May 10, 2024

Via email (*comments.pdab@maryland.gov*)

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Reasons Biktarvy Should Not Be Selected for a Cost Review

Dear Members of the Prescription Drug Affordability Board:

I am writing on behalf of Gilead Sciences, Inc. ("Gilead"), in response to the Prescription Drug Affordability Board's ("PDAB") recent referral of Biktarvy® to the Stakeholder Council for input into whether Biktarvy should be selected to undergo a cost review and identification of proposed therapeutic alternatives for Biktarvy®, as well as to comment on unintended consequences of a UPL, and provide process recommendations.[1] Gilead is a research-based biopharmaceutical company that discovers, develops, and commercializes innovative medicines for people with life-threatening diseases in areas of unmet medical need, and has been a leading innovator in treatments for human immunodeficiency virus (HIV) for more than 30 years.

Gilead previously submitted letters to the Maryland PDAB and Stakeholder Council explaining that Biktarvy should not be selected for cost review because Biktarvy is already affordable and accessible for Marylanders with HIV. These letters also addressed that imposing a UPL on Biktarvy could result in treatment delays and interruptions, which could also result in an increase in the amount of HIV virus in the blood, leading to worse clinical outcomes and development of resistant forms of the virus. A UPL on Biktarvy would thus not only be unnecessary in light of Biktarvy's affordability but could also result in Maryland facing increased healthcare costs and would undermine efforts to end the HIV epidemic, pose an undue risk to public health, and disproportionately affect vulnerable populations. These effects conflict with the Moore Administration's goal of ensuring health equity in Maryland.

This letter builds on the points made in Gilead's prior letters by providing additional information on:

<u>Reasons that Biktarvy is clearly differentiated from other HIV medicines:</u>

- HIV drugs have unique clinical and pharmacological qualities that need to be considered when selecting the most appropriate regimen for a person with HIV, in order to support better medication adherence, improve viral suppression, and reduce the risk of transmitting HIV.
- There is longstanding recognition in public programs that patients need access to the particular HIV medication that was prescribed for them, and that one HIV product cannot simply stand in for another.

- Biktarvy offers a single-tablet regimen that is highly effective, supports rapid start, provides a high barrier to drug resistance, and demonstrates exceptional tolerability and safety; therefore, other HIV drugs are not appropriate comparators for the cost-review process.

Reasons Biktarvy should not be selected for a cost review:

- Biktarvy is affordable and accessible to people with HIV in Maryland.
- The State is overestimating its spending on Biktarvy.
- Maryland's Medicaid program has access to unique lower drug pricing, specially determined for its low-income and disability-eligible enrollees. Policies that would disrupt Medicaid's exclusive access to protected pricing would also disrupt the stability of Maryland's Medicaid program for its most vulnerable patients.

In addition, the process of selecting drugs and conducting cost reviews should be fair, reasoned, and transparent while allowing for meaningful engagement from Gilead and other stakeholders.

***

I. HIV drugs have unique clinical and pharmacological qualities that need to be considered when selecting the most appropriate regimen for a person with HIV in order to support better patient medication adherence, improve viral suppression, and reduce the risk of transmitting HIV.

HIV is a uniquely challenging virus to treat, making HIV medicines especially poor candidates for the cost-review process. HIV aggressively replicates at a rate of one billion new viral particles per day, overwhelming and simultaneously destroying the immune system by targeting the $CD4^+$ T cells needed for a proper immune response.[2] Effectively targeting viral replication requires combining multiple drugs with different mechanisms of action, and this highly individualized approach has been critical to transforming a once-deadly disease into a manageable, chronic condition with minimal impact on life expectancy.[3]

Because of the complexity of treatment, antiretroviral therapy (ART) must be selected taking into consideration both clinical considerations and the ability of a treatment regimen to fit into an individual's overall healthcare experience and effectively support their adherence. For this reason, the U.S. Department of Health and Human Services (DHHS) *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV* states that "selection of a regimen should be individualized" for a particular patient based on factors such as virologic efficacy, toxicity, potential adverse effects, pill burden, dosing frequency, drug–drug interaction potential, resistance-test results, comorbid conditions, and childbearing potential."[4] In addition, studies show that, as people with HIV age, they are more likely to develop additional health issues and tend to develop them earlier than people who do not have HIV.[5,6] This often means they must take multiple medications and may be more prone to drug-drug interactions from medications for different conditions, particularly when their HIV medication includes certain components. When individuals take their medication as prescribed, such adherence prevents HIV from multiplying, which suppresses the HIV virus.[7] Viral suppression stops HIV infection from progressing,

helping people living with HIV stay healthy and live longer, and maintaining an undetectable viral load also effectively eliminates the risk of sexually transmitting the virus to an HIV-negative partner.[8]

