,352
Enrollment Site Costs	0	0.0%	\$0	\$0	\$0	\$7,745,000	\$7,745,000
TOTAL	34,628	100.0%	\$366,624,356	\$60,302,219	\$7,093,777	\$14,098,000	\$448,118,352

* Subgroup of 11,373 clients receiving assistance for premium payments and medical-out-of-pocket costs.
Estimate numbers are rounded for presentation purposes; as a result, numbers may not total exactly.

TABLE 11: FY 2020-21 - Difference Between November Estimate and 2019 Budget Act							
CLIENT GROUP	CASELOAD		SERVICE TYPE EXPENDITURE				
	NUMBER	PERCENT	MEDICATIONS	INSURANCE PREMIUMS	MED OUT-OF-POCKET COST	ADDITIONAL ADMIN COSTS	TOTAL EXPENDITURE
Medication-Only	-596	84.1%	-\$5,585,692	\$0	\$0	-\$182,036	-\$5,767,728
Medi-Cal SOC	-35	5.0%	-\$293,663	\$0	\$0	-\$2,964	-\$296,628
Private insurance*	128	-18.0%	\$1,634,696	\$18,093,416	\$5,158,203	\$48,115	\$24,934,430
Medicare Part D*	-55	7.8%	-\$3,484,329	\$4,916,739	-\$2,166,231	\$12,885	-\$720,936
PrEP-AP	-150	21.1%	\$320,690	\$0	\$208,023	\$30,000	\$558,713
SUBTOTAL	-709	100.0%	-\$7,408,298	\$23,010,156	\$3,199,995	-\$94,000	\$18,707,853
Enrollment Site Costs	0	0.0%	\$0	\$0	\$0	\$637,500	\$637,500
TOTAL	-709	100.0%	-\$7,408,298	\$23,010,156	\$3,199,995	\$543,500	\$19,345,353

* Subgroup increased 1,303 clients receiving assistance for premium payments and medical-out-of-pocket costs.
Estimate numbers are rounded for presentation purposes; as a result, numbers may not total exactly.

a. Medication-Only Clients

This client group includes individuals who do not have private insurance and are not enrolled in Medi-Cal or Medicare Part D. ADAP covers the full cost of prescription medications for these individuals for medications on the ADAP formulary. This group only receives services associated with medication costs.

1. Medication Expenditures:

- For FY 2019-20, Public Health/OA estimates medication expenditures for medication-only clients will be \$303.6 million, which is a \$11.7 million decrease compared to the 2019 Budget Act. The decrease in expenditures is primarily due to increased medication savings from fewer medication-only clients as a result of dis-enrolling medication-only clients whom are eligible for full-scope Medi-Cal and clients transitioning to private insurance with a partial offset for higher medication prices.
 - For FY 2020-21, Public Health/OA estimates medication expenditures for medication-only clients will be \$309.8 million, which is a \$5.6 million decrease compared to the 2019 Budget Act. This decrease is due to the same reasons listed above.
2. Health Insurance Premiums: There are no health insurance premium expenditures for medication-only clients.
 3. Medical Out-Of-Pocket Costs: There are no medical out-of-pocket cost expenditures for medication-only clients.

b. Medi-Cal SOC Clients

This client group includes individuals enrolled in Medi-Cal who have a SOC for Medi-Cal services. This group only receives services associated with medication costs.

1. Medication Expenditures:

- For FY 2019-20, Public Health/OA estimates medication expenditures for Medi-Cal SOC clients will be \$1.0 million, which is a \$425,000 decrease compared to the 2019 Budget Act. The decrease in expenditures is due to a smaller caseload offset by higher SOC amounts for medications.
 - FY 2020-21, Public Health/OA estimates medication expenditures for Medi-Cal SOC clients will be \$1.2 million, which is a \$294,000 decrease compared to the 2019 Budget Act. The decrease in expenditures is due to the same reasons above.
2. Health Insurance Premiums: There are no health insurance premium expenditures for Medi-Cal SOC clients.
 3. Medical Out-Of-Pocket Costs: There are no medical out-of-pocket cost expenditures for Medi-Cal SOC clients.

c. Private Insurance Clients

This client group includes individuals who have some form of health insurance, including insurance purchased through Covered California, privately purchased health insurance, or employer-based health insurance; therefore, this group is sub-divided into three client sub-groups: Covered California clients, non-Covered California clients, and employer-based insurance clients. These groups receive services associated with medication costs, health insurance premiums, and medical out-of-pocket costs.

