MAINE ASSOCIATION OF HEALTH PLANS

Testimony of Katherine Pelletreau
to the Joint Standing Committee on Health Coverage, Insurance and Financial Services

Neither For Nor Against

LD 1115 An Act to Improve Access to HIV Prevention Medications

April 8th, 2021

Good Morning Senator Sanborn, Representative Tepler, Members of the Joint Standing Committee on Health Coverage, Insurance and Financial Services:

My name is Katherine Pelletreau and I am the Executive Director of the Maine Association of Health Plans (MeAHP). MeAHP has five members including Aetna, Anthem Blue Cross and Blue Shield, Cigna, Community Health Options and Harvard Pilgrim Health Care. Collectively, MeAHP's members provide or administer health insurance coverage to over 600,000 Maine people. The organization's mission is to improve the health of Maine people by promoting affordable, safe and coordinated healthcare.

LD 1115 would require carriers to cover at least one "therapeutically equivalent" drug for the prevention of HIV at the tier with the lowest cost sharing. It would also prohibit prior authorization or step therapy for these drugs.

Federal Law and the ACA

Under federal law, carriers are currently required to cover HIV prevention drugs (PrEP). Drugs in this category – Truvada, Descovy, and the newly available generic version of Truvada – have an "A" level recommendation from the United States Preventive Services Task Force (USPSTF).

The Plans treat these drugs similarly to how contraceptives are treated under the ACA. Guidance issued by the Tri-departments (Departments of Labor, Health and Human Services, and the Treasury) explicitly permit plans (in the context of contraceptives) to "cover a generic drug without cost-sharing and impose cost-sharing for equivalent branded drugs". A plan may also "discourage use of brand name pharmacy items over generic pharmacy items through the imposition of cost sharing." [1]

While all three HIV prevention drugs may be covered, the generic, usually the lowest cost option, would be covered as preventive without cost share. The brand drugs, Truvada and Descovy, are more likely to

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[1] https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQ-Part-XXVIII-transparency-reporting-final-8-11-15.pdf

be covered under a preferred brand tier unless approved through the required exception process (prior authorization) to be covered as preventive.

Under Maine law, "therapeutic equivalent" is a generic, defined as "any drug that has identical amounts of the same active ingredients in the same dosage form and in the same concentration that, when administered in the same amounts, will produce or can be expected to have the same therapeutic effect as the drug prescribed."[2]

Truvada and Descovy are not therapeutic equivalents or generics but therapeutic alternatives for HIV prevention. According to the U.S. CDC both are approved but for somewhat different populations and have differing risks and side-effects.

- Truvada® is for all people at risk through sex or injection drug use.
- Descovy® is for people at risk through sex, except for people assigned female at birth who are at risk of getting HIV from vaginal sex.[3]

Both drugs are manufactured by Gilead Sciences Inc. and have similar costs (approx. $2,000 for a 30-day supply). **For Gilead, this bill keeps their last non-generic PrEP drug on equal coverage footing with the generic of Truvada** (approx. $1,455 for a 30-day supply[4]).

There are concerns that there will be additional costs associated with preferred coverage for Descovy over the generic version of Truvada and less access to PrEP treatment. Dr Rochelle Walensky of Harvard University (now heading up the US CDC under the Biden administration) and colleagues studied this very issue and published their findings in the *Annals of Internal Medicine*.[5]

Their study found that "the extra price the US health system may pay for a new, branded version of PrEP (Descovy), rather than an older version (Truvada) whose price is soon due to fall, is not remotely justifiable in terms of its marginally more benign side effect profile. Furthermore, by switching patients to the new version of PrEP in the absence of any clinically meaningful changes in renal or bone markers, doctors may be depriving other patients of PrEP."

Dr. Walensky concludes that:

"TDF (Truvada) going generic presents us with an amazing opportunity to get more people onto this effective prevention method, and especially the poorer people who need it. In HIV we have a history, for very good reasons, of preferring the shiny new drug over the old one, but in this case, the old pill is safe. It would be tragic if access to prevention was blocked by drug companies capitalizing on the profit potential of a new pill."[6]

MeAHP's concern is that this bill would have the effect of requiring health plans to cover Descovy in addition to Truvada or its generic equivalent, at the lowest formulary tier and without prior authorization or step therapy.

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[2] http://legislature.maine.gov/legis/statutes/32/title32sec13702-A.html
[3] https://www.cdc.gov/hiv/basics/prep/about-prep.html
[4] https://www.sfaf.org/resource-library/side-by-side-comparison-truvada-and-descovy-for-prep/
[5] https://www.acpjournals.org/doi/abs/10.7326/m20-5643
[6] https://www.aidsmap.com/news/mar-2020/far-fewer-people-would-get-prep-us-if-generic-tdfftc-replaced-descovy-tafftc-cost

Gilead is marketing Descovy as a superior choice despite the lack of clinical findings on superiority and trying to move the Truvada market to its newer drug. As Plans have seen with other drugs, behind this marketing push is that the patent on one of the two key ingredients in Truvada will expire later this year[7], opening the market to more generics and likely driving the price of the drug down. Gilead chairman and chief executive officer Dan O'Day has publicly spoken about the company's intentions to switch up to 95% of patients under treatment with Truvada to Descovy by the fourth quarter of this year.[8]

Douglas Krakower, MD along with several other medical colleagues, authored a piece in the Annals of Medicine[9] disputing the superiority of Descovy and has called out Gilead for relentless marketing of the new drug.

"I get e-mails, online and print ads. I got a poster about PrEP with Descovy. I had outreach from Gilead with invitations to attend informational dinners about Descovy. I talked with a rep from Gilead who said the favorable safety profile of Descovy made it optimal, which is not correct. It was not a neutral presentation of the data. That is why we tried to do an objective review in our piece."[10]

We urge the Committee to look below the surface of this bill and consider the market dynamics underneath the push for expanded coverage of Descovy.

MeAHP offers no comment on the sections of the bill related to pharmacists and dispensing.

Thank you for your consideration of these comments.

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[7] https://www.healio.com/news/infectious-disease/20201002/teva-announce-availability-price-of-generic-hiv-medications#:~:text=Teva%20Pharmaceuticals%20announced%20the%20availability,HIV%20medications%20Truvada%20and%20Atripla.

[8] https://www.thebodypro.com/article/should-prep-users-on-truvada-switch-to-descovy

[9] https://www.acpjournals.org/doi/10.7326/m19-3337, Tenofovir Alafenamide for HIV Preexposure Prophylaxis: What Can We DISCOVER About Its True Value?, 2/18/2020.

[10] https://www.thebodypro.com/article/should-prep-users-on-truvada-switch-to-descovy, 1/27/2020.