

NOTICE

- TO: All Disability Insurers Providing Health Insurance Coverage in California
- FROM: Insurance Commissioner Ricardo Lara
- DATE: June 10, 2020
- RE: Preventive Health Services Coverage for HIV Preexposure Prophylaxis (PrEP)

Pursuant to Insurance Code section 10112.2, group and individual health insurance policies must comply with section 2713 of the federal Public Health Service Act requiring coverage of specified preventive health services without cost sharing, including "A" and "B" grade recommendations of the U.S. Preventive Services Task Force (USPSTF). On June 11, 2019, the USPSTF 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.¹

The purpose of this Notice is to remind insurers that non-grandfathered health insurance policies, including student health insurance policies,² issued or renewed on or after June 11, 2020 must cover HIV PrEP consistent with the USPSTF recommendation and federal regulations³ and guidance on coverage of preventive health services under Public Health Service Act section 2713. Pursuant to these authorities, preventive health services coverage for HIV PrEP must be provided without cost sharing, including deductible, copayment and coinsurance, in accordance with the following:

- Provide coverage for persons, including adolescents, who are at high risk of HIV infection, as determined by a person's attending health care provider.⁴
- Cover prescription drugs approved by the U.S. Food and Drug Administration for HIV PrEP and recommended for HIV PrEP by the Centers for Disease Control

¹ U.S. Preventive Services Task Force Final Recommendation Statement, <u>Prevention of Human</u> <u>Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis</u> (June 11, 2019).

² Under federal law, student health insurance coverage must comply with Public Health Service Act section 2713. See 45 CFR § 147.145.

³ 45 CFR § 147.130.

⁴ <u>Affordable Care Act Implementation FAQs – Part 12</u>, Question No. 7 (Feb. 20, 2013).

and Prevention (CDC) in its most recently updated clinical practice guidelines and official publications.⁵

- Cover services necessary for HIV PrEP initiation and follow-up care recommended generally by the USPSTF, as further specified in the CDC's most recently updated clinical guidance and determined by a person's attending health care provider, including but not limited to: provider office and telehealth visits⁶ for prescribing and medication management; HIV testing; kidney function testing; serologic testing for hepatitis B and C viruses; hepatitis B vaccination; testing for other sexually transmitted infections, including 3-site testing for gonorrhea and chlamydia; pregnancy testing; and ongoing follow-up and monitoring every three months.
- Cover PrEP drugs and necessary services without cost sharing, including deductible, copayment and coinsurance, when delivered by a network health care provider or obtained at a network pharmacy.⁷
- Do not require prior authorization or step therapy for PrEP drugs.⁸
- Cover PrEP drugs as prescribed by a person's attending health care provider, regardless of sex assigned at birth, recorded gender, or gender identity.⁹
- Do not apply coverage limits to PrEP drugs and necessary services that are inconsistent with the CDC's most recently updated clinical guidance, prescribing information for PrEP drugs, and published medical evidence on PrEP.¹⁰
- Designate PrEP drugs as preventive care not subject to cost sharing in prescription drug formularies.¹¹

Insurers are encouraged to uniformly implement coverage of the PrEP recommendation for all insureds by June 11, 2020, rather than on a rolling basis at renewal.

⁵ Clinical resources available at website of Centers for Disease Control and Prevention, HIV Nexus Clinician Resources, Preventing New HIV Infections, <u>Pre-Exposure Prophylaxis (PrEP)</u>. Centers for Disease Control and Prevention: US Public Health Service: <u>Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline</u> (published March 2018); Centers for Disease Control and Prevention: US Public Health Service: <u>Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical providers' supplement</u> (published March 2018); Centers for Disease Control and Prevention: US Public Health Service: <u>Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: clinical providers' supplement</u> (published March 2018); Tanner MR, Miele P, Carter W, et al. <u>Preexposure Prophylaxis for Prevention of HIV Acquisition Among Adolescents: Clinical Considerations</u> (April 24, 2020). MMWR Recomm Rep 2020;69(No. RR-3):1–12. An update to the CDC's 2017 clinical practice guideline is expected soon.
⁶ To provide adequate access to medically appropriate care during the COVID-19 public health emergency, as required by 10 CCR § 2240.1(e), insurers should cover telehealth visits with network providers prior to the January 1, 2021 operative date of Cal. Ins. § 10123.855. See also CDI, <u>Notice Re: Telehealth During COVID-19 State of Emergency</u> (March 30, 2020) and CDC, <u>Dear Colleague: Information From CDC's Division of HIV/AIDS Prevention</u> (May 15, 2020).

⁷ Subject to 45 CFR § 147.130(a)(2).

⁸ Cal. Ins. § 10123.1933(a)(1), subject to the exception for therapeutic equivalents in paragraph (a)(2). ⁹ Affordable Care Act Implementation FAQs – Part 26, Question No. 5 (May 11, 2015); 10 CCR § 2561.2.

¹⁰ 45 CFR § 147.130(a)(4); Cal. Ins. § 10123.193(e)(3).

¹¹ 10 CCR § 2218.82(d)(6)(B).

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.¹² Prescription drug benefits in which all or most HIV drugs are subject to the highest cost sharing or utilization management restrictions not grounded in evidence-based practices are discriminatory. The Department of Insurance will take appropriate action against an insurer that covers HIV drugs in a discriminatory manner.

Questions concerning this Notice may be directed to Jessica Ryan at jessica.ryan@insurance.ca.gov.

¹² Cal. Ins. §§ 10123.193(e)(1), 10753.05(h)(3), 10965.5(a)(3); 45 CFR § 147.104(e).