HIV+HEP
POLICY INSTITUTE

September 26, 2023

Ellen Montz, PhD
Deputy Administrator and Director
Center for Consumer Information and Insurance Oversight (CCIIO)
Centers for Medicare and Medicaid Services
200 Independence Avenue SW
Washington DC 20201

Subject: Substandard & Discriminatory HIV Medication Coverage & Plan Design by Community Health Choice Texas

Dear Dr. Montz:

The **HIV+Hepatitis Policy Institute** is a national, non-profit organization whose mission is to promote quality and affordable healthcare for people living with or vulnerable to HIV, hepatitis, and other serious and chronic health conditions. **We are writing to express our concern that Community Health Choice Texas "Premier" and "Select" health insurance plans severely limit coverage of antiretroviral medications for the treatment of HIV. Additionally, the insurer engages in adverse tiering by placing almost all HIV drugs that patients use on the highest cost-sharing tier.**

As the entity that reviews, approves, and regulates marketplace plans in Texas, we request that you take immediate action against Community Health Choice for offering these substandard and discriminatory plans that violate the ACA and its implementing regulations. Further, as we approach open enrollment for 2024, we urge you to ensure the plans include the necessary HIV treatments and tier placement in accordance with the ACA and HIV treatment guidelines.

Community Health Choice Texas offers Premier and Select health insurance plans on the federally-facilitated marketplace. Both types of plans have formularies that severely restrict access to antiretroviral HIV treatment medications, with 36 out of 107 HIV drug formulations listed as "not covered" in "Premier" plans and 54 out of 107 not covered in "Select" plans. Many of the covered drugs are generic formulations of medications that are not widely used in the treatment of HIV. Some are even discontinued. **In violation of the ACA, these limited formularies do not adequately cover HIV treatment regimens as specified in national treatment guidelines**.

The following are recommended regimens indicated for people starting HIV treatment under NIH's current *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV*[1]:

- **Biktarvy** (bictegravir/emtricitabine/tenofovir alafenamide)
- **Dovato** (dolutegravir/lamivudine)
    - Except for people with an HIV viral load of > 500,000 copies/ml, HBV coinfection, or those who have not undergone genotypic resistance testing
- **Triumeq** (dolutegravir/lamivudine/abacavir)
    - For HLA-B*5701-negative individuals without chronic Hepatitis B
- **Dolutegravir + emtricitabine or lamivudine + tenofovir disoproxil or tenofovir alafenamide**

While these are the most highly recommended drugs, not every person is the same and the guidelines also describe which drugs are recommended for people with various co-occurring health conditions or drugs the patient should not be prescribed depending, again, on their individual circumstances.[2] Additionally, there are recommended treatments for people who are pregnant, wishing to be pregnant, or for pediatrics.

According to the formulary for the "Select" plans, **not one of the recommended treatments for initial treatment is covered.** For the "Premier" plans Biktarvy and Triumeq are not covered; Dovato is covered; while Triumeq and the fourth regimen are only available when broken up into three separate medications and not as a single tablet regimen.[3]

Plans Do not Meet Clinical Guidelines: According to the regulations implementing the prescription drug component of essential health benefits (45 CFR 156.122(a)(3)(iii)), when developing a formulary all plans must:

> (H) Ensure the issuer's formulary drug list:
> (1) Covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states, and does not discourage enrollment by any group of enrollees; and
> (*2*) Provides appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

The rule also states that "a non-discriminatory benefit design that provides EHB is one that is clinically-based" (45 C.F.R. 156.125(a)).

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[1] https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/.
[2] https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/table-7-antiretroviral-regimen?view=full.
[3] The Premier plan formulary refers to FTC/TDF (Truvada) and FTC/TAF (Descovy) only in the $0 ACA preventive tier, so these drugs' availability as treatment cannot be ascertained; Select plans do not appear to cover Descovy at all.

