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

September 4, 2018

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 common patient assistance program application form 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 company’s 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.
HarborPath 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 13, 2018, 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.

<table>
<thead>
<tr>
<th>Company</th>
<th>Contact Information</th>
<th>Financial Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gilead Sciences</td>
<td>800-226-2056</td>
<td>500% FPL</td>
</tr>
<tr>
<td></td>
<td><a href="https://www.gileadadvancingaccess.com">https://www.gileadadvancingaccess.com</a></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Company</th>
<th>Contact Information</th>
<th>Assistance</th>
<th>Renewal</th>
</tr>
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<tbody>
<tr>
<td>Gilead Sciences</td>
<td>877-505-6986</td>
<td>The Gilead Advancing Access co-pay coupon card covers up to $7,200 in co-payments per year with no monthly limit for Truvada for PrEP.</td>
<td>Automatically renews annually for enrolled patients.</td>
</tr>
</tbody>
</table>
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 HIV Clinical Guidelines Program and on the CDC website.

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.

<table>
<thead>
<tr>
<th>Company</th>
<th>Contact Information</th>
<th>Drugs Covered</th>
<th>Financial Eligibility</th>
<th>Access Information</th>
</tr>
</thead>
</table>
| AbbVie                   | 800-222-6885        | Kaletra       | 500% FPL              | 1. Complete an application; indicating TRAUMA on the application (this will expedite processing).  
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.  
  ▪ 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        | Reyataz       | 500% FPL              | 1. Complete an application; indicate POST EXPOSURE on the application (this will expedite processing).  
2. Fax to: 1-888-281-8985.  
3. Call Bristol-Meyers Squibb, noting that you sent a fax for a POST EXPOSURE case. Turnaround should be 24 hours.  
4. Bristol-Meyers Squibb will send medications to provider or patient. Medications are typically shipped overnight. Remaining shipments are sent 2-day ground. |

AbbVie website: [www.abbviepaf.org/index.cfm](http://www.abbviepaf.org/index.cfm)  
Kaletra website: [www.kaletra.com/](http://www.kaletra.com/)  
Bristol-Myers Squibb website: [www.bms.com](http://www.bms.com)
1. 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

2. 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

3. 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.

1. Complete an application, selecting PHARMACY CARD on the application to have the prescription filled at a pharmacy. Health care provider also must fill out several pages of the application. Be sure to include the most recent 1040 or 1040EZ federal tax return.
2. Fax to: 1-888-526-5168.
<table>
<thead>
<tr>
<th>Company</th>
<th>Phone Number</th>
<th>Website</th>
<th>Cost</th>
<th>Instructions</th>
</tr>
</thead>
</table>
| Merck and Co.    | 800-727-5400 | [www.merckhelps.com/ISENTRESS](http://www.merckhelps.com/ISENTRESS) | 400% FPL | 1. Complete an application; indicating PRESCRIBING PEP on the application (this will expedite processing).  
2. Fax to: 1-915-849-1037.  
3. Call Merck, noting that you sent a fax for PRESCRIBING PEP.  
4. 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). |
   ▪ A Patient Representative (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. |
Cost-Sharing Assistance Programs (CAPs) for PEP

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

<table>
<thead>
<tr>
<th>Company</th>
<th>Contact Information</th>
<th>Drugs Covered</th>
<th>Assistance</th>
<th>Renewal</th>
</tr>
</thead>
<tbody>
<tr>
<td>AbbVie</td>
<td>800-441-4987</td>
<td>Kaletra</td>
<td>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.</td>
<td>Must reapply each year.</td>
</tr>
<tr>
<td>Bristol-Myers Squibb</td>
<td>888-281-8981</td>
<td>Reyataz</td>
<td>The program covers up to the first $7,500 annually for co-payments, deductibles, and co-insurance with no monthly limit for all commercially-insured plans for Reyataz. Patient may use the co-payment assist card for 30-, 60-, or 90-day prescriptions fills.</td>
<td>Automatic annual renewal for enrolled patients.</td>
</tr>
<tr>
<td>Gilead Sciences</td>
<td>800-226-2056</td>
<td>Emtriva and Viread</td>
<td>The program covers up to $3,600 in co-payments per year, with a monthly maximum of $300 for Emtriva and/or Viread prescriptions.</td>
<td>Automatic annual renewal for enrolled patients.</td>
</tr>
<tr>
<td>Janssen Therapeutics</td>
<td>877-227-3728</td>
<td>Prezista</td>
<td>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.</td>
<td>Must reapply each year.</td>
</tr>
<tr>
<td>Merck and Co.</td>
<td>877-264-2454</td>
<td>Isentress and Isentress HD</td>
<td>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.</td>
<td>Must reapply after the coupon expires.</td>
</tr>
<tr>
<td>ViiV Healthcare</td>
<td>844-588-3288</td>
<td><a href="http://www.viivconnect.com/">www.viivconnect.com/</a></td>
<td>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.</td>
<td>Automatic annual renewal for enrolled patients.</td>
</tr>
</tbody>
</table>
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.