Effectively managing HIV infection requires vigilance to avoid creating treatment resistant mutations, which reduce the efficacy of ART. Mutations are more likely to develop in patients with suboptimal adherence to treatment regimen and in patients who are given a regimen with a lower genetic barrier to resistance, including patients whose access to treatment is disrupted by policy interventions. Specific resistance mutations may create the need for varied combinations of medications, which may require taking more pills or otherwise be more inconvenient to take. Thus, given the possibility that resistance could develop to any single drug, it is essential to have a diverse artillery of ARTs available for all patients. The ARTs recommended by DHHS for most patients are those that effectively suppress the virus, have a high barrier to resistance, have minimal adverse events, and are simple to take. The importance of adherence, risk of transmission and HIV drug resistance means that the HIV landscape thus poses unique challenges that make the cost-review and UPL approach particularly inapt.

II. There is longstanding recognition in public programs that patients need access to the particular HIV medication that was prescribed for them, and that one HIV product cannot simply stand in for another.

The Centers for Medicare & Medicaid Services (CMS) recognizes the need for individual treatment in the context of Medicare Part D. With respect to antiretrovirals, CMS has stated there are a "number of multiple drug combinations and adjunctive therapies involved," drug protocols are subject to change, and changing drug resistance plays a role "in determining the selection of among the different antiretroviral drugs."[9] Moreover, CMS has acknowledged that "[t]he need to adjust specific combination antiretroviral therapy in real time is complex and must consider, among other things, viral sensitivity to the drugs, drug interactions, pregnancy status (if applicable), and potentially the patient's pharmacogenomic profile of the cytochrome P450 system."[10] For these reasons, CMS does not allow plans to implement any form of utilization management for antiretrovirals in Medicare Part D.

At the state level, Maryland's Integrated HIV Prevention and Care Plan for 2022-2026 identifies statewide needs to increase both community knowledge and provider education regarding treatment options (always mentioned in plural) and the benefits of ongoing HIV treatment.[11] Simply put, effective treatment regimens must take into account and be formulated according to patient-specific factors.

III. Biktarvy offers a single-tablet regimen that is highly effective, supports rapid start, provides a high barrier to drug resistance, and demonstrates exceptional tolerability and safety; therefore, other HIV drugs are not appropriate comparators for the cost-review process.

Biktarvy, a single-tablet regimen ("STR"), is an "AI" recommended treatment for most people to start on for treatment of HIV under the U.S. Department of Health and Human Services (DHHS) guidelines. Recommendations in DHHS guidelines are based on scientific evidence and expert opinion. Each recommendation statement includes a letter (A, B, or C) that represents the strength of the recommendation and a Roman numeral (I, II, or III) that represents the quality of the evidence that supports the recommendation.[12] The DHHS recommendation means that Biktarvy has demonstrated durable virologic efficacy, a favorable tolerability and toxicity profile, and is easy to use.[13] There are only three other regimens that received a "AI" recommendation for initiating HIV treatment in these guidelines, and Biktarvy has been shown to have specific advantages over each. While Maryland's PDAB statute and regulations state that certain factors regarding "therapeutic alternatives" should be considered "to the extent practicable," the proposed "therapeutic alternatives" list that the Board has identified as potential cost-comparators for Biktarvy contains regimens requiring multiple pills, medications that are not guideline-recommended, and medications that undervalue the clinical value that Biktarvy offers compared to previous generations of treatments. If the Board must use comparators for Biktarvy in the context of the State PDAB cost review, it should only focus on single-tablet regimens. Even focusing on these, Biktarvy is clearly differentiated as outlined below.