In implementing these provisions, CMS stated in the "Letter to Issuers" that "CMS will analyze the availability of drugs recommended by nationally recognized clinical guidelines. In some cases, the review also evaluates whether certain first-line therapies are available without step therapy or prior authorization."[4]

While the plans do not adequately cover those drugs used for *initiating* treatment, they also do not cover many of the other recommended HIV drugs. While each plan does include a couple of complete regimens, the medications that are widely prescribed to treat HIV are mostly not covered. Additionally, some of the covered drugs can be used in combination with other drugs and taken together can form a complete regimen, but this requires the patient to take many drugs at different times of the day. It would be very difficult for a provider to put together an acceptable treatment for HIV.

Included on the formulary is zidovudine (Retrovir, or AZT), the first drug approved for HIV in 1987, which was found not to be very effective and not prescribed anymore for adults. Also included is the second drug approved for HIV in 1991, didanosine (Videx, or ddI), which was discontinued by its manufacturer due to reported adverse events by patients. The formulary includes stavudine (Zerit, or d4T), which was discontinued by its manufacturer in 2018 after the WHO recommended that it be phased out due to high toxicity levels. Others that are covered have extreme side-effects, are rarely prescribed, and many are just not recommended anymore. Many are different formulations of the same drug. So, while the list of covered drugs may appear long when listed in writing, it can be deceiving to the public and regulators. In reality, the formularies include very few acceptable medications for the treatment of HIV today.

Including drugs that have been discontinued and are no longer manufactured makes a mockery of compliance with the Essential Health Benefits rules for the coverage of prescription drugs and brings into question what type of oversight is occurring. It brings into question the validity of the Pharmacy and Therapeutics (P&T) Committee Community Health Choice and the PBM it employs.

On its drug formulary, the insurer states:

> "The Community Health Choice delegated P&T Committee meets quarterly to review new drugs and new information on existing drugs available in the market. The Committee consists of appropriate licensed clinicians. It includes medical professionals employed by Community Health Choice's delegated PBM Navitus, as well as those currently practicing in the community. The task of the Committee is to review scientific evidence balancing the effectiveness and side effects of the drugs. The Committee's review, recommendations, and approval are based on information presented through peer-reviewed journals and treatment guidelines. This evidence-based literature may

[4] https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2018-Letter-to-Issuers-in-the-Federally-facilitated-marketplaces-and-February-17-Addendum.pdf, page 46.

> come from private parties (e g. pharmaceutical companies) or public parties (e.g., government and/or medical associations)."

These substandard HIV treatment formularies were evident in the 2022 plan formulary but were made even worse in 2023 with the removal of Biktarvy. Biktarvy is currently the most prescribed HIV treatment in the United States due to its high barrier to resistance, few drug-drug interactions, and limited side-effects.[5]

This resulted in people having to switch regimens from which they were stable on with little or no notice. Some providers had to negotiate with patients to adopt suboptimal multi-tablet regimens to ensure continuity and coverage. Other providers had to work through cumbersome prior authorization paperwork requesting the continued use of Single Tablet Regimens (STRs), only to be denied, with the recommendation first to attempt a Multi Tablet Regimen (MTR). Some providers resorted to using publicly funded programs such as the AIDS Drug Assistance Program of the Ryan White HIV/AIDS Program in order to sustain their patients on STRs.

People on these plans can no longer access STRs recommended by HHS guidelines for Rapid Start of HIV treatment.[6] Rapid Start refers to starting HIV treatment immediately after diagnosis of HIV—and before resistance testing results are available. It reduces time to viral suppression and improves linkage to and retention in care and is thus a key component of the federal *Ending the HIV Epidemic* plan as well as of the *National HIV/AIDS Strategy*.[7]

Plan Does not Cover Single Tablet Regimens: As noted above, several of Community Health Choice's drug options for people living with HIV require patients to split up the components of commonly prescribed single tablet regimens.

