



NEW YORK STATE
DEPARTMENT *of*
FINANCIAL SERVICES

Andrew M. Cuomo
Governor

Maria T. Vullo
Superintendent

**Insurance Circular Letter No. 21 (2017)
December 1, 2017**

TO: All Insurers Authorized to Write Accident and Health Insurance in New York State, Article 43 Corporations, Health Maintenance Organizations (“HMOs”), Student Health Plans Certified Pursuant to Insurance Law § 1124, and Municipal Cooperative Health Benefit Plans

RE: Health Insurance Coverage for Pre-Exposure Prophylaxis for HIV Prevention

STATUTORY AND REGULATORY REFERENCES: N.Y. Ins. Law §§ 3201, 3216, 3221, 4303, and Article 49; N.Y. Pub. Health Law Article 49; 42 U.S.C. § 300gg-1 et seq.; 42 U.S.C. § 18001 et seq.; 10 NYCRR § 98-2.9; 11 NYCRR § 410.9; 29 C.F.R. Part 2560; 29 C.F.R. Part 2590; 45 C.F.R. Part 147; and 45 C.F.R. Part 156

I. Purpose

The Superintendent of Financial Services (“Superintendent”) has received complaints that issuers may be imposing unreasonable barriers to access to pre-exposure prophylaxis (“PrEP”), a prescription drug used for the prevention of a human immunodeficiency virus (“HIV”) infection, through the use of stringent prior authorization requirements and improper denials of coverage. This circular letter provides direction to insurers authorized to write accident and health insurance in New York State, article 43 corporations, health maintenance organizations, student health plans certified pursuant to Insurance Law § 1124, and municipal cooperative health benefit plans (collectively, “issuers”) regarding coverage for PrEP.

II. Coverage for PrEP

Health service providers generally prescribe PrEP for HIV-negative people who are at high risk for HIV. It has been shown to be highly effective in stopping HIV infection when taken as prescribed.¹ Currently, the only Food and Drug Administration (“FDA”) approved drug for use as PrEP is a combination of emtricitabine and tenofovir, whose brand name is Truvada. The FDA recently approved a generic version of Truvada.

The Department has issued regulations requiring New York health insurance policies or contracts to provide a comprehensive package of items and services, which are known as essential health benefits (“EHB”)(Insurance Regulation 62 (11 NYCRR 52.1(q) and 52.71)). The federal

¹ See <https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis>.

Affordable Care Act contains similar EHB requirements. Pursuant to 45 C.F.R. § 156.122(a)(1), a health insurance policy or contract providing coverage in the individual or small group market would not be considered to be providing EHBs unless, in relevant part, it covers at least the greater of at least one drug in every United States pharmacopeia category and class or the same number of prescription drugs in each category and class as the EHB-benchmark plan. Furthermore, § 52.16(c) of 11 NYCRR 52 (Insurance Regulation 62) prohibits issuers offering individual, small group and large group health insurance policies from limiting or excluding coverage by type of illness, accident, treatment, or medical condition. In order to comply with these requirements, prescription drug coverage must provide coverage for PrEP.

III. Prior Authorization and Clinical Review Criteria

While issuers and their utilization review agents may impose reasonable prior authorization requirements on prescription medications, issuers and their utilization review agents must carefully consider whether any such requirement for PrEP would create an unacceptable barrier to coverage for individuals who would otherwise benefit from the medication. Similarly, when performing prior authorization, concurrent, or retrospective utilization review for PrEP, issuers and their utilization review agents must comply with the procedures described in Articles 49 of the Insurance Law and Public Health Law, as well as 29 C.F.R. Parts 2560 and 2590 and 45 C.F.R. Part 147, including the requirement to use appropriate written clinical review criteria when reviewing for medical necessity. Further, when making coverage determinations, issuers and their utilization review agents must do so in a non-discriminatory manner. There is no justification for denying coverage for PrEP on the ground that the patient is at risk for HIV based on his or her sexual orientation.

IV. Notices of Adverse Determination or Final Adverse Determination

In the event that an issuer or its utilization review agent determines that PrEP is not medically necessary for a particular individual, the written initial adverse determination and final adverse determination must include the information set forth in Insurance Law §§ 4903(e) and 4904(c), Public Health Law §§ 4903(5) and 4904(3), 10 NYCRR § 98-2.9, and 11 NYCRR § 410.9, as well as in 29 C.F.R. § 2560.503-1(g)(1) and 45 C.F.R. § 147.13(b)(2). This includes the reason for the determination, including the clinical rationale for the denial as applicable to the insured, if any; instructions on how to initiate a standard or expedited appeal and an external appeal; and notice of the availability, upon request of the insured or the insured's designee, of the clinical review criteria relied upon to make such determination. The notice should also specify what, if any, additional information must be provided to, or obtained by, the issuer or utilization review agent in order to render a decision on the appeal.

VI. Conclusion

Issuers offering prescription drug coverage must cover PrEP. Such coverage should be subject only to reasonable utilization management measures and must comply with Articles 49 of the Insurance and Public Health Law, as well as 29 C.F.R. Parts 2560 and 2590 and 45 C.F.R. Part 147. No insured may be discriminated against in the prescribing or coverage of medically necessary treatments.

Please direct any questions regarding this circular letter to Thomas Fusco, Supervising Insurance Attorney, Health Bureau, New York State Department of Financial Services, Walter J. Mahoney Office Building, 65 Court Street, Room 7, Buffalo, New York 14202 or by e-mail at Thomas.Fusco@dfs.ny.gov.

Very truly yours,

Lisette Johnson
Bureau Chief, Health Bureau