DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services Center for Consumer Information & Insurance Oversight 200 Independence Avenue SW Washington, DC 20201



December 14, 2023

VIA ELECTRONIC MAIL: cschmid@hivhep.org

Carl E. Schmid, II HIV+Hepatitis Policy Institute 1602B Belmont Street NW Washington, DC 20009

Dear Mr. Schmid,

Thank you for your letter outlining your concerns with the drug coverage of antiretroviral medications for the treatment of HIV and formulary plan designs offered by Community Health Choice of Texas (Community Health Choice). In your letter, you expressed concern about the coverage of HIV medications offered by Community Health Choice Premier and Select health plans.

CMS conducts several formulary reviews as part of the qualified health plan (QHP) certification process. The Non-Discrimination Clinical Appropriateness Review ensures that issuers offer sufficient numbers and types of drugs to effectively treat certain medical conditions, including HIV. The Formulary Outlier Review identifies excessive use of prior authorization or step therapy restrictions. For the 2024 plan year, the Centers for Medicare and Medicaid Services (CMS) introduced the Adverse Tiering Review to assess potential adverse tiering of drugs used to treat high cost, chronic conditions. CMS provides several publicly available prescription drug review tools (Essential Health Benefit (EHB) Drug Count Tool and Rx Crosswalk, Formulary Review Suite Tool, and Adverse Tiering Tool) for issuers and states to review their QHP application data prior to submission.

Based on our review of the Community Health Choice plans specified in your letter, we have identified that for plan years 2022 through 2024, the drug coverage offered by these plans appears to offer sufficient coverage of single tablet regimens and multiple tablet regimens, in addition to coverage in all of the five anti-HIV treatment drug classes available in the Rx Crosswalk, and the majority of these drugs are covered without any step therapy or prior authorization requirements. We also identified that these plans cover at least seven single tablet regimens, including Atripla, Complera, Delstrigo, Dovato, Juluca, Symfi, and Trizivir.

As mentioned in your letter, we agree that Biktarvy, Dovato, Triumeq, and a combination drug therapy of dolutegravir + emtricitabine or lamivudine + tenofovir disoproxil or tenofovir alafenamide are recommended regimens indicated for people starting HIV treatment. Clinical guidelines used to develop our formulary reviews recommend both single tablet and multiple tablet regimens to manage the treatment of HIV, and issuers have the flexibility to determine which drugs to include on their formularies as determined by clinical evidence.

Community Health Choice's formulary coverage includes zidovudine, didanosine, and stavudine. While these drugs are not prescribed very often, they are still recommended for treatment of HIV, particularly in pregnant and pediatric patients with HIV. We note that the brand versions may be discontinued by the original manufacturer but generic formulations are the formulations that are listed as available on RxNav's1 list of active NDCs.

CMS identified that one of the Premier Community Health Choice plans covers all the single tablet regimens of HIV drugs included in the analysis on the highest drug tier (specialty drugs), while other plans cover either at least one single tablet regimen on a lower drug tier or offer the same cost sharing (such as no charge after deductible) across all the drug tiers. The 2024 plan year is first year CMS conducted the Adverse Tiering Review. As such, we have been working closely with QHP issuers to come into compliance with this new review and we plan to continue to work with issuers to prevent adverse tiering in the future.

Thank you for your letter expressing your concerns regarding Community Health Choice's formulary coverage of antiretroviral drugs and plan design.

Sincerely,

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Ellen Montz, Ph.D. Deputy Administrator and Director Center for Consumer Information & Insurance Oversight Centers for Medicare & Medicaid Services