Ryan White Clinics for 340B Access

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VIA EMAIL TO: susan_v_maddux@uhc.com

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RE: United Healthcare Exclusion of Descovy® When Prescribed for HIV PrEP

I am writing on behalf of Ryan White Clinics for 340B Access (RWC-340B) in connection to your June 30, 2020 letter that was recently brought to our attention. According to the letter, UnitedHealthcare Services, Inc. (UHC) will "exclude Descovy® when prescribed for HIV PrEP from coverage." RWC-340B is deeply concerned by UHC's decision and believes UHC's exclusionary coverage policy could interfere with clinical decision-making, compromise patient care and drive up costs for Ryan White clinics (RWCs). RWC-340B requests a meeting with UHC at its earliest convenience with the hope that UHC would be willing to reverse its coverage exclusion after considering more fully the implications of its decision.

RWC-340B is a national association of HIV/AIDS health care clinics and service providers receiving grant support under the Ryan White CARE Act. It was organized in 2013 by a group of RWC providers with one common goal—to preserve the benefits of the 340B program for themselves and for all private non-profit 340B program participants that provide primary care, case management, and other support services to persons living with HIVAIDS (PLWHA). The 340B drug pricing program (340B program) allows RWC-340B members to leverage their 340B savings to support the full continuum of care needed by the HIV/AIDS population – from diagnosis, to linkage to care, to medication adherence, to viral suppression. Although a core characteristic of RWC-340B membership is receipt of Ryan White grant funding, most members also qualify for and participate in the 340B program as federally-qualified health centers (FQHCs), FQHC look-alikes, sexually transmitted disease clinics, family planning clinics and/or safety net hospitals.

UHC's letter states that UHC commercial plan members should "consider Truvada for HIV PrEP" and that any existing prior authorizations for Descovy® will be terminated as of August 30, 2020. This policy effectively makes Truvada® the only HIV PrEP option for UHC commercial plan members. RWC-340B is concerned that UHC's exclusionary coverage policy will harm RWC-340B members and the patients they serve for two reasons: (1) excluding Descovy® from coverage infringes on provider decision-making and is not in the best interests of the patient, and (2) the loss of 340B savings associated with Descovy® will drive up the cost of patient care for RWC-340B members and thereby undermine their ability to provide the full continuum of care needed by their patients. RWC-340B asks that UHC revisit its policy and, towards that end, meet with representatives from RWC-340B to discuss how best to resolve this issue.

United Healthcare's Policy Infringes on Provider Decision-Making and the Patient's Best Interest

A patient's treating healthcare provider is the only individual that should make clinical decisions about his or her patient's care. While studies show that Truvada® and Descovy® yield similar results in reducing the risk of HIV infection, there are clinical indications for which Descovy® is a better treatment option for PrEP than Truvada®. UHC's policy, of course, does not prohibit a provider from prescribing Descovy®, but it effectively eliminates use of Descovy® for patients who do not have the resources to pay for the drug out of pocket. Most of the patients served by RWC-340B member clinics are low-income. RWC-340B is therefore concerned that UHC's new policy infringes on healthcare providers' ability to make the best clinical decisions for their low-income patients. RWC-340B is also concerned that UHC's policy will drive up the overall costs of care for their patients. This is because interference with clinical decision-making may result in more unnecessary HIV seroconversions and more HIV patients to treat.

Both Truvada® and Descovy® can be prescribed as PrEP for individuals who are at risk of contracting HIV. And many of these individuals may remain on PrEP for years. Short term comparative studies of Descovy® and Truvada® for PrEP have shown statistical differences in biomarkers that signal renal disease and loss of bone mineral density in patients taking the medications. So far these studies do not suggest an increased risk of renal impairment or bone loss in the short term, but the biomarker changes could portend long-term consequences. Overall, Descovy® has proven to be a safer drug than Truvada®. For many patient circumstances, Descovy's® profile as a safer drug can play an important role in the treating provider's decisions about the patient's appropriate treatment plan and drug regimen. Patients are also aware of the difference between the two drugs and will refuse to take Truvada® for PrEP knowing that a safer drug is available.