1. Medication Expenditures:

- For FY 2019-20, Public Health/OA estimates medication expenditures for all private insurance clients will be \$22.8 million, which is a \$3.1 million decrease compared to the 2019 Budget Act. The decrease in expenditures is due to a lower caseload than previously anticipated.
- For FY 2020-21, Public Health/OA estimates medication expenditures for all private insurance clients will be \$27.5 million, which is a \$1.6 million increase compared to the 2019 Budget Act. This increase is due to continuing growth in private insurance caseload.

2. Health Insurance Premiums:

- For FY 2019-20, Public Health/OA estimates health insurance premium payment expenditures for all private insurance clients will be \$57.8 million, which is a \$811,000 decrease compared to the 2019 Budget Act. This slight decrease is due to lower overall caseload than previously anticipated and offset by higher premiums for Covered California and non-Covered California clients.
- For FY 2020-21, Public Health/OA estimates health insurance premium payment expenditures will be \$76.7 million, which is a \$18.1 million increase compared to the 2019 Budget Act. This increase is due to the continued growth in private insurance caseload and higher premiums.

3. Medical Out-Of-Pocket Costs:

- For FY 2019-20, Public Health/OA estimates medical out-of-pocket costs for all private insurance clients will be \$5.3 million, which is a \$3.3 million increase compared to the 2019 Budget Act. The increase is due to much higher than projected service utilization.
- For FY 2020-21, Public Health/OA estimates medical out-of-pocket costs will be \$7.2 million, which is a \$5.2 million increase compared to the 2019 Budget Act. This increase is due the same reason listed above.

d. Medicare Part D clients

This client group includes individuals who are enrolled in Medicare and have purchased Medicare Part D plans for medication coverage. This group receives services associated with medication costs, medical out-of-pocket costs, Medicare Part D health insurance premiums, and assistance with Medigap premiums, which cover medical out-of-pocket costs.

1. Medication Expenditures:

- For FY 2019-20, Public Health/OA estimates medication expenditures for Medicare Part D clients will be \$17.4 million, which is a \$4.0 million decrease compared to the 2019 Budget Act. The decrease in expenditures is due to fewer than anticipated clients with Medicare Part D plans in the medication assistance program and lower than anticipated deductibles and co-insurance.
 - For FY 2020-21, Public Health/OA estimates medication expenditures for Medicare Part D clients will be \$17.9 million, which is a \$3.5 million decrease compared to the 2019 Budget Act. This decrease is due to the same reasons listed above.
2. Health Insurance Premiums:
- For FY 2019-20, Public Health/OA estimates Medicare Part D premium payment expenditures will be \$4.1 million, which is a \$2.4 million increase compared to the 2019 Budget Act. This increase is primarily due to a change in how Medigap premium expenditures are displayed and displaying them under Medicare Part D premiums instead of Medicare Part D medical out-of-pocket costs.
 - For FY 2020-21, Public Health/OA estimates Medicare Part D premium payment expenditures will be \$6.6 million, which is a \$4.9 million increase compared to the 2019 Budget Act. This increase is due to the adjustment listed above and a higher caseload.
3. Medical Out-Of-Pocket Costs:
- For FY 2019-20, Public Health/OA estimates medical out-of-pocket costs will be \$768,000, which is a \$2.7 million decrease compared to the 2019 Budget Act. This decrease is primarily due to the adjustment listed above.
 - For FY 2020-21, Public Health/OA estimates medical out-of-pocket costs will be \$1.3 million, which is a \$2.2 million decrease compared to the 2019 Budget Act. This decrease is due to the same reason listed above.
- e. PrEP clients

This client group includes HIV-negative persons at risk for acquiring HIV who are taking PrEP. For insured clients, PrEP-AP covers the gap between what the client's health insurance plan and the manufacturer's medication co-payment assistance program will pay towards medication costs, along with any PrEP-related medical out-of-pocket costs. Clients without health insurance receive benefits related only to PrEP-related medical costs, as PrEP medication is received free from the manufacturer's medication assistance program.

