

Pharmaceutical Company Patient Assistance Programs and Cost-Sharing Assistance Programs for Pre-exposure Prophylaxis (PrEP) and Post-exposure Prophylaxis (PEP)

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What is a Patient Assistance Program (PAP)?

A patient assistance program is a program run by, or in association with, pharmaceutical companies to provide free or low-cost medications to people with low-incomes who do not qualify for any other insurance or assistance programs, such as Medicaid, Medicare, or AIDS Drug Assistance Programs (ADAPs). Each individual company has different eligibility criteria for enrollment in their patient assistance program.

What is a Cost-sharing Assistance Program (CAP)?

A cost-sharing assistance program is a program operated by pharmaceutical companies to offer cost-sharing assistance (including deductibles, co-payments and co-insurance) to people with private health insurance to obtain HIV drugs at the pharmacy. Pharmaceutical company CAPs cannot be used by individuals covered by Medicaid or Medicare.

PrEP Patient Assistance Program (PAP)

The following provides an overview of PAP contact information and financial eligibility criteria for Descovy and Truvada, the only U.S. Food and Drug Administration (FDA)-approved brand-name HIV drug products for PrEP. Several generic versions of Truvada – tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) – are commercially available in the U.S. at substantially reduced costs, but are generally not available via manufacturer PAPs.

Company	Contact Information	Financial Eligibility	
Gilead Sciences	800-226-2056 www.gileadadvancingaccess.com/	500% FPL	

Ready, Set, PrEP

In addition to Gilead Sciences' Advancing Access program, the U.S. Department of Health and Human Services launched *Ready, Set, PrEP* in December 2019 to provide free PrEP medications to HIV-negative individuals who don't have health insurance coverage for prescription drugs. There are no financial eligibility requirements to qualify for *Ready, Set, PrEP*.

PrEP Cost-sharing Assistance Program (CAP)

The following provides an overview of CAP contact information and assistance offered for Truvada and Descovy.

Company	Contact Information	Assistance	Renewal
Gilead Sciences	877-505-6986 www.gileadadvancingaccess.com/	The Gilead Advancing Access co-pay coupon card covers up to \$7,200 in co- payments per year with no monthly limit for Truvada and Descovy for PrEP.	Automatically renews annually for enrolled patients.

Manufacturer cost-sharing assistance for generic TDF/FTC is not available. Support from the Patient Assistance Foundation (see Page 9) and <u>state PrEP assistance programs</u> may be available.

PEP Patient Assistance Program (PAP)

PAPs are available for PEP, but each company has different policies for applying and delivery of medications. Please see detailed instructions for each pharmaceutical company below.

As per the U.S. Centers for Disease Control and Prevention's <u>Updated Guidelines for Antiretroviral Postexposure Prophylaxis after Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016</u>, the following 28-day regimens are recommended for PEP:

- TDF/FTC 300/200 mg (Truvada or generic) once daily plus either:
 - dolutegravir 50 mg (Tivicay) 1 tablet once daily*
 - o raltegravir 400 mg (Isentress) 1 tablet twice daily

Alternative regimens:

- TDF/FTC 300/200 mg (Truvada or generic) once daily plus:
 - o darunavir 800 mg (Prezista) and ritonavir 100 mg (Norvir or generic) − 1 tablet each once daily

All CDC recommended and alternative PEP regimen components are highlighted (in blue) in the following table.

^{*}If within the first trimester of pregnancy (post-LMP or by ultrasound dating) OR may become pregnant within the next 28 days, the recommendation is Truvada plus Isentress.

Company	Contact Information	Drugs Covered	Financial Eligibility	Access Information
AbbVie	800-222-6885 www.abbvie.com/myAbbVieAssist	Kaletra and Norvir	500% FPL for Kaletra; no income limits for Norvir	 Complete an application; indicating TRAUMA on the application (this will expedite processing). Fax to: 866-483-1305. Call AbbVie, noting that you sent a fax for a TRAUMA case. AbbVie will send medications to provider. If received by 12:30 PM, will have overnight delivery (about 24 hours). If received after 12:30 PM, will have next day delivery (about 48 hours).
Gilead Sciences	800-226-2056 www.gileadadvancingaccess.com	Atripla, Biktarvy, Complera, Descovy, Emtriva, Genvoya, Odefsey, Stribild, Truvada , Tybost, and Viread	500% FPL	 Fax a letter of medical necessity (OR the first page of the Advancing Access Enrollment form) to 1-800-216-6857, including: Patient's name Therapy needed Date of exposure Provider's signature Call Gilead at 1-800-226-2056 and notify them you have a patient who needs PEP (Hours: Monday - Friday 9am-8pm EST.) Tell them you faxed in a letter of medical necessity. Give them time of fax Number of pages Your fax number Have the patient's information available: Name Address Phone number Date of birth Social security number Number of people claimed as dependents