<u>Biktarvy offers a complete regimen in a single tablet</u>

In order to suppress the HIV virus, multiple antiretrovirals with different mechanisms of action must be combined to make what is considered a complete regimen. A single-tablet regimen (STR) includes multiple agents to treat HIV in one tablet and is approved as a complete regimen to treat HIV. A multi-tablet regimen, on the other hand, is one that combines multiple different medications across multiple pills taken separately, sometimes with different dosing intervals. Patients on STRs like Biktarvy have higher rates of adherence to HIV treatment and, subsequently, higher rates of achieving undetectable levels of virus in the body compared to patients on multi-tablet regimens ("MTRs").[14,15,16] This is because some patients may have difficulty adhering to complex treatment regimens due to factors such as the number of pills, dosing schedule, and dietary restrictions. As such, though MTR therapeutic alternatives may exist for a specific patient, this does not mean such alternatives represent the best choice to assure meaningful personal and public health outcomes for that patient. By improving treatment adherence and persistence, patients on STRs like Biktarvy are expected to better control their HIV, resulting in decreased rates of hospitalization and lower overall healthcare costs.[17,18,19,20,21] The majority of drugs identified by Maryland as potential alternatives for Biktarvy are not complete single tablet regimens for the treatment of HIV and therefore are inappropriate comparators.

Biktarvy supports rapid start

Biktarvy can be started immediately after HIV diagnosis— known as "rapid start" of HIV treatment—before results of recommended resistance testing or baseline laboratory testing are available.[22] Rapid start is not only associated with rapid suppression of the virus, but is also linked to individual receiving ongoing treatment for their HIV at higher rates.[23,24,25,26,27,28] Biktarvy is the only unboosted single-tablet option that is recommended by the DHHS for rapid start.[29]

Biktarvy has a high barrier to resistance

HIV can develop resistance to certain medications if they are not taken consistently and correctly, particularly with medications with a lower barrier to resistance. Once resistance develops, certain medications may no longer be effective against the resistant strain, leading to treatment failure and reduced treatment options. Biktarvy has a high barrier to resistance due to its unique pharmacokinetic and pharmacodynamic properties. For example, it is the only unboosted STR label-indicated and DHHS-recommended for patients with pre-existing M184V/I, an HIV resistance mutation seen in a large share of viruses tested for resistance in persons who have been on HIV treatment.[30]

Biktarvy is approved across broad populations

Furthermore, unlike other guideline-recommended STRs for treatment initiation, the efficacy and safety profile of Biktarvy have been evaluated in people living with HIV who have hepatitis B virus (HBV) coinfection, an infection which is 10-20 times more prevalent in the HIV population, and disproportionately prevalent in select subpopulations, such as persons who inject drugs.[31,32,33] Biktarvy is approved for individuals with end stage renal disease on chronic hemodialysis with history of treatment and pregnant women switching treatments, differentiating it from other STRs considered as potential therapeutic alternatives by the Board.[34]

For these reasons and many others, there are no true therapeutic alternatives for Biktarvy, which is uniquely proven to work across many diverse populations, with a high barrier to resistance and lower risk of producing viral resistance, and recommended for rapid start. The proposed therapeutic alternatives do not provide appropriate cost comparators for Biktarvy, as summarized in Table 1.

Finally, although the PDAB has posted a list of proposed therapeutic alternatives for Biktarvy on its website, the PDAB has not identified the criteria for selecting them. Accordingly, the basis for the identification of these drugs as therapeutic alternatives for Biktarvy is unclear. Further, because no UPL Action Plan has been published, it is unknown how the PDAB will use or consider any data concerning the proposed therapeutic alternatives. This lack of clarity limits stakeholders' ability to offer meaningful guidance.

Table 1: Biktarvy and Therapeutic Alternatives Proposed by the Board

Biktarvy and Proposed Therapeutic Alternatives	DHHS AI Recommended as Initial Regimen for Most People with HIV	DHHS Recommended Single Tablet Regimen for Rapid Start	Reported Treatment-Emergent Resistance in Clinical Trials**	DHHS Recommended for HIV & HBV coinfection
Biktarvy	Yes	Yes	None	Yes
Triumeq	Yes	No	Yes	No
Genvoya	No	No	Yes	Yes
Stribild	No	No	Yes	Yes
Dovato	Only in individuals with HIV RNA <500,000 copies/mL, with no HBV coinfection	No	Yes	No
Descovy*	Only in combination with another agent	N/A	Yes	In combination with a 3rd agent
Tivicay *	Only in combination with 2 other agents	N/A	Yes	Only if combined with tenofovir + a 3rd agent
Isentress *	No	N/A	Yes	No
Reyatz *	No	N/A	Yes	No
Prezista *	No	N/A	Yes	No
Pifeltro *	No	N/A	Yes	No
Sustiva *	No	N/A	Yes	No