1. Medication Expenditures:
- For FY 2019-20, Public Health/OA estimates medication expenditures for PrEP-AP will be \$1.7 million, which is a \$874,000 decrease compared to the 2019 Budget Act. This decrease is primarily due to lower than anticipated medication expenditures for a higher than anticipated caseload.

- For FY 2020-21, Public Health/OA estimates medication expenditures will be \$2.9 million, which is a \$321,000 increase compared to the 2019 Budget Act. This increase is due to higher caseload in PrEP clients.
- 2. Health Insurance Premiums: There are no health insurance premium expenditures for PrEP-AP clients.
- 3. Medical Out-Of-Pocket Costs:
 - For FY 2019-20, Public Health/OA estimates medical out-of-pocket costs will be \$1.3 million for PrEP clients, which is a \$396,000 decrease compared to the 2019 Budget Act. This decrease is primarily due to less than anticipated client utilization.
 - For FY 2020-21, Public Health/OA estimates medical out-of-pocket costs will be \$1.9 million for PrEP-AP clients, which is a \$208,000 increase compared to the 2019 Budget Act. This slight increase is due to higher caseload and client slightly higher client utilization.

VI. Historical Program Data and Trends

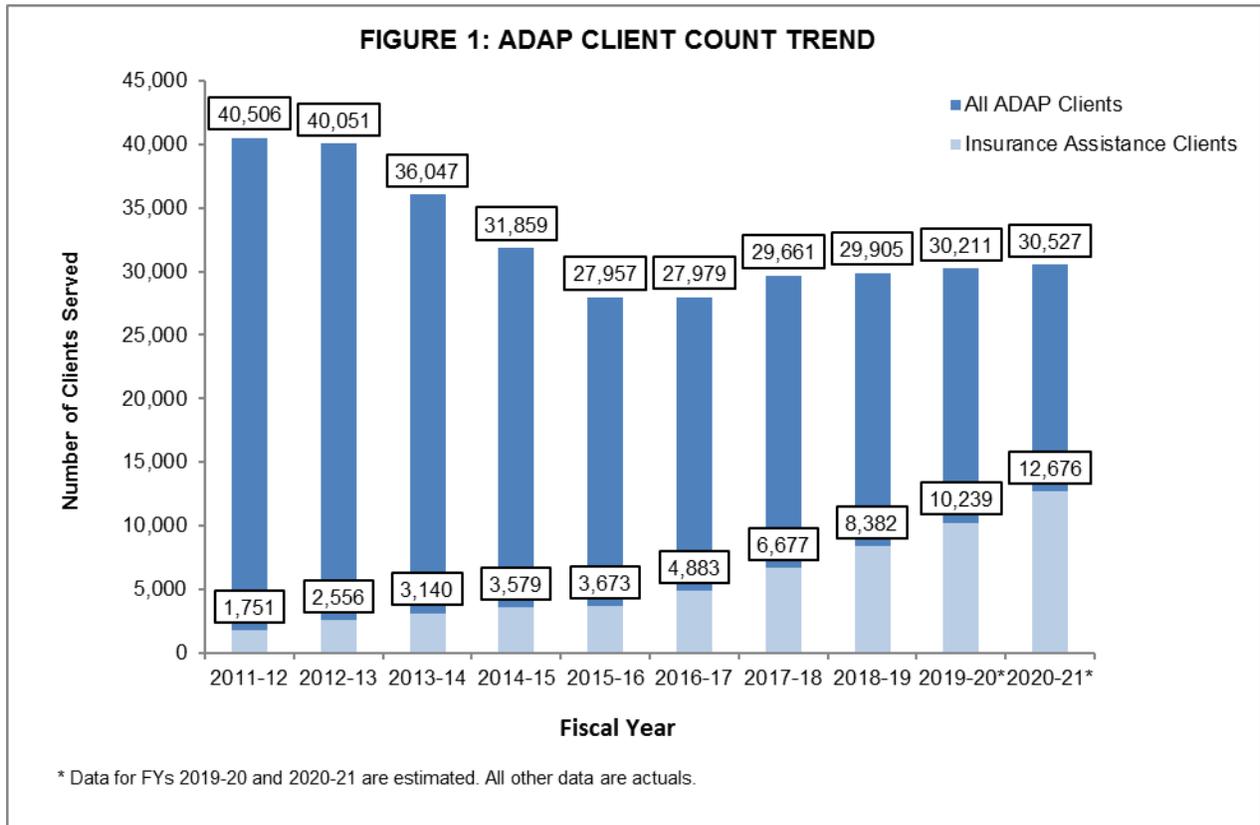
For all figures in this section, the data prior to FY 2019-20 is the observed historical data. Estimates for FY 2019-20 and FY 2020-21 are based on the overall projections and include all assumptions.

