HIV+HEP
POLICY INSTITUTE

June 1, 2026

Mr. Mike Chaney
Commissioner of Insurance
Mississippi Insurance Department
1001 Woolfolk State Office Building
501 North West Street
Jackson MS 39205

Subject: Complaint on Blue Cross Blue Shield of Mississippi PrEP & HIV Treatment Coverage Restrictions

Dear Commissioner Chaney:

The **HIV+Hepatitis Policy Institute** is a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people and communities affected by HIV, hepatitis, and other serious and chronic health conditions. We are submitting this formal complaint against **Blue Cross Blue Shield of Mississippi** (BCBSMS) regarding certain formularies offered on the individual and fully insured markets in Mississippi. First, BCBSMS is **violating federal preventive health coverage requirements** by covering only one of four **pre-exposure prophylaxis** (PrEP) medications to prevent HIV. Second, BCBSMS' medical policy **deeming long-acting injectables for the treatment of HIV "not medically necessary"** does not allow for a meaningful formulary exceptions process as required by federal Essential Health Benefit (EHB) regulations.

BCBSMS Does Not Offer Adequate PrEP Coverage

Under the ACA, insurers must cover preventive services given an "A" or "B" grade recommendation by the United States Preventive Services Task Force (USPSTF) without cost-sharing. After the first PrEP drug, Truvada (emtricitabine/tenofovir disoproxil), was approved, the USPSTF gave PrEP an "A" grade in 2019 recommending that "clinicians offer [PrEP] with effective antiretroviral therapy to persons who are at high risk for HIV acquisition." It subsequently reaffirmed this "A" grade in 2023, after a second daily oral formulation (Descovy or emtricitabine/tenofovir alafenamide) and the first long-acting injectable PrEP regimen (Apretude or cabotegravir) had been approved by the FDA.

The two daily oral PrEP drugs (Truvada and Descovy) have different side effect profiles and pill sizes, with Descovy offering advantages to those with kidney or bone density concerns or discomfort with larger pills. Apretude, an injectable taken once every two months, offers

advantages to the many individuals who are unable to adhere to daily oral PrEP, including people with mental illness, people engaged in substance use, or the unstably housed, or who have confidentiality concerns related to storage of an oral medication. In the HPTN 083 clinical trial, Apretude demonstrated 66 percent greater effectiveness than daily oral Truvada, with incidence rates of 0.41 versus 1.22 per 100 person—years, respectively.[1] Modeling we conducted with RTI International has shown that long-acting PrEP is estimated to avert 139,296 person-years of HIV treatment, compared to 74,540 for oral PrEP, an increase of 87 percent.[2]

Federal insurance regulators followed the 2023 USPSTF recommendation with coverage guidance in an October 2024 FAQ which clarified that insurers must cover all PrEP formulations included in the USPSTF without cost-sharing or prior authorization:[3]

> *The 2023 USPSTF recommendation for PrEP specifies three formulations of medications approved by the FDA for use as PrEP. Therefore, plans and issuers must cover, without cost sharing, the three FDA-approved PrEP formulations (two oral and one injectable) and are not permitted to use medical management techniques to direct individuals prescribed PrEP to utilize one formulation over another.*

BCBSMS' coverage of PrEP medications plainly violates these PrEP coverage requirements. According to BCBSMS' Preventive Health Services policy,[4] BCBSMS only offers formulary coverage of generic Truvada (emtricitabine/tenofovir disoproxil) and does not cover any of the newer PrEP drugs. These coverage gaps are also corroborated by formulary search webpages provided by BCBSMS, which identify twenty other antiretroviral medications as alternatives to these PrEP drugs, all but one of which are not approved for use as PrEP.[5] This non-coverage of PrEP formulations is a clear violation of federal preventive coverage requirements in place for all non-grandfathered health insurance plans since 2024.

BCBSMS also has sweeping and, we believe, unprecedented medical policies stating that long-acting injectable PrEP regimens are "not medically necessary," which further contravene both the letter and the intent of these PrEP coverage requirements, and are not aligned with clinical guidelines, as discussed further below.