*Incomplete regimens. Cells shaded in gray are NOT complete regimens and must be combined with other agents. A complete antiretroviral therapy regimen combines two to three antiretrovirals with different mechanisms of action to suppress the virus. The first five drugs on this table are combination products made up of multiple agents with different mechanisms.
** Based on Gilead studies

IV. Biktarvy is affordable and accessible to people with HIV

The PDAB's current UPL authority extends to drugs that are "[p]urchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government," "[p]aid for through a health benefit plan on behalf of a unit of State or local government," and "[p]urchased for or paid for by the Maryland State Medical Assistance Program."[35] Below we address affordability and access in each of these market segments.

- Maryland Medicaid: Enrollees in Maryland's Medicaid program who rely on Biktarvy fill their prescriptions for no more than $1. Furthermore, Maryland Medicaid does not generally currently require a prior authorization, in which a provider must provide documentation about why a medicine is needed, before patients are able to receive medicine to treat HIV. This means that people with HIV can obtain treatment in a timely way based solely on the recommendation of their doctor and without bureaucratic hurdles.

- State or local government health benefit plan: The vast majority of individuals who are insured through Maryland's health plans for state and local government employees have access to Biktarvy on their plan's preferred brand tier. This means that these people with HIV can receive Biktarvy at the lowest cost-sharing amount for a branded drug. For instance, the State of Maryland prescription benefits administered through CVS Caremark have between $15-$25 copayment for preferred brand drugs for a 45-day supply.[36] If these individuals nonetheless face challenges affording their medicines, Gilead's Advancing Access® program may be available to reduce or eliminate out-of-pocket costs.[37]

On top of these programs, Marylanders with HIV can benefit from additional assistance through the Ryan White HIV/AIDS program (Ryan White) administered by the Health Resources and Services Administration (HRSA). Ryan White helps low-income people with HIV access medicines, medical care, and support services by providing grants to cities, states, counties, and community organizations. Ryan White has five parts, and Part B includes the AIDS Drug Assistance Program (ADAP), which supports access to medicines.[38] Maryland's AIDS Drug Assistance Program, or "MADAP," pays for HIV medicines for clients without insurance and assists individuals with insurance with copay and deductible payments. People eligible to participate in MADAP can obtain Biktarvy with a $0 copay. [39,40] To be eligible, a Maryland resident with HIV must not be on Medicaid and must earn 500 percent of the federal poverty level or less. These affordability protections are unique to HIV treatments, which makes the cost-review process uniquely unnecessary for Biktarvy and other HIV medicines.

The Maryland PDAB was set up to protect Marylanders from the high costs of prescription drugs. Based on the information presented, selecting Biktarvy for cost review would be an ineffective use of the Board's resources and time as it is already affordable for Marylanders.

V. The State is overestimating its spending on Biktarvy

The PDAB recently released a "sample database" which includes data about the eight drugs identified by the PDAB as candidates for potential cost-reviews.[41] Because the public has neither access to the data or full dashboard supporting this database nor a detailed understanding of the data sources and methodology used by the PDAB, stakeholders with analytical expertise are limited in their ability to comment on potential errors, provide missing context, or explain discrepancies between the database and other sources. This lack of disclosure of the information on which the PDAB is relying is particularly concerning because of several inconsistencies between "sample database" data and Gilead's data for Biktarvy.

