

# DEPARTMENT OF REGULATORY AGENCIES

## Division of Insurance

### 3 CCR 702-4

#### LIFE ACCIDENT AND HEALTH

##### Amended Regulation 4-2-73

#### CONCERNING HUMAN IMMUNODEFICIENCY VIRUS PRE-EXPOSURE PROPHYLAXIS PRESCRIPTION DRUGS AND BASELINE AND MONITORING SERVICES

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##### **Section 1 Authority**

This regulation is promulgated and adopted by the Commissioner of Insurance under the authority of §§ 10-1-109(1), 10-16-104(18)(b)(X), and 10-16-109, C.R.S.

##### **Section 2 Scope and Purpose**

The purpose of this regulation is to establish the requirements for individual and group health benefit plans to provide coverage for human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) as well as baseline and monitoring services in accordance with Article 16 of Title 10 of the Colorado Revised Statutes, and the Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (2010) and the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010), together referred to as the "Affordable Care Act" (ACA).

##### **Section 3 Applicability**

This regulation applies to all carriers marketing and issuing individual and group health benefit plans subject to the individual and group laws of Colorado on or after the effective date of this regulation. This regulation does not apply to grandfathered health benefit plans or short-term limited duration insurance policies.

##### **Section 4 Definitions**

- A. "Carrier" shall have the same meaning as found at § 10-16-102(8), C.R.S.
- B. "Health benefit plan" shall have the same meaning as found at § 10-16-102(32), C.R.S.

- C. "Human immunodeficiency virus" and "HIV" mean, for the purposes of this regulation, the virus that attacks the immune system that can lead to acquired immunodeficiency syndrome or AIDS if not treated.
- D. "Pre-exposure prophylaxis" and "PrEP" mean, for the purposes of this regulation, medication or medications intended to prevent HIV infection when an individual is exposed to HIV.
- E. "Serodiscordant sex partner" means, for purposes of this regulation, having a sexual relationship with a partner who is living with HIV.
- F. "United States Preventive Services Taskforce" and "USPSTF" shall have the same meaning as found at § 10-16-104(18)(c)(IV), C.R.S.
- G. "Urgent prior authorization request" shall have the same meaning as found at § 10-16-124.5(8)(b), C.R.S.

## **Section 5 Carrier Coverage Requirements**

- A. Consistent with USPSTF Recommendations, carriers must provide coverage for the federal Food and Drug Administration (FDA)-approved medication prescribed for pre-exposure prophylaxis (PrEP) without copayment or cost-sharing for individuals who, according to their provider or pharmacist pursuant to § 12-280-125.7, C.R.S., are indicated for PrEP. Carriers shall provide such coverage without copayment or cost-sharing for the PrEP medication that is clinically indicated for the individual according to the prescribing provider or pharmacist. Based on Centers for Disease Control and Prevention Guidelines, individuals indicated for PrEP include:
  - 1. Men who have sex with men, are sexually active, and have one of the following characteristics:
    - a. Having a serodiscordant sex partner;
    - b. Inconsistent use of condoms during receptive or insertive anal sex; or
    - c. A sexually transmitted infection (STI) with syphilis, gonorrhea, or chlamydia within the past 6 months.
  - 2. Heterosexually active women and men who have one of the following characteristics:
    - a. Having a serodiscordant sex partner;
    - b. Inconsistent use of condoms during sex with a partner whose HIV status is unknown and who is at high risk (e.g., a person who injects drugs or a man who has sex with men and women); or
    - c. An STI with syphilis or gonorrhea within the past 6 months.
  - 3. Persons who inject drugs and have one of the following characteristics:
    - a. Shared use of drug injection equipment; or
    - b. Engage in any of the behaviors or have any of the conditions identified in Sections 5.A.1. or 5.A.2.
  - 4. Persons who engage in transactional sex, such as sex for money, drugs, or housing, including commercial sex workers or persons trafficked for sex work.

