

Pharmaceutical Company Patient Assistance Programs and Cost-Sharing Assistance Programs for Pre-exposure Prophylaxis (PrEP) and Post-exposure Prophylaxis (PEP) June 27, 2017

What is a Patient Assistance Program (PAP)?

A patient assistance program is a program run through 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 application and enrollment in their patient assistance program.

HarborPath is a non-profit organization that helps uninsured individuals living with HIV/AIDS gain access to brand-name prescription medicines at no cost.

Applying for PAPs

In 2012, the Department of Health and Human Services (DHHS), along with seven pharmaceutical companies, the National Alliance of State and Territorial AIDS Directors (NASTAD), and community stakeholders developed a <u>common patient assistance</u> <u>program application form</u> that can be used by both providers and patients. Before, patients and advocates had to fill out different sets of paperwork for each company; the new application should help simplify this process; however the form still has to be sent to each PAP to receive access to medications. This form combines common information collected on each individual companies form to allow individuals to fill out one form. Once the form is completed, case managers or individuals then submit the single form to each individual company, reducing the overall amount of paperwork necessary to apply for a patient assistance program. <u>HarborPath</u> operates as a streamlined, online portal for PAP access. HarborPath creates a single place for application and medication fulfillment. This "one stop shop" portal provides a streamlined, online process to qualify individuals and deliver the donated medications of the participating pharmaceutical companies through a mail-order pharmacy.

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.

What is Pre-exposure Prophylaxis (PrEP)?

Pre-exposure prophylaxis (PrEP) is the use of antiretroviral (ARV) medication to prevent possible HIV infection with HIV-negative individuals who may be at higher risk of infection. PrEP is currently recommended for sexually active men who have sex with men (MSM), heterosexual men and women, and intravenous drug users (IDU). Additional information on PrEP is available on the U.S. Centers for Disease Control and Prevention (CDC) website.

As of June 6, 2017, Truvada[™] (Gilead Sciences) is the only ARV approved by the U.S. Food and Drug Administration (FDA) for use as PrEP.

The following provides an overview of PAP contact information and financial eligibility criteria for Truvada.

Company	Contact Information	Financial Eligibility
Gilead Sciences	877-505-6986 <u>www.truvada.com</u>	500% FPL

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

Company	Contact Information	Assistance	Renewal
Gilead Sciences	877-505-6986 <u>www.truvada.com</u>	The program covers the first \$300 per month/\$3,600 per year of co-payments for Truvada.	Automatically renews annually for enrolled patients.

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What is Post-exposure Prophylaxis (PEP)?

Post-exposure prophylaxis is the use of antiretroviral (ARV) medication for 28 days with HIV-negative individuals who may have been exposed to HIV through high risk sexual behavior, sharing of injection drug equipment, or accidental needle stick to prevent possible HIV infection. PEP must be given within 72 hours of possible exposure. Additional information on PEP is available at the <u>HIV Clinical</u> <u>Guidelines Program</u> and on the CDC <u>website</u>.

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.

Company	Contact Information	Drugs Covered	Financial Eligibility	Access Information
AbbVie	800-222-6885 or www.kaletra.com	Kaletra	500% FPL	 Complete an application; indicating TRAUMA on the application (this will expedite processing). Fax to: 1-732-584-0905. 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).
Bristol-Myers Squibb	888-281-8981 or <u>www.bms.com</u>	Reyataz	300 - 500% FPL	 Complete an application; indicating POST EXPOSURE on the application (this will expedite processing). Fax to: 1-888-281-8985. Call Bristol-Meyers Squibb, noting that you sent a fax for a POST EXPOSURE case. Bristol-Meyers Squibb will send medications to provider or patient. Medications are shipped overnight, except on Fridays.
Gilead Sciences	877-505-6986 or <u>www.viread.com</u>	Emtriva and Viread	500% FPL	1. Fax a letter of medical necessity to 1-800-226-2056, including:

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				 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 Household income Any insurance coverage Provider name Provider name Provider address Provider name Social signature of consent for any patient under 18 years of age Gilead Sciences will give you a voucher number to place on the prescription.
Janssen Therapeutics	800-652-6227 or <u>www.jjpaf.org</u>	Prezista	200% FPL	 Complete an application, selecting PHARMACY CARD on the application. Fax to: 1-888-526-5168. Call Janssen Therapeutics 1 to 2 hours after sending the fax to receive pharmacy card number. Write the number on the prescription. The patient may go to the pharmacy to fill the prescription with no out-of-pocket expense.

Merck and Co.	800-850-3430 or <u>www.isentress.com</u>	lsentress	500% FPL	 Complete an application; indicating PRESCRIBING PEP on the application (this will expedite processing). Fax to: 1-866-410-1913. Call Merck, noting that you sent a fax for PRESCRIBING PEP. Merck will send medications to provider. If received by 12:30 PM (PST), will have overnight delivery (about 24 hours). If received after 12:30 PM (PST), will have next day delivery (about 48 hours).
ViiV Healthcare	877-784-4842 or <u>www.ViiVhealthcareforyou.com</u>	Epivir, Lexiva, and Tivicay	500% FPL	 Call ViiV Healthcare, indicating IMMEDIATE ACCESS. Registered Advocate (i.e., on-going medical provider or case manager) must call on patient's behalf. First-time advocate can register at the same time of call for a patient. Application and all documentation for income and insurance must be faxed in after call and approval. Upon approval, patient can pick up medication that day from any retail pharmacy, with \$10 co-pay.

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	800-222-6885 or <u>www.kaletra.com</u>	Kaletra	The cost-sharing assistance covers the first \$200 per Kaletra prescription per month.	Must reapply each year.
Bristol-Myers Squibb	888-281-8981 or <u>www.bms.com</u>	Reyataz	The program covers up to \$6,800 annually for co- payments, deductibles, and co-insurance in all commercially-insured plans for Reyataz.	Must reapply each year.
Gilead Sciences	877-505-6986 or <u>www.viread.com</u>	Emtriva and Viread	The program covers the first \$300 per month/\$3,600 per year of co-payments for Emtriva and Viread.	Automatically renews annually for enrolled patients.
Janssen Therapeutics	800-652-6227 or <u>www.jjpaf.org</u>	Prezista	The co-payment assistance starts after the first \$5 paid by the consumer, then unlimited co- payment coverage.	Must reapply each year.
Merck and Co.	800-850-3430 or www.isentress.com	lsentress	The program covers the first \$400 per-month of co-payments for each of 12 eligible prescriptions.	Must reapply after 12 prescriptions filled.
ViiV Healthcare	877-784-4842 or www.ViiVhealthcareforyou.com	Epivir, Lexiva, and Tivicay	The program covers up to \$200 per-month of co- payments on each ViiV prescription (with the exception of Tivicay). For Tivicay, the program covers the first \$400 per-month of co-payments.	Must reapply every two years.

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 including an MRI/CAT scan discount program and medical bill mediation.

Additional Resources

The following resources may be of interest to individuals seeking access to PrEP and/or PEP.

Clinical Trials

www.clinicaltrials.gov

A service of the U.S. National Institutes of Health, ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

Fair Pricing Coalition (FPC) www.fairpricingcoalition.org

As part of their advocacy work, the Fair Pricing Coalition (FPC) negotiates with companies to ensure that Patient Assistance Programs (PAPs) are adequately generous and easy to apply for.

Health Insurance Marketplace www.healthcare.gov

The official site of the Health Insurance Marketplace, Healthcare.gov allows individuals and families to sign-up for insurance coverage through the Affordable Care Act.

Treatment Action Group

www.treatmentactiongroup.org

Treatment Action Group collaborates with activists, community members, scientists, governments, and drug companies to make safer, more effective and less toxic treatment for viral hepatitis available.