- Maryland's "sample database" grossly overestimates total spend in Commercial and Medicare compared Gilead's own sales data. This is concerning because one of the selection criteria, which resulted in Biktarvy's consideration for potential cost review, is "highest total spend in the most recent available calendar year."
- Maryland did not publish Medicaid data, one of the main populations of interest for the UPL, leaving open the question of whether data being used to assess Biktarvy's affordability in this segment is also inaccurate.
- Gilead compared Biktarvy's patient out-of-pocket (OOP) costs in the "sample database" with IQVIA's Longitudinal Access and Adjudication Data (LAAD), an industry gold standard dataset for patient claims data.[42] The All-Payer Claims Database (APCD), which the Board relied on in identifying drugs for as cost review candidates, significantly overestimates final patient OOP costs. The APCD does not take accurate account of secondary benefits, such as manufacturer cost-sharing assistance, Medicare payments for dual-eligible patients, and MADAP payments that offset a portion of the patient's costs. As a result of the Board's reliance on the APCD, the Board's dashboard overestimates the patient OOP costs for Biktarvy by approximately 8 times for the commercial segment and by approximately 3 times for the Medicare Part D segment when compared to IQVIA's LAAD. Continuing to rely on the APCD in making affordability determinations would be a profound mistake, resulting in erroneous determinations.
- The "sample database" lacks consistency as the data years for each market segment is different (2022 for commercial and 2020 for Medicare). Moreover, the "sample database" does not include all data reportedly included in the non-public version of the dashboard, which purportedly included 2021 data for Medicaid.[43] This raises questions about how the board is considering "the most recent available calendar year" and weighting data from different sources and years.

These inconsistencies, lack of transparency, and inaccuracies in the "sample database" create doubt about whether Biktarvy should have been selected for potential cost review.

VI. Maryland's Medicaid program has access to unique lower drug pricing, specially determined for its low-income and disability-eligible enrollees. Policies that would disrupt Medicaid's exclusive access to protected pricing would also disrupt the stability of Maryland's Medicaid program for its most vulnerable patients.

Medicaid programs currently pay no more than the "best price" for which Biktarvy is sold to most purchasers in the United States, consistent with federal law. Under the Medicaid Drug Rebate Program, Gilead and other manufacturers enter into national rebate agreements with the federal Secretary of Health and Human Services in exchange for Medicaid coverage of their prescription drugs. Under these agreements, manufacturers provide a mandatory rebate that results in Medicaid programs receiving a net price that is no more than the lowest price at which a manufacturer sells its product in the commercial market. Certain providers that serve uninsured or underinsured people living with HIV – including Ryan White HIV/AIDS Program grantees and federally qualified health centers – also can access HIV drugs through the 340B drug discount program at a price that reflects the Medicaid "best price."

Such pricing guardrails, specific to the Medicaid program, ensure that eligible patients with low incomes have access to care. Special considerations that are unique to the Medicaid program and its enrollees inform pricing policies in this specific context. These considerations are not appropriately extended to other purchasers or payer types covering different populations, such as commercially sponsored or employer-sponsored health benefits. For example, HIV products such as Biktarvy are disproportionately provided at the Medicaid "best price" compared with other prescription drugs because HIV is more prevalent among low-income, historically marginalized, and minority populations – who are also more likely to be covered by Medicaid or receive their medicines from 340B providers. To illustrate, forty percent of nonelderly adults with HIV are covered by Medicaid, compared to only fifteen percent of nonelderly adults overall.[44] Similarly, IQVIA found that the share of sales accounted for by 340B were twice as high for antivirals as for drugs overall.[45]

If Maryland were to impose a UPL on an HIV medicine that would change the dynamics around Medicaid's access to a unique "best price," such changes would impact and potentially disrupt drug access not only for Medicaid enrollees in Maryland but possibly other patients in Maryland with different coverage as well. The impact of such changes in public policy could be particularly harmful for patients enrolled in Medicaid, in addition to being economically unsustainable for pharmacies, providers, or manufacturers, resulting in disruptions to patient access—as can be seen in other countries where government price setting has resulted in reduced patient access and comments submitted by pharmacies and community health centers.[46] And this disruption would occur without improving affordability for Marylanders with HIV because Biktarvy is already affordable to those insured by Medicaid or other populations where the UPL would apply.

Given the potential for perverse consequences, Gilead urges the PDAB to take caution and avoid disrupting care for people living with HIV by declining to select Biktarvy for cost review. Additionally, the Board should finalize and approve its UPL Action Plan as required in statute

before drugs are selected for cost reviews. This will help ensure that unintended consequences of a UPL can be further assessed.

VII. The process of selecting drugs and conducting cost reviews should be fair, reasoned, and transparent while allowing for meaningful engagement from Gilead and other stakeholders.

The PDAB and the Stakeholder Council should provide appropriate procedures for engagement with patients and other stakeholders to make reasoned cost determinations, including reasonable efforts to protect privacy and provide feasible commenting opportunities. To date, the PDAB has not established any process for patients or other stakeholders to share their experiences other than through general public comment. This process is inadequate for drugs like Biktarvy, considering public stigma often associated with HIV and the socioeconomic barriers that confront many people living with HIV. In addition, a 90-second speaking allotment for live public testimony during meetings is not enough time for stakeholders to offer substantive comments.