CMS has cautioned issuers against using a multi-tablet regimen and has identified this practice as potentially discriminatory. As noted in the 2017 *Letter to Issuers*, which remains in effect:

> "CMS also cautions issuers to avoid discouraging enrollment of individuals with chronic health needs. For example, if an issuer does not cover a single-tablet drug regimen or extended-release product that is customarily prescribed for HIV patients and is just as effective as a multi-tablet regimen, absent an appropriate reason for the exclusion (such as a substantial difference in the cost of the two regimens), such a plan design might effectively discriminate against, or discourage enrollment by, such HIV patients would benefit from such innovative therapeutic options." [8]

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[5] https://www.contagionlive.com/view/biktarvy-a-regimen-of-choice-for-hiv-therapy; https://blogs.jwatch.org/hiv-id-observations/index.php/continued-activity-of-nrtis-despite-resistance-is-a-real-thing/2023/06/02/.
[6] https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/initiation-antiretroviral-therapy-adult-adolescent-arv.pdf.
[7] https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025/.
[8] https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/final-2017-letter-to-issuers-2-29-16.pdf, page 47.

Single-tablet regimens are a combination of different antiretroviral drugs into a simple easy to take pill. It is critical for people living with HIV to take their treatment regimen exactly as prescribed, which is far simpler with STRs than with multi-tablet regimens, which can require taking many different pills multiple times a day. Studies have consistently shown that STRs help people living with HIV with treatment adherence and persistence, thereby increasing viral suppression and decreasing the risk of hospitalization as well as overall healthcare costs.[9] For example, a study examining claims data from commercial and Medicare plans found that healthcare costs for patients treated with STRs were $3,849 per person per month as opposed to $4,649 for patients treated with multi-tablet regimens.[10]

Most of the Covered HIV Treatment Drugs Are in a Very High-Cost Tier

Community Health Choice plan formularies list 107 formulations of HIV antiviral drugs, tiered as follows:

Tier	Select		Premier	
$0 (ACA)	1	2%	2	3%
1	5	9%	9	13%
2	5	9%	8	11%
3	6	11%	6	8%
Specialty	36	68%	46	65%
Total	**53**	**100%**	**71**	**100%**

As described above, a high percentage of the drugs the insurer covers are on the highest Specialty tier. This includes many low-cost generic drugs that are rarely used.
Some Select plans require 50% coinsurance for drugs on the specialty tier while some Premier plans require 45% coinsurance. This means that for some plans around two-thirds of covered drug formulations are only available with unaffordable patient cost-sharing.

Not only does Community Health Choice not cover the HIV drug treatments people with HIV need, but the drugs on the lowest tiers, as described above, include generic drugs that are not prescribed, and many are different formulations of the same drug. So, while they may have some drugs on lower tiers, federal regulators must examine what drugs they are.

The ACA explicitly prohibits discrimination based on health status.[11] In the *Notice of Benefit and Payment Parameters* for the 2023 plan year, the Department of Health and Human Services (HHS) elaborated on non-discriminatory plan design protections. HHS amended § 156.125(a) to include an explicit requirement that a nondiscriminatory health plan that provides Essential

[9] https://aidsrestherapy.biomedcentral.com/articles/10.1186/s12981-020-00268-1; https://pubmed.ncbi.nlm.nih.gov/30574301/.
[10] https://www.ispor.org/docs/default-source/euro2022/gilead-ispor-eu-posteroct-18-pdf.pdf?sfvrsn=c40c7af8_0.
[11] 42 USC 300gg-4.

Health Benefits (EHB) is one that is "clinically based." HHS went on to finalize a list of presumptively discriminatory plan designs, which includes "adverse tiering," noting:

> ***It is presumptively discriminatory under § 156.125 for an issuer providing EHB to place all drugs for a particular condition on a high-cost tier to discourage enrollment by those with that condition.***[12]

Community Health Choice Texas' formulary will undoubtedly dissuade people living with HIV from enrolling in these plans. Moreover, it fails to meet the ACA's consumer protections for non-discriminatory formulary design. The formulary design creates arbitrary financial and administrative barriers to HIV treatment and will undoubtedly have negative individual and public health consequences.

