RICARDO LARA
CALIFORNIA INSURANCE COMMISSIONER

BULLETIN 2021-10

TO: **All Disability Insurers Providing Health Insurance Coverage in California**

FROM: **Insurance Commissioner Ricardo Lara**

DATE: **December 29, 2021**

RE: **Preventive Services Coverage for HIV Preexposure Prophylaxis (PrEP) with Provider-Administered Antiretroviral Drug Therapy**

I. Background

Pursuant to California Insurance Code section 10112.2 and section 2713 of the federal Public Health Service Act, non-grandfathered group and individual health insurance policies[1] must cover certain preventive health services without patient cost sharing, including "A" and "B" grade recommendations of the U.S. Preventive Services Task Force (USPSTF), for plan years that begin on or after the date that is one year after the date the recommendation or guideline is issued.

The USPSTF, on June 11, 2019, issued a new "A" grade recommendation for preexposure prophylaxis (PrEP) with effective antiretroviral therapy for persons who are at high risk of human immunodeficiency virus (HIV) acquisition.[2] On June 10, 2020, I issued a Notice to disability insurers providing health insurance coverage in California, clarifying the services that must be covered without cost sharing under the USPSTF recommendation for PrEP. My Notice specified that in addition to the antiretroviral drug itself, services necessary for PrEP initiation and ongoing follow-up and monitoring, as specified in the Centers for Disease Control and Prevention's (CDC's) most recently updated clinical guidance and determined by a person's attending health care provider, must also be covered without cost sharing.[3]

[1] Under federal law, student health insurance is considered individual coverage and must comply with Section 2713 of the Public Health Service Act (42 USC § 300gg-13), including by covering "A" and "B" grade recommendations of the USPSTF without cost sharing. See 45 CFR §§ 147.130, 147.145.
[2] U.S. Preventive Services Task Force Final Recommendation Statement, *Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis* (June 11, 2019).
[3] Insurance Commissioner Ricardo Lara, *Notice Re: Preventive Health Services Coverage for HIV Preexposure Prophylaxis (PrEP)* (June 10, 2020).

On July 21, 2021, the federal Departments of Labor, Health and Human Services, and the Treasury released *FAQs About Affordable Care Act Implementation Part 47*, affirming the requirements set forth in my June 10, 2020 Notice.[4] FAQs Part 47 confirmed that the CDC's clinical practice guideline on PrEP is incorporated in the USPSTF recommendation. Also consistent with my previous Notice, FAQs Part 47 provides that "[t]he USPSTF Final Recommendation Statement encompasses FDA-approved PrEP antiretroviral medications …." Therefore, both FAQs Part 47 and my Notice require insurers to cover antiretroviral drug therapy approved by the FDA, as well as services that are integral to the furnishing of PrEP,[5] under the preventive care benefit without any cost sharing, including a deductible, coinsurance, or copayment, when obtained from a participating provider or pharmacy.

Federal law permits limited, reasonable medical management of preventive care drugs under some circumstances.[6] But state law, at Insurance Code section 10123.1933, categorically prohibits insurers from imposing prior authorization or step therapy requirements on antiretroviral drugs for preventing HIV, except if one or more therapeutic equivalents are available and at least one is covered without prior authorization or step therapy.[7] Furthermore, under section 10123.1933, an insurer cannot decline to cover any pharmaceutically unique drug that is FDA approved for PrEP. For example, an insurer cannot designate an outpatient prescription drug without another available FDA-approved therapeutic equivalent drug "non-formulary," because prior authorization (an "exception") would be needed to obtain a coverage determination.[8]

If one therapeutic equivalent of a PrEP drug is covered without utilization management restrictions and cost sharing, then an insurer may require prior authorization or step therapy, or impose cost sharing, for other therapeutic equivalents of that drug. However, the insurer must adhere to the federal requirement to make available an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on patients and providers, and refrain from disapproving any requests that are based on an individualized determination of medical necessity by the attending

[4] Departments of Labor, Health and Human Services, and the Treasury, *FAQs About Affordable Care Act Implementation Part 47* (July 19, 2021).
[5] See discussion on integral services in Departments of Treasury, Labor, and Health & Human Services, *Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency*, 85 Fed. Reg. 71,142, 71,174-75 (Nov. 6, 2020).
[6] Although federal law generally permits requiring prior authorization or step therapy for preventive care drugs, an insurer must defer to the prescribing provider's clinical judgment concerning the medical necessity for a prescribed drug, meaning it cannot deny a prior authorization or step therapy exception request, or a request to waive cost sharing, for any preventive care drug, including FDA-approved female contraceptives and PrEP drugs, based on lack of medical necessity. See Departments of Labor, Health and Human Services, and the Treasury, *FAQs About Affordable Care Act Implementation Part 26* (May 11, 2015) at pages 4-5, and FAQs Part 47, *supra* note 4, at pages 2, 5-6.
[7] Senate Bill 159 § 5 (Wiener, Ch. 532, Stats. 2019), enacting Cal. Ins. Code § 10123.1933.
[8] Requiring "prior notification" is equally prohibited because it is legally indistinguishable from prior authorization. Cal. Ins. Code § 10123.201(g)(1) (on January 1, 2022 and thereafter, subdivision (i)(1)).

