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March 24, 2022

The Honorable Shane Pendergrass  
Chair, House Health and Government Operations Committee  
Room 241  
House Office Building  
Annapolis, Maryland 21401

**Senate Bill 355- HIV Prevention Drugs - Prescribing and Dispensing by Pharmacists and Insurance Requirements**

Dear Chairman Pendergrass,

The League of Life and Health Insurers of Maryland, Inc. respectfully opposes Senate Bill 355- HIV Prevention Drugs - Prescribing and Dispensing by Pharmacists and Insurance Requirements unless amended and urges the committee to give the bill an unfavorable report as currently introduced.

Among other actions, Senate Bill 355 would prohibit insurers from requiring prior authorization or step therapy for “preexposure prophylaxis” (PrEP) or “postexposure prophylaxis” (PEP) for HIV prevention. League members have concerns with removing prior authorization for PrEP due to the complicated medical implications of being prescribed the drugs currently on the market.

Currently, Gilead markets the only two oral drugs that have been approved by the FDA for PrEP: Truvada (emtricitabine/tenofovir disoproxil fumarate [TDF] and Descovy (emtricitabine/tenofovir alafenamide fumarate [TAF]). Both drugs have similar efficacy in prevention of HIV infection, however, Descovy is not approved for use by cis-gender women who are risk for sexually-acquired HIV, as it was not found to be effective in this population. In general, first-line therapy for PrEP should be Truvada due to established efficacy in all persons at risk through sex or injection drug use.

Descovy does not provide a clinically significant advantage over Truvada regarding adverse reactions. Both Truvada and Descovy have warnings related to renal toxicity due to the tenofovir component. Patients with preexisting renal impairment and those taking nephrotoxic agents are at increased risk. Truvada is not recommended for PrEP in patients with CrCl <60mL/min; Descovy is not recommended with CrCl <30mL/min. The tenofovir component of both Truvada and Descovy also decreases bone mineral density (BMD) through disruption in vitamin D metabolism. The incidence and negative impact that Descovy [TAF] has on BMD is less than that observed with Truvada [TDF], but may not be clinically significant due to the low incidence of fracture in this patient population. A higher incidence of dyslipidemia has been reported with Descovy [TAF] compared to Truvada [TDF]. Descovy should be reserved for patients with

established HIV-1 infection, or for PrEP in individuals who have otherwise had clinically significant adverse reactions to Truvada.

Additionally, per IPD Analysis, the annual cost of generic Truvada is about \$330, while Descovy costs about \$23,500 per year. While the ingredients are similar to generic Truvada, Brand Descovy is not recommended for PrEP, and is not referenced in the CDC National Guidelines.

Carriers apply a prior authorization for Descovy for PRE-exposure prophylaxis of HIV (PrEP), when a known exposure has not already occurred, with preference for using \$0 generic Truvada first. PrEP is indicated for members that are at high risk of acquiring HIV due to lifestyle – through sexual encounters or injection drug use. First-line therapy for PrEP should be generic Truvada due to established efficacy in all persons at risk, while Descovy is indicated for PrEP in only select populations, and may be used only if members have had an adverse reaction to generic Truvada or have an existing diagnosis of low bone mineral density, osteoporosis, osteopenia, or reduced kidney function, CrCL <60mL/min." <sup>1</sup>

PrEP is not only about preventing HIV through sexual activity, but is also used to prevent transmittal of HIV from mother to baby. If used correctly, PrEP can reduce the risk of HIV transmittal to a baby to 1% or less. It should, however, be done under a doctor's supervision to make sure that it is being used correctly by the patient.<sup>2</sup> This is another reason why preserving prior authorization for PrEP is important.

For these reasons, the League urge the committee to give Senate Bill 355 an unfavorable report unless amended to preserve prior authorization for PrEP.

Very truly yours,



Matthew Celentano  
Executive Director

cc: Members, House Health and Government Operations Committee

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<sup>1</sup> Centers For Disease Control and Prevention “Pre Exposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update” <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>

<sup>2</sup> Centers for Disease Control and Prevention <https://www.cdc.gov/hiv/basics/hiv-prevention/mother-to-child.html#:~:text=If%20you%20have%20a%20partner,during%20pregnancy%2C%20or%20while%20breastfeeding.>