Ensuring HIV Treatment Coverage Fulfills Administration Efforts to End HIV and Promote Health Equity

Access to HIV treatment medications is key to the federal government's efforts to end HIV, as embodied in both the *End the HIV Epidemic* initiative (for which Harris County is one of 57 priority Phase I jurisdictions with a substantial HIV burden) as well as in the *National HIV/AIDS Strategy (2022-2025).*[13] Without access to safe, effective, and well-tolerated HIV treatment drugs suitable for all groups of patients (including those with different comorbid conditions and HIV drug resistance profiles), people living with HIV will be less likely to achieve viral suppression. People with undetectable amounts of HIV are unable to transmit the virus, a principle known as Undetectable = Untransmittable, or U=U.

Since HIV disproportionately affects racial minorities in Houston and Harris County, a discriminatory health insurance formulary disproportionately burdens Houston's Black community and compounds health inequities. Though Black people are 18.4% of Houston's population, Black individuals comprise 48% of the 28,592 people living with HIV in Houston.[14] Black people also account for 47% of 954 new HIV diagnoses in Houston. In 2020, Black men are living with HIV at 4.9 times the rate of White men. The rate for Black women is 18.6 times the rate for White women.

The **HIV+Hepatitis Policy Institute** is a strong defender of the Affordable Care Act. In order to ensure that the ACA is working for patients, including those with or at risk of HIV, there must be proper and sufficient oversight and enforcement. Unfortunately, over the years, we have witnessed many instances of insurers continuing to discriminate against people with or at risk of HIV through their benefit design or practices. And, sadly, state and federal regulators are not doing enough to enforce the ACA's strong patient protections.

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[12] HHS, Final 2023 Notice of Benefit and Payment Parameters, https://www.federalregister.gov/documents/2022/05/06/2022-09438/patient-protection-and-affordable-careact-hhs-notice-of-benefit-and-payment-parameters-for-2023.

[13] https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025/.

[14] https://aidsvu.org/local-data/united-states/south/texas/houston/.

In December 2022, we filed a discrimination complaint against North Carolina Blue Cross/Blue Shield for putting almost all HIV drugs, including generics, on the highest cost-sharing tiers. We continue to hear of PrEP users being illegally charged for PrEP and its associated services. We continue to forward complaints but know of no action that is being taken and insurers are not punished.

In fact, we note that in 2016, a discrimination complaint was filed against Community Health Choice in a formal Section 1557 complaint to HHS Office for Civil Rights concerning its benefit design discriminating against people living with HIV due to placing almost all HIV drugs on the highest cost-sharing tiers.[15] And now we continue to see that same insurer engaging in similar practices.

As the key regulator of health insurance throughout the United States and given the direct role CCIIO plays in Texas, **we call on CCIIO to fully review health insurance plans for benefit designs that discriminate against certain individuals, including adverse tiering and inadequate formularies, and ensure that the preventive services coverage and zero cost-sharing requirements are carried out. Further, we urge you to provide the states with the tools needed to ensure necessary compliance, oversight, and enforcement**.

We look forward to hearing what actions you take relative to Community Health Choice Texas and that the 2024 plans are fully ACA compliant.

If you have any questions, comments, or would like to discuss these issues further, please contact Carl Schmid, HIV+Hepatitis Policy Institute at cschmid@hivhep.org or (202) 462-3042.

Sincerely,

Carl E. Schmid, II
Executive Director

cc: Jeff Wu, Deputy Director for Policy, CCIIO
Melanie Fontes Raine, Director, HHS Office for Civil Rights
Cassandra J. Brown, Texas Commissioner of Insurance

[15] https://chlpi.org/resources/2016-ocr-complaint-community-health-choice-texas/.