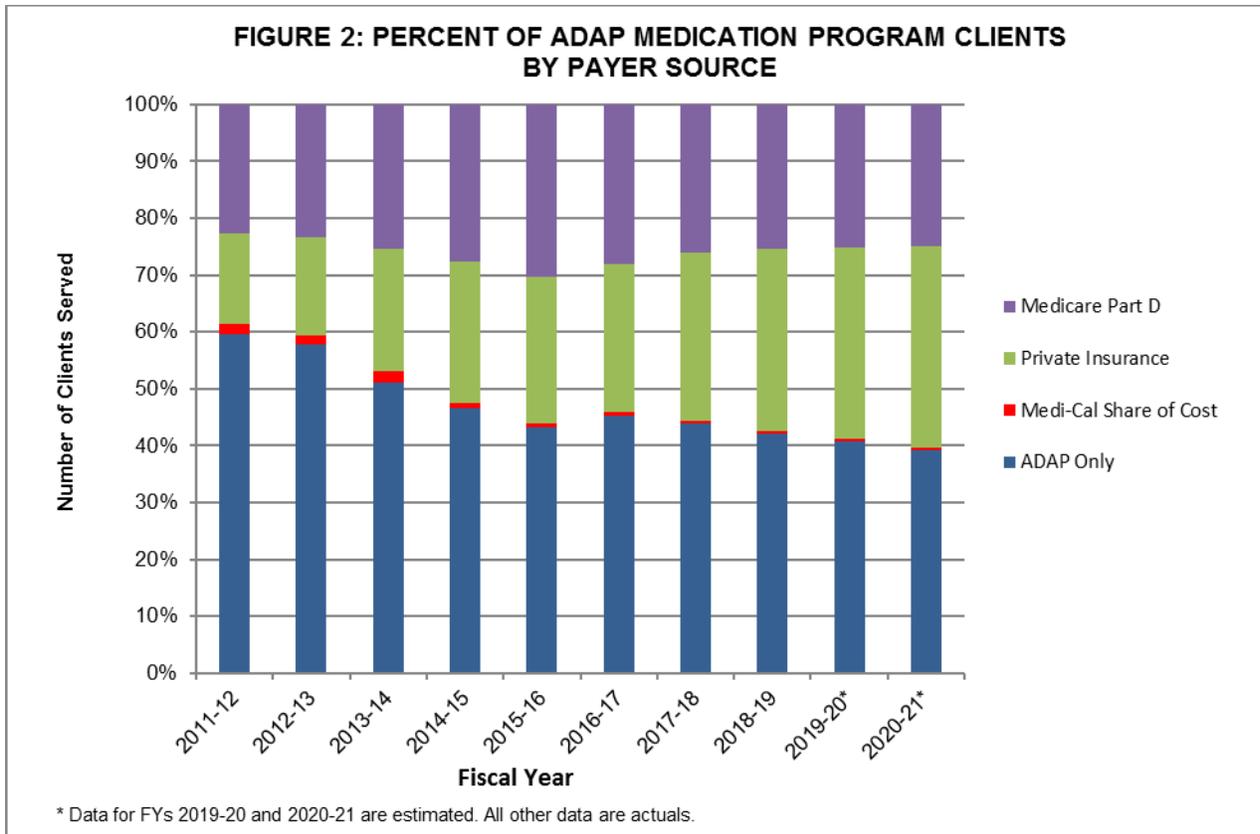
Figure 1 is a summary of total client counts in ADAP by FY, excluding PrEP-AP clients. The number of ADAP medication program clients who are also receiving insurance assistance is also shown.

