



WHITMAN-WALKER HEALTH

Mailing Address:

Elizabeth Taylor Medical Center
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Larry J. Merlo
President and CEO, CVS Health

Troyen Brennan, M.D.
Executive V.P. and CMO, CVS Health

Thomas M. Moriarty
Executive V.P., Chief Policy,
External Affairs Officer, General Counsel, CVS Health

Dear Mr. Merlo, Dr. Brennan, and Mr. Moriarty:

We are writing to you on behalf of numerous clients who have health insurance through CVS Caremark and who have encountered difficulties accessing PEP in a timely manner from your company. Specifically, Caremark members in need of a rapid PEP prescription experience alarming access barriers due to the classification of the antiretroviral drugs that are used for this therapy as “specialty drugs” that must be obtained by mail order from your specialty pharmacy, CVS Specialty. Other troublesome requirements placed on these drugs include prior authorization, and higher cost for patients who opt out of mail-order. These requirements and the lengthy process required to opt out of mail order, result in very dangerous delays for Caremark members who need PEP because of the extreme time-sensitivity of that therapy.

Whitman-Walker Health (WWH) is a Washington, DC community health center specializing in HIV care and in the health and wellness of lesbian, gay, bisexual and transgender (LGBT) communities. In addition to being the largest HIV health care provider in the Washington metropolitan region, we are one of the oldest medical-legal partnerships in the nation, and have provided both medical and legal services to our patients for more than 30 years. Whitman-Walker’s services include a pharmacy that is open to the general public. One of the array of HIV prevention services that we offer to our community is providing expedited Post-Exposure Prophylaxis (PEP) treatment to individuals who have been exposed to HIV.

As we are sure you know, PEP is a 28-day treatment, based on a combination of antiretroviral drugs, that is administered to an individual who has experienced a sexual, occupational or other likely exposure to HIV and who tests HIV-negative shortly after the time of exposure. The timeliness factor in obtaining these medications is of great importance. PEP, which is a uniquely

urgent treatment, must be started within 72 hours after a possible exposure to HIV to prevent becoming HIV infected. Research shows improved health outcomes and higher rates of protection with same-day initiation for HIV treatment. The Centers for Disease Control and Prevention (CDC) emphasizes that starting PEP as soon as possible after a potential HIV exposure increases the effectiveness of the treatment.¹

Many individuals in need of PEP come to WWH some hours or days after their exposure. We have instituted protocols to ensure rapid medical consultations, HIV testing and counseling of these individuals to ensure that they receive their prescription as quickly as possible, and our pharmacy staff is on alert to rapidly fill PEP prescriptions. Obtaining the prescribed drugs by mail order is dangerous given the extreme time-sensitivity of this therapy. Although Caremark members can opt out of the mail-order requirement, in our experience these patients and WWH providers and pharmacy staff who assist them in opting out encounter a number of barriers. These barriers delay the process and jeopardize the effectiveness of the prescription, and, therefore, endanger the Caremark members' health. Documented cases of patients encountering difficulties filling these prescriptions include the following:

1. Patients facing higher costs if they wish to opt-out and use local pharmacies. Having to pay more for faster access to this time sensitive treatment is not only more stressful, but also increases the risk of seroconversion for lower income individuals.
2. CSP customer service representatives not being familiar with the opt-out process, and variation in plans that are eligible for an override
3. Patients and providers or pharmacy staff experiencing lengthy delays when attempting to override the mail-order requirement with CSP staff by phone.

These obstacles are not merely inconvenient; given the extreme time-sensitivity of PEP therapy, the resulting delays can mean the difference between a successful 28-day treatment, and an HIV infection resulting in a lifetime course of antiretroviral medication. In every case, Caremark's mail-order requirement, prior authorization, and time and cost variable of the opt-out process, impose unnecessary burdens and stresses on patients and WWH staff in highly sensitive and already-stressful circumstances. Many of the individuals who have experienced an exposure-prone incident that requires PEP therapy are in significant distress – they are recent victims of sexual assault, or just learned that a sex partner is HIV-positive, or that a condom was not used or that it broke during sex. Some of them have limited literacy with technology and are easily intimidated or discouraged by complicated procedures imposed by their insurer.

We submit that there is no convincing reason to require that PEP drugs be obtained by mail order, or after complying with a complex opt-out procedure or prior authorization. PEP therapy is well understood by specialists, including our providers at WWH. The criteria for prescribing

¹ For more information, see the CDC's resources at <https://www.cdc.gov/hiv/risk/pep>.

PEP are well-established and not subject to significant abuse or error. The rationale found on your website for CVS Specialty program revolves around the many options you give your members, namely around pickup and delivery, and your ability to get them the medication they need, when they need it.² The laudable and important goals of flexibility for your members, and responsiveness to their specific needs are undercut by the mail-order and opt-out requirements that currently exist for PEP drugs. **To reiterate – PEP is extremely time-sensitive: its effectiveness in preventing HIV seroconversion depends on how early patients start the treatment, and after 72 hours has passed it is no longer recommended.**

We write to strongly recommend removing the mail order requirement on anti-retroviral drugs prescribed as PEP. Protocols for PEP commonly consist of including Truvada, Isentress, Tivicay, or Stribild, all of which currently are subject to the mail order pharmacy requirement.

We look forward to discussing this issue with you and hope that we can arrive at a quick resolution. To contact us, please reach out to Guillaume Bagal.

Thank you for your prompt attention to this matter.

Very truly yours,

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² Why Choose CVS Specialty? CVS Specialty website. <https://www.cvsspecialty.com/wps/portal/specialty>. Accessed July 14, 2017.