Moreover, the Board's opportunities for public comment arise arbitrarily and unpredictably, with comment windows often opening upon the Board's taking of certain actions (such as posting particular information on the website) that are not scheduled or announced in advance. That was the case with respect to the comment windows for letters responding to the list of proposed therapeutic alternatives and the list of drugs referred to the Stakeholder Council for input. As a result, stakeholders do not know in advance when a comment window will be open, which makes planning challenging, particularly when the Board does not update its website regularly and uses the listserv only occasionally or belatedly. Any 30-day comment period is generally too short for most stakeholders to prepare and engage meaningfully, but the uncertainty of when the 30-day period will begin and close creates additional process concerns.

The PDAB and the Stakeholder Council must also provide manufacturers with a meaningful opportunity to weigh in before the PDAB makes decisions. Manufacturers can offer a unique and valuable perspective to the PDAB. They can correct or clarify outdated or incomplete data, explain technical details, and contextualize information about the drug at issue. In selecting eight drugs for potential cost reviews, the PDAB failed to provide manufacturers and other stakeholders with an opportunity to serve this critical role. Instead, the PDAB selected drugs for discussion in private, based on a vague and unpredictable methodology, and in reliance on data that it has not made available to the public and which appears to be inaccurate. In addition to potential concerns regarding Maryland's Open Meetings Act,[47] this approach deprives manufacturers of a meaningful opportunity to comment on the inclusion of their drugs on the initial drug list. The PDAB should address this issue and ensure that Gilead has an opportunity to meaningfully participate in the selection and (if necessary) the cost review process going forward.

Lastly, the PDAB has not made recordings of its meetings available to the public, despite multiple requests by members of the Stakeholder Council and concerns raised by the General

Assembly. Other State PDABs do provide this tool. Given these potential barriers, the PDAB's current process does not allow for meaningful patient and other stakeholder engagement in the process.

***

Biktarvy is the only unboosted single tablet HIV regimen that is recommended by DHHS guidelines for use in rapid start. It better supports adherence and persistence than other HIV drugs.[48,49,50] It is also the only STR FDA-approved and DHHS-recommended for patients with pre-existing M184V/I, a common resistant mutation, in people who have been taking HIV medicines. And, unlike other guideline recommended STRs for starting treatment, Biktarvy has been studied in people living with HIV who have hepatitis B virus coinfection and pregnant women. To give people with HIV in Maryland confidence that they will be able to continue accessing Biktarvy, Gilead urges the PDAB not to select Biktarvy for a cost review.

Sincerely,

DocuSigned by:
Kristie Banks
3B4BECBA5AB74F3...

Kristie Banks
Vice President, Managed Markets
Gilead Sciences, Inc.

DocuSigned by:
Betty Chiang
DE32260A4A3E4AA...

Betty Chiang, M.D.
Vice President, Medical Affairs
Gilead Sciences, Inc.

---

[1] https://pdab.maryland.gov/documents/comments/biktarvy_proposed_therapeutic_alternatives.pdf
[2] Center for Substance Abuse Treatment. Substance Abuse Treatment for Persons With HIV/AIDS. Treatment Improvement Protocol (TIP) Series, No. 37. 2000. No. (SMA) 12-4137. Rockville, MD: Substance Abuse and Mental Health Services Administration.
[3] Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Panel on Antiretroviral Guidelines for Adults and Adolescents; 2023 Dec 6. Available from: Link
[4] HHS, Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, G-4 (Mar. 23, 2023), https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv.
[5] Collins LF, Armstrong WS. What It Means to Age With HIV Infection: Years Gained Are Not Comorbidity Free. *JAMA Netw Open.* 2020;3(6):e208023. doi:10.1001/jamanetworkopen.2020.8023.
[6] Gross, AM, et al. Methylome-wide analysis of chronic HIV infection reveals five-year increase in biological age and epigenetic targeting of HLA. Molecular Cell. 2016, 62(2). 157-168.
[7] https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-treatment-adherence
[8] Eisinger RW, Dieffenbach CW, Fauci AS. HIV Viral Load and Transmissibility of HIV Infection: Undetectable Equals Untransmittable. *JAMA.* 2019 Feb 5;321(5):451-452.
[9] Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule, 79 Fed. Reg. 1918, 1944 (Jan. 10, 2014).
[10] *Id.*

