

From: DMHC Licensing eFiling

Subject: APL 21-018 – Guidance Regarding Preventive Health Services Coverage for HIV Preexposure Prophylaxis (PrEP)

Date: Tuesday, July 6, 2021, 3:00 PM

Attachments: APL 21-018 - Preventive Coverage for HIV Preexposure Prophylaxis (7.6.2021).pdf

Dear Health Plan Representative:

Please find attached All Plan Letter (APL) 21-018, regarding Preventive Coverage for HIV Preexposure Prophylaxis.

Thank you.



Gavin Newsom, Governor
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ALL PLAN LETTER

DATE: July 6, 2021

TO: All Health Care Service Plans

FROM: Jenny Mae Phillips
Deputy Director
Office of Plan Licensing

SUBJECT: APL 21-018 (OPL) – Guidance Regarding Preventive Health Services Coverage for HIV Preexposure Prophylaxis (PrEP)

The Department of Managed Health Care (the DMHC or Department) issues this All Plan Letter (APL) to provide additional guidance to health care service plans (plans) regarding coverage for Human Immunodeficiency Virus (HIV) antiretroviral drugs, including preexposure prophylaxis or postexposure prophylaxis. This APL includes guidance on prior authorization and step therapy as well as preventative health services and cost sharing.

I. BACKGROUND

As of January 1, 2020, plans are prohibited from subjecting antiretroviral drugs, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, unless a therapeutic equivalent drug exists, then the plan must cover at least one of the versions without prior authorization or step therapy.¹ Pursuant to APL 20-001 (OPL) – Newly Enacted Statutes Impacting Health Plans,² plans were required to affirm compliance by March 6, 2020.

On July 8, 2020, the Department issued APL 20-026 (OPL) - Preventive Health Services Coverage for HIV Preexposure Prophylaxis (PrEP), which explained the federal mandate that all group or individual plans³ must cover preventive health services for HIV PrEP to any individual who is determined by the attending health care provider to be at high risk of contracting HIV. Additionally, the federal mandate requires plans to

¹ California Health and Safety Code section 1342.74.

² [APL 20-001 \(OPL\) - Newly Enacted Statutes Impacting Health Plans \(1_15_20\).pdf \(ca.gov\)](#).

³ Contract issued, amended, renewed, or delivered on or after September 23, 2010. See Health and Safety Code section 1367.002.

cover preventative health service for HIV PrEP without cost sharing. Plans were required to affirm compliance by August 7, 2020.

II. PROHIBITION ON PRIOR AUTHORIZATION AND STEP THERAPY UNDER HEALTH AND SAFETY CODE SECTION 1342.74

Senate Bill 159 (Wiener, Ch. 532, Stats. 2019) prohibits commercial and Medi-Cal plans with prescription drug benefits from requiring prior authorization or step therapy for antiretroviral drugs that are medically necessary for the prevention of HIV, including preexposure prophylaxis or postexposure prophylaxis. (Cal. Health & Saf. Code §1342.74(a)(1).) Plans may impose prior authorization or step therapy on a particular drug only if the United States Food and Drug Administration (FDA) has approved one or more “therapeutic equivalents”⁴ of that particular drug. Plans are not required to cover all therapeutic equivalents of a particular drug without prior authorization or step therapy, so long as the plan covers at least one therapeutic equivalent without prior authorization or step therapy. (Cal. Health & Saf. Code §1342.74(a)(2).)

For example, on September 30, 2020, a generic version for the PrEP drug Truvada became available. In light of this, a plan may impose prior authorization and step therapy on the brand name Truvada so long as the plan offers the generic version of Truvada without prior authorization or step therapy. The plan, however, must continue to cover the PrEP drug Descovy without step therapy or prior authorization because the FDA has not approved a therapeutic equivalent for Descovy.

In addition, removing antiretroviral drugs that are medically necessary for the prevention of HIV, including preexposure prophylaxis or postexposure prophylaxis, from a formulary is a form of prior authorization and step therapy and is inconsistent with the requirements of Health & Safety Code section 1342.74. The law makes no distinction between a prior authorization requirement and a formulary exception – formulary removal creates a barrier to access which is prohibited under Health & Safety Code section 1342.74. As such, plans are expected to keep these drugs, including drugs with no therapeutic equivalent, such as Descovy, on their formularies.

III. COST SHARING ON PREVENTATIVE HEALTH SERVICES UNDER SECTION 2713 OF THE FEDERAL PUBLIC HEALTH SERVICE ACT

APL 20-026 outlined the basic requirements of zero cost sharing for preventative services for PrEP as it relates to the individual.⁵ In summary, non-grandfathered plans must cover PrEP as stated in the USPSTF recommendation, consistent with federal

⁴ Please see the FDA’s definition of “therapeutic equivalence,” including information on how to determine if the FDA has evaluated a particular drug as therapeutically equivalent at [Drugs@FDA Glossary of Terms](#).

⁵ [APL 20-026 \(OPL\) - Preventive Coverage for HIV Preexposure Prophylaxis](#). See page 2.

regulations⁶ and federal guidance on preventive health services. APL 20-026 clarified the following, “all plans must cover preventive health services for HIV PrEP to any individual who is determined to be at high risk of contracting HIV by the attending health care provider,^[7] and must do so without cost sharing.”

Plans are reminded that the USPSTF recommendation for PrEP includes a discussion of implementation considerations, **including** baseline and follow-up testing and monitoring for PrEP.⁸ The recommendation also incorporates the Center for Disease Control and Prevention’s (CDC) clinical guidelines⁹ and publications. Plans must cover these baseline and follow-up testing and monitoring services at zero cost share.¹⁰

IV. FILING REQUIREMENTS

By August 6, 2021, all plans must submit an **Amendment via eFiling** titled, “**APL 21-018 PrEP Compliance Filing**,” with an Exhibit E-1 which provides the following information.

- a) An affirmation that the plan: (1) updated all contracts, and policies and procedures as necessary to be in compliance with SB 159 and the USPSTF recommendation; (2) utilizes the FDA definition of therapeutic equivalence, as is required by the Health and Safety Code section 1342.74; (3) updated the plan formulary to reflect both SB 159 and preventative services cost sharing requirements; and, (4) covers baseline and follow-up testing and monitoring service for PrEP without cost sharing.

OR

- b) An explanation as to why the affirmation statement does not apply to the Plan.

If you have questions or concerns regarding this APL, please contact your assigned OPL reviewer.

⁶ 45 CFR § 147.130.

⁷ Affordable Care Act Implementation FAQs – Part 12, Question No. 7 (Feb. 20, 2013).

⁸ U.S. Preventive Services Task Force Final Recommendation Statement, Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis (June 11, 2019), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis#fullrecommendationstart>.

⁹ Plans should be aware that an update to the CDC’s 2017 clinical practice guideline is expected soon, and that zero cost sharing services for PrEP coverage may change as a result.

¹⁰ 45 CFR § 147.130(a)(2)(ii); <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis#fullrecommendationstart>.