



WHITMAN-WALKER HEALTH

Mailing Address:

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Steve Nelson
Chief Executive Officer, UnitedHealthcare

Dr. Sam Ho
Chief Medical Officer, UnitedHealthcare

Thad Johnson
Chief Legal Officer, UnitedHealthcare

Dear Mr. Nelson, Dr. Ho, and Mr. Johnson:

We are writing to you on behalf of numerous clients who have health insurance through UnitedHealthCare (UHC) and who have encountered difficulties accessing PEP in a timely manner from your company. Specifically, UHC 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, OptumRx. This requirement and the lengthy process required to opt out of mail-order, result in very dangerous delays for UHC 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 the therapy. Although UHC 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 UHC members' health. Documented cases of patients encountering difficulties filling these prescriptions include the following:

1. Patients having difficulty accessing the opt-out form. While it was previously listed on OptumRx's page along with numerous forms, UHC members were required to login into OptumRx with a username and password to use it. We are currently unable to locate the form on the OptumRx website.
2. OptumRx customer service representatives not being familiar with the opt-out process.
3. Patients having to call OptumRx to opt out more than once.
4. Patients and providers or pharmacy staff experiencing lengthy delays when attempting to reach OptumRx 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, UHC's mail-order requirement and 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. PEP therapy is well understood by specialists, including our providers at WWH. The criteria for prescribing PEP are well-

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

established and not subject to significant abuse or error. The rationale found on your website for the mail-order requirement on specialty drugs is that it allows members to live healthier lives and payers to save money.² Making the case for home delivery pharmacy, your website cites two studies linking home delivery with better patient outcomes.³ The first study demonstrated improved adherence among diabetic patients who used home delivery compared to retail pharmacies.⁴ However, the study population in that analysis were Medicare beneficiaries, therefore 65 years of age or older, or suffering from a disability. Individuals who need PEP tend to be younger and more mobile, a demography that is less likely to mirror your findings with diabetic patients.⁵ The second study you cited demonstrated improved cholesterol levels for patients who used home delivery compared to retail pharmacies. However, those improvements were measured as having “achieved better cholesterol control in the first 3-15 months following the initiation of therapy.” As PEP is a 28-day treatment, this study does little to support the benefit of mail order requirement for such an urgent treatment. **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 Description of UHC special pharmacy program. <https://www.uhc.com/employer/pharmacy/specialty-pharmacy>.

³ UHC page on home delivery pharmacy. <https://www.uhc.com/employer/pharmacy/home-delivery>

⁴ Zhang L, Zakharyan A, Stockl KM, Harada AS, Curtis BS, Solow BK. Mail-order pharmacy use and medication adherence among Medicare Part D beneficiaries with diabetes. *J Med Econ.* 2011;14(5):562–7

⁵ Merchant RC, et al. Incidence of visits for health care worker blood or body fluid exposures and HIV post exposure prophylaxis provision at Rhode Island emergency departments. *J Acquir Immune Defic Syndr.* 2008 Mar 1;47(3):358–68