5. Men who have sex with men and women who engage in any of the behaviors or have any of the conditions identified in Sections 5.A.1. through 5.A.4.
  6. Transgender women and men who are sexually active and who engage in any of the behaviors or have any of the conditions identified in Sections 5.A.1. through 5.A.4.
- B. Carriers must provide coverage for PrEP baseline and monitoring services, consistent with USPSTF recommendations, articulated in the FAQs about Affordable Care Act Implementation Part 47, without copayment or cost sharing for services obtained from participating providers when HIV PrEP medication is prescribed.
1. Baseline and monitoring services include: HIV testing; Hepatitis B and C testing; creatinine testing and calculated estimated creatinine clearance (eCrCl) or glomerular filtration rate (eGFR); pregnancy testing; sexually transmitted infection screening and counseling; and adherence counseling.
  2. Office visits associated with baseline and monitoring services must also be covered without cost sharing, when the service is not billed separately from an office visit, and the primary purpose of the office visit is the delivery of the recommended preventive service.
  3. Carriers cannot limit or restrict the frequency of PrEP baseline and monitoring services in a manner inconsistent with the USPSTF PrEP recommendation. Carriers also cannot limit or restrict the number of times an individual may start PrEP if the individual meets the criteria specified in the USPSTF recommendation and PrEP is deemed to be medically appropriate by the individual's health care provider.
- C. No more than 50% of drugs on a carrier's formulary used for the prevention of HIV may be placed on the plan's highest cost formulary tier. This section C only applies to individual and small group health benefit plans.
- D. Carriers shall not require a covered person to undergo step therapy or receive prior authorization before a pharmacist may prescribe and dispense PrEP, pursuant to § 10-16-152, C.R.S.
- E. Carriers shall consider any request for PrEP from a provider, as specified in § 10-16-124.5(8)(b), C.R.S., other than from a pharmacist, to be an urgent prior authorization request, and a carrier must comply with the requirements for an urgent prior authorization request found in Colorado Insurance Regulation 4-2-49, "Concerning the development and implementation of a uniform drug benefit prior authorization process, the required drug appeals process, and the coverage of certain opioid dependence and other substance use disorder treatment drugs."
- F. Carriers shall not impose additional utilization management procedures or requirements that restrict or limit access to PrEP.

## **Section 6 Severability**

If any provision of this regulation or the application of it to any person or circumstances is for any reason held to be invalid, the remainder of this regulation shall not be affected.

## **Section 7 Incorporated Materials**

The U.S. Preventive Services Task Force A and B Recommendations as published on the effective date of this regulation and does not include later amendments or editions of the Recommendations. A copy of the Recommendations may be examined during regular business hours at the Colorado Division of Insurance, 1560 Broadway, Suite 850, Denver, Colorado 80202. A certified copy of the

Recommendations may be requested from the Colorado Division of Insurance, 1560 Broadway, Suite 850, Denver, Colorado 80202. A charge for certification or copies may apply. A copy may also be obtained online at:

<https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>

The Centers for Disease Prevention Control and Prevention Guidelines as published on the effective date of this regulation and does not include later amendments or editions of the Guidelines. A copy of the Guidelines may be examined during regular business hours at the Colorado Division of Insurance, 1560 Broadway, Suite 850, Denver, Colorado 80202. A certified copy of the Guidelines may be requested from the Colorado Division of Insurance, 1560 Broadway, Suite 850, Denver, Colorado 80202. A charge for certification or copies may apply. A copy may also be obtained online at <https://www.cdc.gov/hiv/effective-interventions/prevent/prep/index.html>

The FAQs about Affordable Care Act Implementation Part 47 as published on the effective date of this regulation and does not include later amendments or editions of the FAQs. A copy of the FAQs may be examined during regular business hours at the Colorado Division of Insurance, 1560 Broadway, Suite 850, Denver, CO 80202. A certified copy of the FAQs may be requested from the Division of Insurance, 1560 Broadway, Suite 850, Denver, Colorado 80202. A charge for certification or copies may apply. A copy may also be obtained online at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf>.

## **Section 8      Enforcement**

Noncompliance with this regulation may result in the imposition of any of the sanctions made available in the Colorado statutes pertaining to the business of insurance, or other laws, which include the imposition of civil penalties, issuance of cease and desist orders, and/or suspensions or revocation of license, subject to the requirements of due process.

## **Section 8      Effective Date**

This regulation shall be effective March 2, 2022

## **Section 9      History**

New regulation effective January 1, 2021.

Amended regulation effective March 2, 2022