BCBSMS Must Also Cover Newly-Approved and Future PrEP Formulations

BCBSMS also does not cover Yeztugo (lenacapavir), the most recently approved PrEP formulation, which requires injections only every six months. Its transformative promise was recognized by its designation as *Science* Magazine's "2024 Breakthrough of the Year,"[6] and its

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[1] https://pubmed.ncbi.nlm.nih.gov/34379922/

[2] https://hivhep.org/wp-content/uploads/2024/02/PrEP_Cost_HIV_Incidence_Updates_Memo_20231128.pdf

[3] https://www.cms.gov/files/document/faqs-implementation-part-68.pdf

[4] Policy number L.2.01.409, https://www.bcbsms.com/policy-search/medical/policy-detail/preventive-health-services (last updated April 2026).

[5] For example, https://www.bcbsms.com/BlueLand/rx/rxDirectFormularyDrugSearch.do?year=2026&dotcom=true&coverageType=lg

[6] https://www.science.org/content/article/breakthrough-2024

use has also been recommended in an updated CDC clinical PrEP guideline.[7] FDA's approval of Yeztugo was based on the overwhelmingly successful results of clinical trials, including PURPOSE 1, in which the twice-yearly injectable resulted in *zero* incident HIV infections among 2,134 women—the first Phase III PrEP trial to achieve this—compared to sixteen infections among 1,068 women receiving oral PrEP. The PURPOSE 2 trial focused on men found that Yeztugo was 89 percent more effective than daily oral PrEP.[8] The two studies had to be stopped early by their Data Monitoring Committees once interim results proved Yeztugo was significantly more effective than oral PrEP, making it unethical to continue withholding it from the control group.[9]

Most insurers have added Yeztugo coverage, demonstrating their understanding that preventive coverage mandates encompass all FDA-approved PrEP drugs.

The USPSTF PrEP recommendations are not product-specific, instead recommending the use of "effective antiretroviral therapy … to decrease the risk of acquiring HIV," and noting that "effective formulations of PrEP with current US Food and Drug Administration approval include" the three drugs that had been approved at that time, without limiting the recommendation to those formulations. We would note that when federal regulators issued the first PrEP coverage guidance in 2021, a new daily oral drug (Descovy) had been approved by the FDA since the first USPSTF PrEP recommendation in 2019; however, the requirements of the 2021 guidance were explicitly extended to also include Descovy.

Similarly, Medicare uses the USPSTF PrEP recommendation in its PrEP National Coverage Determination, which prohibits cost-sharing and prior authorization for "any drug approved by the FDA for this indication," showing CMS' understanding that the USPSTF recommendation is not product-specific.[10]

Failure to recognize that the USPSTF PrEP recommendation and subsequent FAQs apply to any FDA-approved PrEP formulations would mean that Yeztugo and PrEP formulations in the drug development pipeline would take three to six years after FDA approval to become broadly available to Americans in need of PrEP. This assumes that the USPSTF continues to function as it has in the past and conducts its reviews on a typical five-year cycle.

Medical Necessity of Long-Acting Antiretrovirals

Long-acting formulations also offer great promise for HIV treatment regimens, not just PrEP. The availability of new long-acting antiretrovirals, replacing daily pills with injections with far longer dosing intervals, represents a transformative advance in the HIV response, dramatically improving adherence, mitigating stigma, and offering a realistic path to ending the HIV

[7] https://www.cdc.gov/mmwr/volumes/74/wr/mm7435a1.htm
[8] https://www.who.int/news/item/26-09-2024-long-acting-injectable-lenacapavir-continues-to-show-promising-results-for-hiv-prevention
[9] https://www.nejm.org/doi/full/10.1056/NEJMoa2407001 and https://pubmed.ncbi.nlm.nih.gov/34379922/
[10] https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=377&ncdver=1

epidemic among people not well-served by a lifetime of daily oral regimens. Their importance is reflected in broadly accepted federal guideline recommendations both for PrEP[11] and for HIV treatment.[12]

Yet BCBSMS has medical policies that state explicitly that Cabenuva (cabotegravir/rilpivirine),[13] the first and only complete treatment regimen available as a long-acting injectable, as well as Apretude[14] and Yeztugo[15] are "considered not medically necessary" HIV treatment or PrEP, respectively, "as there are other alternatives covered by the plan." The alternative medications cited on a BCBSMS formulary search tool include nine daily oral single-tablet regimens, and seven single- or two-drug medications that cannot be safely taken without additional antiretroviral components.[16]

Despite decades of progress in tolerability and dosing, 60 percent of people with HIV in the United States have suboptimal adherence to antiretroviral therapy, making long-acting retroviral treatments a key new tool to address adherence challenges. In the recently reported LATITUDE trial, switching to Cabenuva reduced the cumulative risk of virological failure by nearly half compared to daily oral therapy—22.8 percent versus 41.2 percent at 48 weeks—among patients with a history of adherence challenges. BCBSMS' short-sighted medical policy denies all access to transformational long-acting therapies.[17]

By categorically deeming all long-acting antiretroviral PrEP and treatment regimens not medically necessary, BCBSMS has made it impossible for enrollees to access them through any pathway. Federal EHB rules require that plans maintain an exceptions process through which enrollees can gain access to non-covered drugs when clinically appropriate[18]—but BCBSMS' categorical policy that these treatment and PrEP regimens are "not medically necessary" predetermines the outcome of any such request, and renders the exceptions process a dead letter.