				 Household income Any insurance coverage Provider name Provider address Provider phone number Parental/guardian signature of consent for any patient under 18 years of age Gilead Sciences will give you a voucher number to place on the prescription. The patient may go to the pharmacy to fill the prescription with no out-of-pocket expense.
Johnson & Johnson Patient Assistance Foundation, Inc. (Janssen Pharmaceuticals)	800-652-6227 www.jjpaf.org	Edurant, Intelence, Prezcobix, Prezista, and Symtuza	300% FPL	 Patient completes all relevant information on application page 2, and signs and dates the Patient Declaration/Authorization to Assign Representatives for Program Enrollment on page 2. Include a copy of the front and back of patient's insurance card. Include a copy of the patient's most recent 1040 or 1040EZ Federal tax return OR check the box in Section 4 on page 2 of the application. Healthcare Professional (HCP) to complete and sign and date page 3. Mail or fax complete application with documentation to 1-888-526-5168. Immediate access is available through the use of pharmacy card. At the request of the physician, a pharmacy card number will be provided to the patient, immediately upon eligibility/approval. He/she can then go to the pharmacy with a valid prescription to pick up their medication.
Merck and Co.	800-727-5400 www.merckhelps.com/	Isentress, Isentress HD, Delstrigo, and Pifeltro	At or below 500% FPL	 Complete an application; indicating PRESCRIBING PEP on the application or URGENT. Please note all HIV enrollments are handled immediately upon receipt. Product is shipped overnight if patient is eligible. Fax application to: 1-915-849-1037.

				 3. Also, call Merck Patient Assistance Program at 1-800-727-5400, noting that you sent a fax for PRESCRIBING PEP. 4. Merck Patient Assistance Program will send medications directly to patient or provider as noted on enrollment form. If received by 3:00 PM (EST), will have overnight delivery to their zip code by ~10:30am next day. If received after 3:00 PM (EST), will have next day delivery.
ViiV Healthcare	844-588-3288 www.viivconnect.com/	Cabenuva, Combivir, Epivir, Epzicom, Lexiva, Retrovir, Rukobia Selzentry, and Tivicay, Tivicay PD	500% FPL Cannot be eligible for Medicaid	 1. There are three ways to enroll a patient: Patient or Patient Rep (i.e., on-going medical provider or case manager) may fax the completed enrollment form Patient Rep may enroll the patient via the online portal at www.viivconnect.com Patient Rep may call ViiVConnect at 1-844-588-3288 (toll free); Monday-Friday, 8 AM – 11 PM (EST) to speak live with an Access Coordinator to enroll non-Medicare Part D patients. First Time Patient Reps can register at the same time of call for a patient. NOTE: Access Coordinators can obtain the necessary information over the phone and provide the patient with same day access through the presumptive fill process for eligible patients. Presumptive enrollment (enrollment by phone through a Patient Representative) is for first time non-Medicare Part D applicants only.

Cost-Sharing Assistance Programs (CAPs) for PEP

The following provides an overview of CAP contact information, drugs covered, and assistance offered.

Company	Contact Information	Drugs Covered	Assistance	Renewal
AbbVie	800-441-4987 www.abbvie.com/myAbbVieAssist	Kaletra and Norvir	The co-payment assistance program provides a Kaletra savings card which can cover up to \$400 per month with a \$4,800 maximum benefit per year. The savings card can only be used once every 30 days. Participants cannot be receiving government-funded prescription assistance.	Automatic annual renewal for enrolled patients.
Gilead Sciences	800-226-2056 www.gileadadvancingaccess.com/	Atripla, Complera, Descovy, Emtriva, Genvoya, Odefsey, Stribild, Truvada, Tybost, and Viread	The program covers up to \$7,200 in co-payments for Truvada per year.	Automatic annual renewal for enrolled patients.

Janssen Therapeutics	877-227-3728 www.janssencarepath.com/hcp	Edurant, Intelence, Prezcobix, Prezista, and Symtuza	Eligible patients who have commercial health insurance coverage pay \$0 per prescription of Prezista, up to a \$7,500 maximum program benefit per calendar year. Depending on the health insurance plan, savings may apply toward co-pay, co-insurance, or deductible.	Must reapply each year.
Merck and Co.	877-264-2454 www.merckhelps.com/	Isentress, Isentress HD, Delstrigo, and Pifeltro	The program covers out-of-pocket costs up to a maximum total program savings of \$6,800. Coupon may be redeemed once every 21 days before the expiration date printed on the coupon, on each qualifying prescription up to 180 tablets each.	Must reapply after the coupon expires.
ViiV Healthcare	844-588-3288 www.viivconnect.com/	Cabenuva, Combivir, Epivir, Epzicom (oral solution only), Lexiva, Retrovir, Rukobia, Selzentry, and Tivicay, Tivicay PD	The Viiv CONNECT savings card covers up to \$4,800 per year with no monthly limit for out-of-pocket costs for Lexiva and Retrovir prescriptions. For Tivicay, the card covers up to \$7,500 per year with no monthly limit. Total savings cannot exceed \$7,500 per year.	Automatic annual renewal for enrolled patients.

Foundations Providing Access to Care Assistance for PrEP/PEP

Needy Meds

http://www.needymeds.org/

Needy Meds offers resources that are helpful to uninsured and underinsured patients.

Patient Advocate Foundation

copays.org

The Patient Advocate Foundation offers a co-payment and insurance premium assistance program for insured individuals whose annual income is less than 400% FPL. The yearly maximum award is \$7,500 to help cover the out-of-pocket costs incurred for HIV treatment (the award is not drug-specific). Patients must have health insurance which covers the medication for which the patient seeks assistance. Patients must reapply every 12 months.