provider.[9] Insurers are admonished that with respect to exception requests not just for PrEP but for all preventive care drugs, including both outpatient and provider-administered drugs, they must defer to the clinical judgment of the prescribing provider regarding medical necessity and thus approve all such exception requests within the applicable time limit (within 72 hours of receipt or, if exigent circumstances exist, within 24 hours of receipt).[10]

On December 8, 2021, the CDC published an update to its clinical practice guideline on PrEP that includes clinical recommendations for both oral PrEP and long-acting injectable (LAI) PrEP with cabotegravir.[11] The CDC recommends PrEP with intramuscular cabotegravir injections for HIV prevention in adults and adolescents who are at substantial risk of acquiring HIV infection. The updated guideline also includes recommendations for services needed to initiate PrEP and provide follow-up care, for both oral and LAI PrEP with cabotegravir. Shortly after the CDC guideline was released, on December 20, 2021, the FDA approved the manufacturer's application to market LAI cabotegravir for PrEP.

II. Coverage Requirements for PrEP with Provider-Administered Drug Therapy

Consistent with the foregoing, once providers begin administering LAI cabotegravir, insurers must cover the drug, its administration, and other integral services that are necessary to initiate therapy and provide ongoing follow-up, as set forth in the 2021

[9] FAQs Part 26 and Part 47, *supra* note 6. Pursuant to Insurance Code section 10123.191(i), all health insurance products must comply with the federal essential health benefits exception request and independent external review processes described in paragraph (c) of Section 156.122 of Title 45 of the Code of Federal Regulations. Insurers must process exception requests to cover, and waive cost sharing, for preventive care drugs as required by Insurance Code section 10123.191(i) (note that Ch. 742, Stats. 2021 (A.B. 347 § 4) removed the limitation (the word "outpatient") in paragraph (i) that applied the paragraph only to outpatient prescription drugs, and thus the essential health benefits exception request and external review requirements also apply to provider-administered drugs effective January 1, 2022). An exception request for PrEP should be approved on the same day coverage of the drug is requested (per FAQs Part 47, pages 5-6), and is subject to the 24-hour exigent circumstances coverage determination time limit because delay in beginning PrEP poses a serious threat to the life and health of a person who is at risk of contracting HIV.

[10] FAQs Part 26, *supra* note 6, at pages 4-5 ("If an individual's attending provider recommends a particular service or FDA-approved item based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or item without cost sharing. The plan or issuer must defer to the determination of the attending provider. Medical necessity may include considerations such as severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service, as determined by the attending provider. … This exceptions process must make a determination of the claim according to a timeframe and in a manner that takes into account the nature of the claim (e.g., pre-service or post-service) and the medical exigencies involved for a claim involving urgent care.").

[11] Centers for Disease Control and Prevention: U.S. Public Health Service: *Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline* (published December 2021). Clinical resources available on the Centers for Disease Control and Prevention website under HIV Nexus Clinician Resources, Preventing New HIV Infections, *Pre-Exposure Prophylaxis (PrEP)*.

update to CDC's PrEP guideline, as preventive care without cost sharing.[12] The scope of the USPSTF recommendation, as further elucidated for purposes of clinical application in the CDC's clinical practice guideline on PrEP, is not limited to drugs discussed in the recommendation statement or approved only for self-administration. Furthermore, Insurance Code section 10123.1933 prohibits requiring prior authorization or step therapy for LAI cabotegravir or any other provider-administered brand-only prescription drug approved by the FDA for PrEP in the future. Insurers shall establish, and review and revise their existing, policies and procedures accordingly.

III. Prescription Drug Benefit Designs Cannot Discriminate Based on HIV+ Status

Finally, insurers are reminded that it is unlawful to employ benefit designs, including for prescription drugs, that will have the effect of discouraging the enrollment of individuals with significant health needs or discriminate based on health condition or protected class.[13] Prescription drug benefits in which all or most HIV drugs are subject to the highest cost sharing or utilization management restrictions that are not grounded in evidence-based practices are discriminatory. Following the enactment of my sponsored Senate Bill 280 (Limón, Ch. 636, Stats. 2021), insurers are advised to proactively eliminate any remaining prescription drug benefit designs in non-grandfathered large group products that have the effect of discriminating based on HIV positive status or another health condition. The Department of Insurance will take appropriate action against an insurer that covers HIV drugs in a discriminatory manner in contravention of the law.

Questions concerning this Bulletin may be directed to Jessica Ryan, Attorney III, at jessica.ryan@insurance.ca.gov.

[12] A delay associated with review by a Pharmacy and Therapeutics Committee should be unnecessary, as LAI cabotegravir must be covered as a preventive care benefit and comprehensive, authoritative clinical guidance on its use for PrEP is available from the CDC.
[13] Cal. Ins. Code §§ 10112.282 (operative January 1, 2022), 10123.193(e)(1), 10753.05(h)(3), 10965.5(a)(3); 45 CFR § 147.104(e).