Healthcare providers report specific clinical indications where Descovy® is a better treatment option than Truvada®. Among them are the following:

- Baseline renal insufficiency;
- Risk factors for renal insufficiency such as hypertension, use of illicit drugs like methamphetamine and cocaine, baseline proteinuria, or being African American;
- Low body weight;
- Physical inactivity, or extreme physical activity such as marathon training;
- Alcohol abuse;
- Nicotine abuse;
- Family history of kidney disease;
- Family history of osteoporosis; and
- Anticipated duration of greater than two years.

Healthcare providers have a legal and ethical duty to obtain informed consent from their patients before initiating medical treatment. The obligation to obtain informed consent extends to medication therapies, especially when the medication involved is life sustaining like Descovy® and Truvada®. For patients who meet any of the above listed criteria, a healthcare provider would generally recommend that the patient start on Descovy®. UHC's new exclusionary coverage policy does not give healthcare providers the ability to make that decision.

UHC's problematic policy is infringing not only on the healthcare provider's clinical decision-making authority, but also on the patient's ability to make his or her own medical decisions. Patients who are already stable on Descovy® may not wish to switch medications. If a patient wishes to remain on Descovy®, UHC's letter states that the patient's physician may request a clinical review for "a patient with documented clinical reasons that may support coverage of Descovy®". However, RWC-340B members have reported that their prior authorization requests are routinely being denied even though both the charts and medical histories of their patients favor continued use of Descovy® based on the patients' being stable on Descovy®. RWC-340B is also aware that some healthcare providers are being told that there is no appeal process for medical necessity considerations because UHC's policy "is a formulary exclusion rather than a restriction." Even if prior authorization is still available, it is our understanding that the new Descovy® prior authorization request form[1] includes additional coverage criteria that was not required prior to September 1, 2020, some of which demand medical tests that RWCs are not capable of performing.[2] One of the reasons RWC-340B would like to meet with UHC is to help clarify UHC's prior authorization review process for Descovy® and whether this option is available to healthcare providers in a meaningful way.

The importance of allowing both healthcare providers and patients to choose Descovy® over Truvada® for patient care reasons was recently demonstrated by a proposed policy change within the Medicare Part D program. HIV antiretroviral drugs are considered a "protected class" of drugs under the Medicare Part D statute.[3] This means that Medicare Part D plans are required to include HIV drug therapies, including Descovy®, on their formularies and are prohibited from blocking access to them through the use of prior authorization or step therapy requirements. In 2018, the Centers for Medicare and Medicaid Services (CMS) proposed an exception that would have allowed Part D plans to exclude certain protected drugs from coverage or subject them to prior authorization or step therapy procedures.[4] The proposal prompted significant opposition from the HIV/AIDS community, convincing CMS to retract its proposed changes.[5] Although UHC's policy only applies to commercial plans, it raises the same concerns with a one-size-fits-all approach that lead CMS to preserve Descovy's® protected class status. Several states have already taken action to protect patient's access to antiretroviral medications.

Reduction in 340B Savings Is Detrimental to Ryan White Clinics and Their Patients

RWCs are on the front lines of caring for low-income and vulnerable patients in their communities. They work tirelessly to keep patients on their HIV medications so that their viral loads are suppressed to levels that render them non-infectious. RWCs that participate in the 340B program have achieved impressive rates of viral suppression among their patients. According to a report by the Health Resources and Services Administration, RWCs achieved a record level viral suppression rate of 88.1% in

[1] UnitedHealthcare, Prior Authorization/Medical Necessity, effective Sept. 1, 2020, available at https://www.uhcprovider.com/content/dam/provider/docs/public/prior-auth/drugs-pharmacy/commercial/a-g/COMM-Medical-Necessity-Descovy®.pdf.

[2] *E.g.* coverage criteria 2(B)(1)(a)(3). Initial authorization may be approved by showing low bone density using one of the following: (1) a diagnosis of osteoporosis as defined by a BMD T-score of less than -2.5; (2) medical records documenting a prior low-trauma or non-traumatic fracture; (3) the patient is less than 20 years old; or (4) diagnosis of osteopenia as defined by a BMD T-score between -1 and -2.5.