[11] Maryland Integrated HIV Prevention and Care Plan including the Statewide Coordinated Statement of Need 2022-2026; Submission to the Health Services Resource Administration HIV/AIDS Bureau and the Centers for Disease Control and Prevention Division of HIV Prevention, December 9, 2022
[12] https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/introduction?view=full
[13] https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/what-start-initial-combination?view=full.
[14] Cohen, J., Beaubrun, A., Bashyal, R., Huang A, Li J, Baser O. Real-world adherence and persistence for newly-prescribed HIV treatment: single versus multiple tablet regimen comparison among US Medicaid beneficiaries. *AIDS Res Ther*. 2020;17(1):12. Published 2020. doi.org/10.1186/s12981-020-00268-1
[15] Hines DM, Ding Y, Wade RL, Beaubrun A, Cohen JP. Treatment Adherence And Persistence Among HIV-1 Patients Newly Starting Treatment. *Patient Prefer Adherence.* 2019;13:1927-1939.
[16] Sax PE, Eron JJ, Frick A, et al. Patterns of Adherence in Bictegravir- and Dolutegravir-based Regimens. Poster presented at: Conference on Retroviruses and Opportunistic Infections; March 8-11, 2020; Boston, Massachusetts.
[17] Sutton S, Magagnoli J, Hardin J. Impact of Pill Burden on Adherence, Risk of Hospitalization, and Viral Suppression in Patients with HIV Infection and AIDS Receiving Antiretroviral Therapy. *Pharmacotherapy.* 2016; 36(4):385-401.
[18] Cohen CJ, Meyers JL, Davis KL. Association between daily antiretroviral pill burden and treatment adherence, hospitalisation risk, and other healthcare utilisation and costs in a US medicaid population with HIV. BMJ Open. 2013;3(8):e003028.
[19] Sutton S, Hardin JW, Bramley TJ, D'Souza AO, Bennett CL. Single- versus multiple-tablet HIV regimens: adherence and hospitalization risks. *American Journal of Managed Care.* 2016;22(4):242-248.
[20] Kapadia SN, Grant RR, German SB, et al. HIV virologic response better with single-tablet once daily regimens compared to multiple-tablet daily regimens. *SAGE Open Med.* 2018;6:2050312118816919.
[21] Seybolt L, Conner K, Butler I, et al. Rapid Start Leads to Sustained Viral Suppression in Young People in the South. Poster presented at Conference on Retroviruses and Opportunistic Infections; March 8-11, 2020; Boston, Massachusetts. Abstract 1073.
[22] AIDS Education & Training Center Program. Rapid (Immediate) ART Initiation & Restart: Guide for Clinicians. https://aidsetc.org/sites/default/files/resources_files/ncrc-rapid-art-6-10-21_0.pdf. Published May 2022.
[23] Gay CL, Willis SJ, Cope AB, Kuruc JD, McGee KS, Sebastian J, Crooks AM, McKellar MS, Margolis DM, Fiscus SA, Hicks CB, Ferrari G, Eron JJ; Duke-UNC Acute HIV Infection Consortium. Fixed-dose combination emtricitabine/tenofovir/efavirenz initiated during acute HIV infection; 96-week efficacy and durability. AIDS. 2016 Nov 28;30(18):2815-2822.
[24] McNulty M, Schmitt J, Friedman E, Hunt B, Tobin A, Maheswaran AB, Lin J, Novak R, Sha B, Rolfsen N, Moswin A, Rose B, Pitrak D, Glick N. Implementing Rapid Initiation of Antiretroviral Therapy for Acute HIV Infection Within a Routine Testing and Linkage to Care Program in Chicago. J Int Assoc Provid AIDS Care. 2020 Jan-Dec;19:2325958220939754.
[25] O'Shea JG, Gallini JW, Cui X, Moanna A, Marconi VC. Rapid Antiretroviral Therapy Program: Development and Evaluation at a Veterans Affairs Medical Center in the Southern United States. AIDS Patient Care STDS. 2022 Jun;36(6):219-225. doi: 10.1089/apc.2022.0039. Epub 2022 May 18.
[26] Pathela P, Jamison K, Braunstein S, et al. Initiating antiretroviral treatment for newly diagnosed HIV patients in sexual health clinics greatly improves timeliness of viral suppression. *AIDS.* 2021;35(11):1805–1812.
[27] Bacon O, Chin JC, Hsu L, et al. The Rapid ART Program Initiative for HIV Diagnoses (RAPID) in San Francisco. Presented at: Conference on Retroviruses and Opportunistic Infections; March 4-7, 2018; Boston, Massachusetts. Abstract 93.
[28] Poschman K, Spencer EC, Goldberg D, et al. Impact of HIV Test-and-Treat Initiative in Miami-Dade County, Florida. Poster Presented at: Conference on Retroviruses and Opportunistic Infections (CROI) 2019. Seattle, WA. Abstract 903.
[29] An unboosted HIV regimen refers to a regimen that doesn't include a medication called a "booster." Boosters, usually ritonavir or cobicistat, work by decreasing the hepatic metabolism of certain HIV drugs, therefore