Figure 2 shows the proportion of ADAP medication program clients enrolled in the various payer groups by FY.

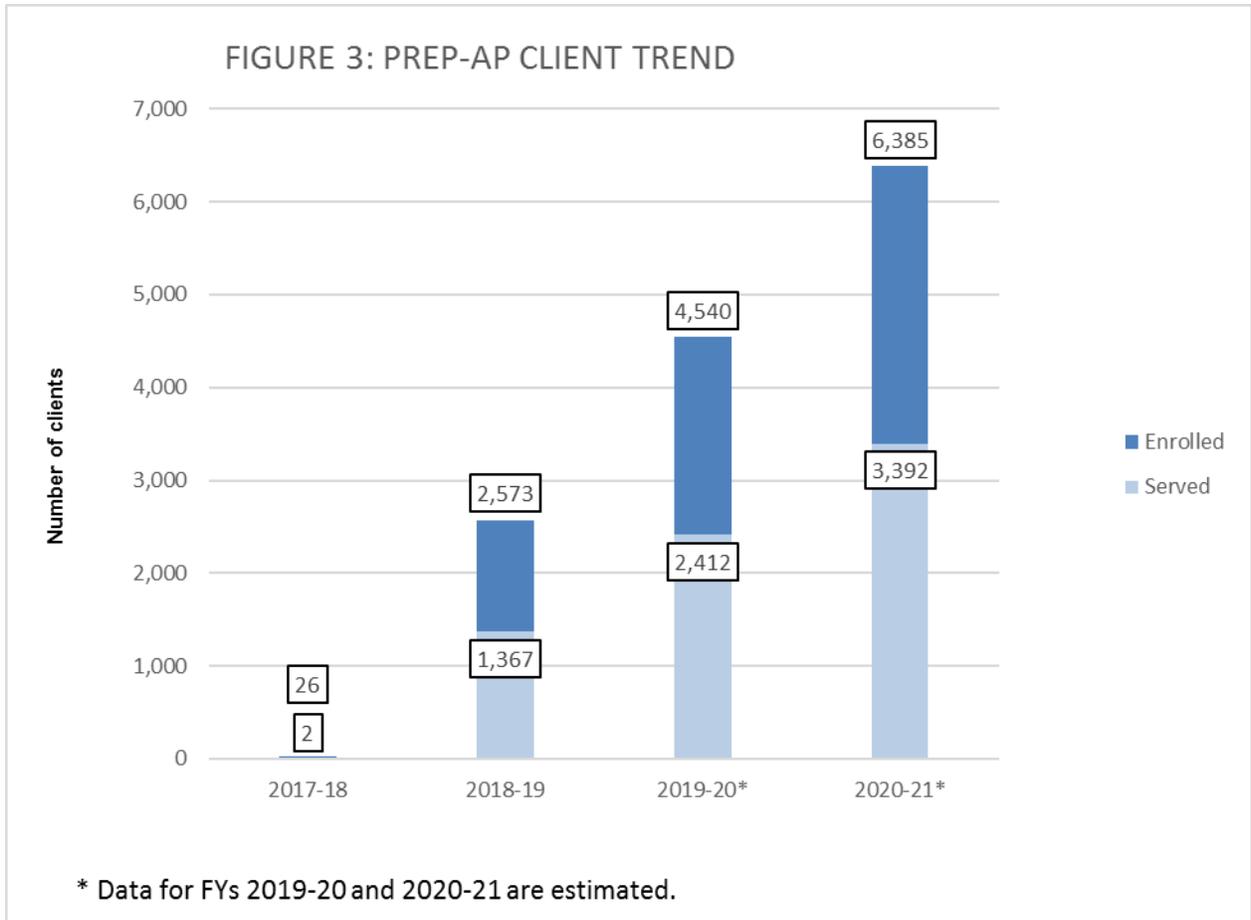
Figure 3 is a summary of estimated client counts in PrEP-AP by FY.