[3] 42 U.S.C. 1395w-104(b)(3)(G).

[4] Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62,152 (Nov. 30, 2018).

[5] Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 84 Fed. Reg. 23,832 (May 23, 2019).

2019, which exceeded the 2018[6] national average by over 26%.[7] These positive, demonstrable results are due in large part to the 340B program, which allows RWCs to close the gaps in the continuum of care that would otherwise make viral suppression impossible to achieve. The important role of both the Ryan White HIV/AIDS Program and the 340B program in helping RWCs keep their patients virally suppressed was documented more recently in an RWC-340B study entitled "Value of Ryan White Providers and Impacts Associated with Resource Reduction".[8] The report confirms that any "resource reductions" – including any reductions in 340B savings – could have long-term, harmful consequences for both Ryan White patients and our nation's fight against the HIV/AIDS epidemic.[9]

RWCs are in the best position to understand the needs of their community and the patients they serve. RWCs participating in the 340B program are well versed in designing and directing programs to meet community needs, having built successful and appropriate models of care that focus on providing comprehensive health services to PLWHA. RWCs rely on the 340B discounts associated with drugs like Descovy® to help pay for the range of services needed by the PLWHA population. Among other things, RWCs use 340B savings (1) to pay for drugs needed by their patients who cannot afford them, (2) to pay for case management and other support services that are neither covered by insurance nor paid for through grant funding, and (3) to provide care retention services that help increase patient viral suppression rates. UHC's Descovy® policy therefore undermines the ability of RWCs to use 340B program resources to meet the needs of their patients which, in turn, threatens their fight against the AIDS epidemic in the U.S. The financial impact of UHC's policy is especially concerning because it comes in the midst of the COVID-19 public health emergency, which has already stretched the finances and human resources of RWC-340B members to their limits.

We would also like to point out that the detrimental effect of UHC's coverage policy on RWCs could have a direct and adverse impact on UHC's own members. Individuals with limited means are at greater risk of contracting and spreading HIV and, for this reason, are in greater need of the comprehensive services that 340B RWCs offer. UHC members who are low-income and HIV positive or at risk of becoming HIV positive are therefore more likely to be patients of a 340B RWC. RWC infectious disease providers are already facing difficult challenges caring for a highly marginalized and stigmatized patient population. Their ability to meet the needs of their patients is further compromised by coverage policies that lack evidence-based scientific support. UHC's policy to exclude Descovy® from coverage will result in reduced 340B savings for RWC-340B members, effectively jeopardizing their ability to provide low cost medications and services to UHC enrollees.

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[6] At the time this letter was drafted, the national viral suppression rate for 2019 had not yet been publicly released. The national viral suppression rate for 2018 can be found on the Centers for Disease Control and Prevention website at https://www.cdc.gov/mmwr/volumes/68/wr/mm6848e1.htm.

[7] US Health Resources & Services Administration. December 2019. "Ryan White HIV/AIDS Program Annual Client-Level Data Report 2019." https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2019.pdf; *see also* HIV.gov, HRSA Announces Highest HIV Viral Suppression Rate in New Ryan White HIV/AIDS Program Client-Level Data Report (Dec. 11, 2019), https://www.hiv.gov/blog/hrsa-announces-highest-hiv-viral-suppression-rate-new-ryan-white-hivaids-program-client-level-0; RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction*, 2 (Sept. 2020), https://www.rwc340b.org/wp-content/uploads/2020/09/RWC340B-White-Paper-FINAL.pdf.

[8] *Value of Ryan White Providers and Impacts Associated with Resource Reduction, supra* note 3.

[9] *Id.*

For the reasons described above, RWC-340B respectfully requests that UHC reconsider its coverage change and allow RWC healthcare providers the flexibility to prescribe Descovy® in circumstances in which they decide that, based on their clinical judgment, Descovy® is more appropriate for the patient than Truvada®. RWC-340B is committed to continuing a dialogue with UHC to discuss this important matter and, towards that end, requests an opportunity to meet with the decision-makers at UHC who are in a position to address RWC-340B's concerns.

Sincerely,

Shannon Stephenson
President