From: Subject:	DMHC Licensing eFiling APL 20-026 (OPL) - Preventive Health Services Coverage for HIV Preexposure
	Prophylaxis (PrEP)
Date:	Wednesday, July 8, 2020 2:00 PM
Attachments:	<u>APL 20-026 (OPL) - Preventive Coverage for HIV Preexposure Prophylaxis</u> (7.8.20).pdf

Dear Health Plan Representative:

Please find the attached APL 20-026 for guidance and filing instructions regarding preventative health services coverage for Human Immunodeficiency Virus (HIV) Preexposure Prophylaxis (HIV PrEP) with no cost sharing.

Thank you.



Gavin Newsom, Governor State of California Health and Human Services Agency DEPARTMENT OF MANAGED HEALTH CARE 980 9th Street, Suite 500 Sacramento, CA 95814 Phone: 916-324-8176 | Fax: 916-255-5241 www.HealthHelp.ca.gov

ALL PLAN LETTER

DATE: July 8, 2020

TO: All Health Care Service Plans

- FROM: Nancy Wong Acting Deputy Director Office of Plan Licensing
- **SUBJECT:** APL 20-026 (OPL) 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 guidance and filing instructions to health care service plans (plans) regarding preventative health services coverage for Human Immunodeficiency Virus (HIV) preexposure prophylaxis (HIV PrEP) with no 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 therapeutically equivalent drug exists, then the plan must cover at least one of the versions without prior authorization or step therapy¹. Plans were required to make a compliance filing by March 6, 2020 (see, "APL 20-001 (OPL) – Newly Enacted Statutes Impacting Health Plans") affirming compliance.

II. COST SHARING

In addition, pursuant to Health and Safety Code section 1367.002, all group or individual health care service plans² must comply with Section 2713 of the federal Public Health Service Act, and all other federal regulations and guidance, regarding coverage and cost sharing of preventative services. Specifically, the federal law requires that preventative services must be provided without cost sharing for evidence-based items or services that have in effect a rating of A or B in the current recommendations of the

¹ California Health and Safety Code section 1342.74.

² Contract issued, amended, renewed, or delivered on or after September 23, 2010. See Health and Safety Code section 1367.002.

United States Preventive Services Task Force (USPSTF). On June 11, 2019, the USPSTF recommended that clinicians offer PrEP to persons who are at high risk of contracting HIV, and issued a Grade "A" rating.

As a result, 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 provider³, and must do so without cost sharing. These preventative health services include, but are not limited to:

- 1. Prescription drugs for HIV PrEP drugs approved by the U.S. Food and Drug Administration and recommended for HIV PrEP by the Centers for Disease Control and Prevention (CDC).⁴
- 2. Services necessary for initial HIV PrEP care as well as follow-up care, as recommended by the USPSTF and the CDC.
- 3. PrEP drugs and necessary services when delivered by a network health care provider or obtained at a network pharmacy.⁵
- 4. PrEP drugs designated in prescription drug formularies as preventive care.⁶

Further, there are additional requirements regarding HIV PreP all plans should be aware of. These include, but are not limited to:

- 1. Plans may not require prior authorization or step therapy for PrEP drugs.⁷
- Plans may not limit sex-specific recommended preventive services based on an individual's sex assigned at birth, gender identity or recorded gender and must cover those PrEp drugs as assigned by the individual's attending health provider.⁸
- 3. Plans shall provide coverage for HIV testing, even if it is unrelated to a primary diagnosis.⁹
- 4. For combination antiretroviral drug treatments medically necessary for the prevention of AIDS/HIV, plans and insurers are prohibited, until January 1, 2023, from having utilization management policies or procedures that rely on a multitablet drug regimen instead of a single-tablet drug regimen, except as specified.¹⁰

³ Affordable Care Act Implementation FAQs – Part 12, Question No. 7 (Feb. 20, 2013). ⁴ clinical guidelines

⁵ Subject to 45 CFR § 147.130(a)(2).

⁶ 10 CCR § 2218.82(d)(6)(B).

⁷ California Health and Safety Code section 1342.74. Subject to the exception in paragraph (a)(2).

⁸ Affordable Care Act Implementation FAQs – Part 26, Question No. 5 (May 11, 2015).

⁹ California Health and Safety Code section 1367.46.

¹⁰ California Health and Safety Code section 1342.72.

5. No plan or PBM may prohibit dispensing PrEP.¹¹

The Department encourages that the preventative services covered without cost sharing should be implemented as soon as possible.

III. FILING REQUIREMENTS

By <u>August 7, 2020</u> all health plans must submit an <u>Amendment via eFiling</u> titled, "Preventive Health Services Coverage for HIV Preexposure Prophylaxis (PrEP)," with the following exhibits and information

- a) Exhibit E-1: Affirm the Plan shall update all contracts as necessary to reflect the changes (including, but not limited to PBM contracts, plan to plan agreements, etc.) and shall revise all policies and procedures as necessary to reflect the changes (including, but not limited to Utilization Management, Claims Processing, etc.). If the affirmation does not apply, explain in the Exhibit E-1 why it does not apply to the Plan, AND
 - State either:
 - The plan has updated its policies & procedures, contracts, and all other necessary documents to reflect the preventative health services coverage for HIV PrEP.

OR

 The plan will update its policies & procedures, contracts, and all other necessary documents to reflect the preventative health services coverage for HIV PrEP by _____.

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

¹¹ California Health and Safety Code section 1342.74.