

Pharmaceutical Company Patient Assistance Programs and Cost-sharing Assistance Programs: **HIV Prevention**

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What is a Patient Assistance Program?

Patient assistance programs (PAPs) are run by, or in association with, pharmaceutical companies to provide free or low-cost medications to people with low incomes who generally do not qualify for any other insurance or assistance programs (such as Medicaid, Medicare, or AIDS Drug Assistance Programs). Some company PAPs may be open to certain insured people with low incomes to help with affordability challenges associated with out-of-pocket medication cost-sharing requirements.

Manufacturer PAPs maintain their own eligibility criteria, electronic enrollment portals, printable/fillable applications, and may offer expedited verification processes and first-time fills via a retail pharmacy in support of rapid antiretroviral therapy initiation.

The table on **Page 2** provides an overview of **pre-exposure prophylaxis (PrEP)** PAP contact information, drugs covered, and financial eligibility. The table on **Page 5** provides an overview of PAP contact information and financial eligibility for U.S. Centers for Disease Control (CDC)-recommended drugs for **non-occupational post-exposure prophylaxis (nPEP)**.

What is a Cost-Sharing Assistance Program?

A cost-sharing assistance program (CAP) 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; ADAP clients should be sure to check with their ADAP program before enrolling in a pharmaceutical company CAP. The table on **Page 3** provides an overview of CAP contact information and assistance offered.

The table on **Page 3** provides an overview of PrEP CAP contact information, drugs covered, and financial eligibility. The table on **Page 8** provides an overview of manufacturer CAP details for CDC-recommended drugs for **non-occupational post-exposure prophylaxis (nPEP)**.

Pharmaceutical Company Patient Assistance Programs for PrEP

The following provides an overview of PAP contact information and financial eligibility criteria for antiretroviral drug products manufactured by two companies for the PrEP: Gilead Sciences (Descovy and Truvada) and ViiV Healthcare (Apretude). In addition to the brand-name antiretrovirals from these companies, several generic versions of Truvuada –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	DRUGS COVERED	FINANCIAL ELIGIBILITY
Gilead Sciences	800-226-2056 gileadadvancingaccess.com	Descovy and Truvada	500% FPL
ViiV Healthcare ¹	844-588-3288 ViiVconnect.com	Apretude	500% FPL

¹ In addition to financial eligibility requirement, applicant must have no prescription drug coverage, or have a Medicare Part B, Medicare Part D, or Medicare Advantage Plan, and have spent at least \$600 or more on out-of-pocket prescription expenses during the current calendar year, or have a private insurance plan limited to generic-only coverage, outpatient use only, or therapeutic class exclusion (non-coverage) of drug

Pharmaceutical Company Cost-sharing Assistance Programs for PrEP

The following provides an overview of CAP contact information and assistance offered for Truvada, Descovy, and Apretude. Manufacturer CAPs for generic TDF/FTC are not available.

COMPANY	CONTACT INFORMATION	ASSISTANCE
Gilead Sciences	800-226-2056 gileadadvancingaccess.com	Descovy & Truvada: \$7,200 per year
ViiV Healthcare ¹	844-588-3288 ViiVconnect.com	Apretude : \$7,500 per year (medical and pharmacy benefit cost-sharing ; up to \$350 per year for copay assistance associated with provider administration)

Other Programs Providing Medication Assistance for PrEP

Patient Advocate Foundation

copays.org

The Patient Advocate Foundation offers a cost-sharing 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 reapply every 12 months.

Pharmaceutical Company Patient Assistance Programs for nPEP

PAPs are available for nPEP, but each company has different policies for applying and delivery of medications. Please see detailed instructions for each pharmaceutical company in the table beginning on the next page.

As per the U.S. Centers for Disease Control and Prevention's [Updated Guidelines for Antiretroviral Postexposure Prophylaxis after Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016](#), 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*
 - raltegravir 400 mg (Isentress) – 1 tablet twice daily

Alternative regimens:

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

*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.