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[11] 2021 CDC PrEP Clinical Practice Guideline (https://stacks.cdc.gov/view/cdc/112360); 2025 CDC Clinical Recommendation for the Use of Injectable Lenacapavir as HIV PrEP (https://www.cdc.gov/mmwr/volumes/74/wr/mm7435a1.htm); 2023 USPSTF Recommendation Statement on Prevention of Acquisition of HIV: Preexposure Prophylaxis (https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis)

[12] https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf

[13] Policy number L.5.01.582 and S.5.01.582, https://www.bcbsms.com/policy-search/medical/policy-detail/cabenuva-cabotegravir-and-rilpivirine

[14] Policy numbers L.5.01.625 and S.5.01.625, https://www.bcbsms.com/policy-search/medical/policy-detail/apretude-cabotegravir-kit

[15] Policy numbers L.5.01.633 and S.5.01.633, https://www.bcbsms.com/policy-search/medical/policy-detail/yeztugo-lenacapavir

[16] For example, https://www.bcbsms.com/BlueLand/rx/rxDirectFormularyDrugSearch.do?year=2026&dotcom=true&coverageType=bck

[17] https://viivhealthcare.com/hiv-news-and-media/news/press-releases/2026/february/daily-oral-therapy-for-people-with-adherence-challenges/

[18] 45 CFR 156.122(c)

Federal preventive health rules described earlier separately prohibit BCBSMS from failing to cover any PrEP drug or from imposing prior authorization for the purpose of steering enrollees toward a particular PrEP drug.

While plans are not required to cover Cabenuva, BCBSMS should not be able to categorically preclude a finding of "medical necessity." Enrollees must have a meaningful opportunity to access an exceptions process to demonstrate that any non-covered medication is clinically appropriate and medically necessary for them.

We believe that BCBSMS' medical policy under which no long-acting antiretroviral PrEP and HIV treatment regimen can ever be deemed "medically necessary" is unique among health insurers in the United States and threatens progress in fighting the HIV epidemic. We note that BCBSMS imposes similar restrictions and has received complaints from patient groups regarding long-acting drugs for other disease states, such as intravitreal angiogenesis inhibitors for ophthalmological treatment.

In conclusion, we would like to note the importance of coverage of antiretrovirals for the prevention and treatment of HIV for the people of Mississippi, who face an exceptionally high HIV burden, with the third-highest incidence of HIV among all states in 2022.[19] It will be difficult for Mississippians to protect their health without access to newer long-acting antiretroviral formulations.

BCBSMS is the largest insurer on the commercial market in Mississippi, and as such, its formulary decisions are of key importance to Mississippians affected by HIV and all Mississippians. BCBSMS has a pattern of being an outlier in its coverage decisions. We note that BCBSMS was called out in a December 2025 editorial in the *Magnolia Tribune* by Senator Cindy Hyde-Smith for its failure—unique among Blues across the entire country—to cover Mavacamten, a drug used to treat hypertrophic cardiomyopathy.[20]

We urge the Mississippi Insurance Department to require BCBSMS to update its PrEP coverage to comply with federal preventive health requirements and to review BCBSMS' medical necessity policies for long-acting antiretroviral formulations.

If you have any questions, comments, or would like to discuss these issues further, please contact Carl Schmid, Executive Director, HIV+Hepatitis Policy Institute at cschmid@hivhep.org or (202) 462-3042, or Kevin Herwig, Health Policy Manager, HIV+Hepatitis Policy Institute at kherwig@hivhep.org or (617) 666-6634.

Sincerely,

[19] https://ahead.hiv.gov/mississippi/

[20] https://magnoliatribune.com/2025/12/04/putting-patients-before-profit-a-call-for-transparency-in-health-coverage/

Carl E. Schmid, II
Executive Director

cc: Senator Cindy Hyde-Smith, United States Senate
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