Figure 4 is the number of medications on the ADAP formulary by FY; the number of ARV medications is also shown.

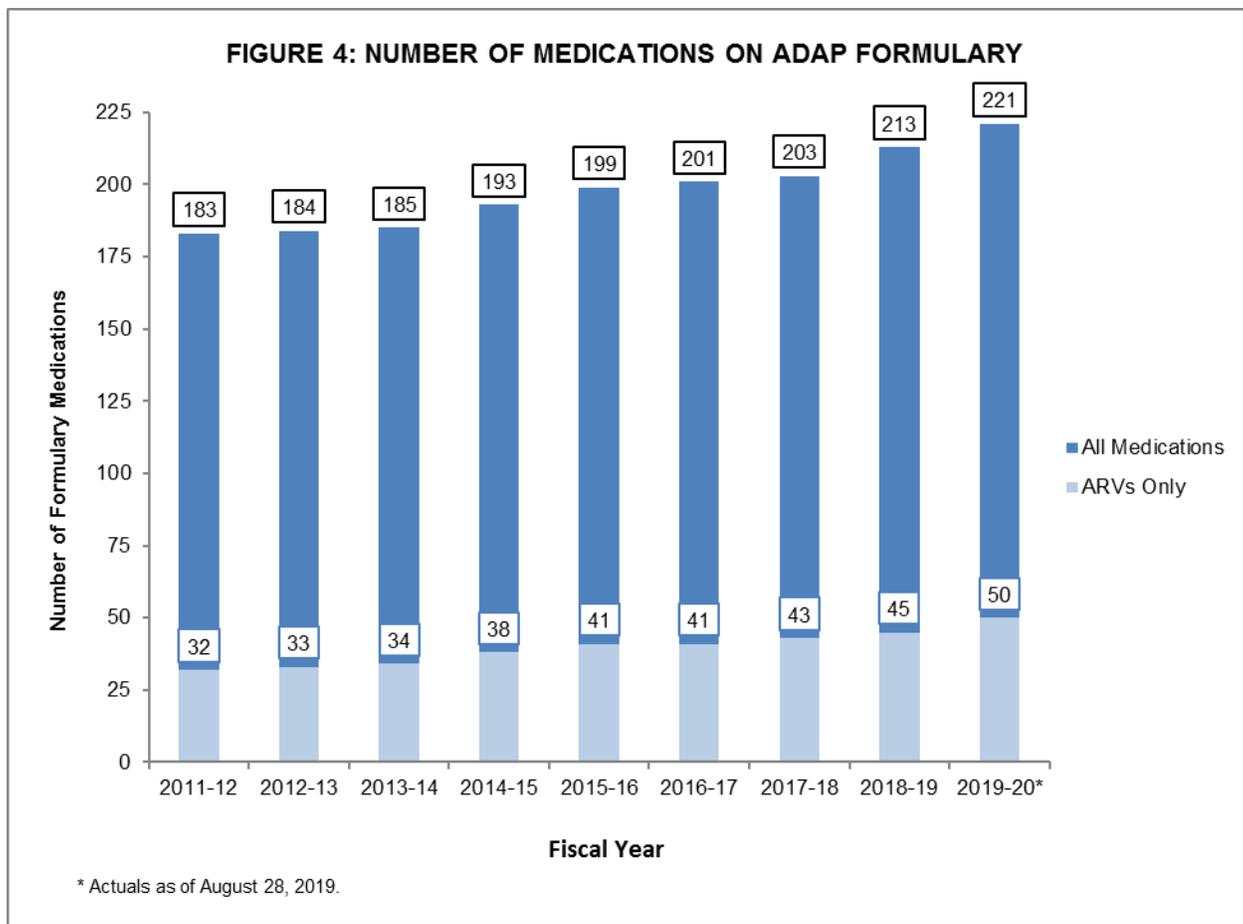




Note: In Figures 1 and 2, all client counts represent the number of clients served who incur program costs. Enrolled clients who do not incur program costs are excluded from these counts.



Note: In Figure 3, both clients served and enrolled are displayed.



Additions to the ADAP Formulary

- Doravirine (Pifeltro™), an ARV, was added to the formulary on May 3, 2019.
- Doravirine/lamivudine/tenofovir disoproxil fumarate (Delstrigo™), a FDC ARV, was added to the formulary on May 3, 2019.
- Ibalizumab (Trogarzo™), an ARV, was added to the formulary on May 3, 2019.
- Dolutegravir/lamivudine (Dovato™), a FDC ARV, was added to the formulary on May 24, 2019.
- Tenofovir alafenamide (Vemlidy™), a hepatitis B drug, was added to the formulary on May 24, 2019.
- Naloxone spray and injection (Narcan™/Evizo™), opioid antagonist, was added to the formulary on September 16, 2019.
- Efavirenz/lamivudine/tenofovir disoproxil fumarate (Symfi Lo™), a FDC ARV, was added to the formulary on September 20, 2019.
- Pitavastatin (Zypitamag™), a statin, was added to the formulary on September 20, 2019.

VII. Current HIV Epidemiology in California

Approximately 135,000 people in California at the end of 2017 had been diagnosed with HIV and reported to Public Health/OA. However, Public Health/OA estimates that 12 percent of all PLWH in California are unaware of their infection. Therefore, Public Health/OA estimates that there were approximately 153,000 PLWH in California as of the end of 2017. Since the epidemic began in 1981, approximately 100,000 Californians diagnosed with HIV have died, with over 1,800 dying in 2017 alone.