Only CDC–recommended and alternative PEP regimen components are noted in the following table. PAP details for all brand-name antiretroviral drugs including in manufacturer PAPs can be found in this fact sheet: "[Pharmaceutical Company Patient Assistance Programs and Cost-sharing Assistance Programs: HIV Treatment](#)"

MANUFACTURER (CDC-RECOMMENDED nPEP DRUG)	FINANCIAL ELIGIBILITY	ACCESS INFORMATION
AbbVie (Norvir)	No income limit	<ol style="list-style-type: none"> 1. Complete an application; indicating TRAUMA on the application 2. Fax to: 866-483-1305 3. Call AbbVie, noting that you sent a fax for a TRAUMA case 4. AbbVie will send medications to provider <ul style="list-style-type: none"> • Overnight shipment if received by 11:00 am CST • Next-day shipment if received after 11:00 am CST
Gilead Sciences (Truvada)	500% FPL	<ol style="list-style-type: none"> 1. Complete and sign an application; fax to: 800-216-6857. Requestor may also contact Advancing Access directly to complete phone-based application 2. Call Advancing Access at 800-226-2056 and notify representative of client needing nPEP (Hours: Monday - Friday 9:00 am – -8:00 pm EST) <ul style="list-style-type: none"> • Inform representative if application was faxed (not required, can initiate via phone); representative will require HIPAA consent to proceed. • If faxed: provide time of fax sent, number of pages, and submitter’s fax number • Required information for phone initiation: drug needed, patient information (name, address, phone, DOB, household income and size, insurance coverage), and provider information (name, address, phone), and parental/guardian consents (if individual is <18 years of age) 3. Advancing Access will process application and reach out to the requestor for pharmacy information and/or missing information.

<p>Johnson & Johnson Patient Assistance Foundation, Inc. (Prezista)</p>	<p>300% FPL</p>	<ol style="list-style-type: none"> 1. Patient completes all information on application page 2, and signs and dates the Patient Declaration/Authorization to Assign Representatives for Program Enrollment on page 2. <ul style="list-style-type: none"> • Include a copy of the front and back of patient’s insurance card (if applicable). • 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. 2. Healthcare professional to complete and sign and date page 3. 3. Fax complete application with documentation to 888-526-5168. 4. Call Johnson & Johnson Patient Assistance Foundation and notify representative of faxed application and client needing immediate access for nPEP. 5. 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. Patient can then go to the pharmacy with a valid prescription to pick up their medication.
<p>Merck & Co. (Isentress)</p>	<p>400% FPL</p>	<ol style="list-style-type: none"> 1. Patient and provider completes an application 2. Healthcare profession should call 800-727-5400 and inform representative that product is urgently needed; application submission details will be provided. 3. Merck PAP will ship medication directly to patient or provider for next-day delivery.
<p>ViiV Healthcare (Tivicay)</p>	<p>500% FPL</p>	<ol style="list-style-type: none"> 1. Patient Representative should call 844-588-3288 to speak with ViiVConnect Access Coordinator about Presumptive Fill. Presumptive Fill allows a patient to receive up to three 30-day fills in a lifetime at a local retail pharmacy. 2. ViiVConnect may provide Presumptive Fill to uninsured patients that meet all other eligibility criteria 3. Patient Representative will confirm that patient has no insurance/prescription coverage 4. Eligibility requirements include: uninsured or no prescription coverage, applicant first and last name, applicant address, medication required, household size and annual household income. 5. Patients enrolled in applicable Medicare plans must submit Enrollment Form for eligibility review.

Pharmaceutical Company Cost-Sharing Assistance Programs for nPEP

COMPANY	CONTACT INFORMATION	ASSISTANCE
AbbVie	800-441-4987 abbvie.com/patients/patient-support/patient-assistance/savings-card.html	Norvir: first \$100 per month/\$1,200 per year
Gilead Sciences	800-226-2056 gileadadvancingaccess.com	Truvada: \$7,200 per year
Janssen Pharmaceuticals	866-836-0114 janssencarepath.com	Prezista: \$7,500 per year
Merck & Co.	800-727-5400 merckhelps.com	Isentress: \$6,800 per year
ViiV Healthcare ¹	844-588-3288 ViiVconnect.com	Tivicay: \$5,000 per year