Of the approximately 135,000 people living with diagnosed HIV (PLWDH) in California, approximately 39.1 percent are White; 36.1 percent are Hispanic/Latinx; 17.2 percent are Black/African American; 4.0 percent are Asian; 3.1 percent are multi-racial; 0.3 percent are American Indian/Alaskan Native; and 0.2 percent are Native Hawaiian/Pacific Islander. While Whites and Hispanics/Latinxs make up the largest percentage of PLWDH in California, the rate of HIV among Blacks/African Americans is substantially higher (1,019 per 100,000 population, versus 348 per 100,000 among Whites, and 312 per 100,000 among Hispanics/Latinxs).

Most of California's living HIV cases are attributed to male-to-male sexual transmission (67.7 percent); 8.7 percent of living cases are attributable to high-risk heterosexual contact (defined as contact with a sex partner or partners of the opposite gender who are either known to be HIV infected or known to be someone who injects drugs, has hemophilia, or is a man who has sex with other men); 6.9 percent to men who have sex with men who also inject drugs; 5.9 percent to injection drug use; 0.6 percent to perinatal exposure; and 10.3 percent to other or unknown sources, including other heterosexual contact.

There are approximately 4,800 new HIV cases reported in California each year. The number of PLWH in the state is expected to grow by approximately 3.0 percent each year for the next two years, and it is expected that this trend will continue for the foreseeable future until more progress is made in preventing new HIV infections. This increase is attributed to stable incidence rates and longer survival of those infected, primarily due to the effectiveness and availability of treatment.