prolonging their presence in the body. Unboosted regimens tend to have fewer drug interactions due to the fact that boosters affect not only the metabolism of HIV drugs but other medications as well.

[30] Stanford HIV Drug Resistance Database: https://hivdb.stanford.edu/cgi-bin/MutPrevBySubtypeRx.cgi.

[31] Zhou K, Terrault N. Management of Hepatitis B in Special Populations. Best Pract Res Clin Gastroenterol. 2017 June;31(3):311–320. doi: 10.1016/j.bpg.2017.06.002. Available from: Link

[32] Avihingsanon A, Lu H, Leong CL, Hung CC, Koenig E, Kiertiburanakul S, Lee MP, Supparatpinyo K, Zhang F, Rahman S, D'Antoni ML, Wang H, Hindman JT, Martin H, Baeten JM, Li T; ALLIANCE Study Team. Bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir, emtricitabine, and tenofovir disoproxil fumarate for initial treatment of HIV-1 and hepatitis B coinfection (ALLIANCE): a double-blind, multicentre, randomised controlled, phase 3 non-inferiority trial. Lancet HIV. 2023 Oct;10(10):e640-e652. doi: 10.1016/S2352-3018(23)00151-0. Epub 2023 Jul 23. PMID: 37494942. Available from: Link

[33] Biktarvy® [package insert]. Foster City CA: Gilead Sciences. 2022. Link

[34] BIKTARVY SmPC, Gilead Sciences, April 2023, and BIKTARVY USPI, Gilead Sciences, October 2022.

[35] Md. Code, Health-Gen. § 21-2C-14.

[36] https://dbm.maryland.gov/benefits/Documents/CVS_Caremark_Handbook.pdf

[37] https://www.gileadadvancingaccess.com/

[38] https://ryanwhite.hrsa.gov/

[39] https://health.maryland.gov/phpa/OIDPCS/Pages/MADAP.aspx

[40] https://alivemaryland.org/wp-content/uploads/2022/08/MADAP-FAQ-082922A.pdf

[41] https://pdab.maryland.gov/documents/comments/drugs_referred_stakeholder_council_dashboard_2024.xlsx

[42] Longitudinal Access and Adjudication Data (LAAD). United States: IQVIA (2020, 2022)

[43] https://pdab.maryland.gov/documents/comments/drugs_referred_stakeholder_council_dashboard_2024.xlsx, Tab "Dictionary-Eligible Drug List"

[44] Kaiser Family Foundation (March 2023), "Medicaid and People with HIV."

[45] IQVIA. The 340B Drug Discount Program: Complexity, Challenges, and Change.

[46] *See,* Richard Kane. PhRMA. New global analysis shows patient access challenges around the world. April 12, 2023. *See also,* NACDS letter to the Maryland Prescription Drug Affordability Board. Re: Upper Payment Limit Action Plan. November 13, 2023. A*lso,* Mid-Atlantic Association of Community Health Centers letter to The Honorable Pamela Beidle. Re: Senate Bill 388. February 7, 2024. https://phrma.org/en/Blog/New-global-analysis-shows-patient-access-challenges-around-the-world.

[47] *See* Md. Code Ann., Gen. Provis. § 3-301.

[48] Cohen, J., Beaubrun, A., Bashyal, R., Huang A, Li J, Baser O. Real-world adherence and persistence for newly-prescribed HIV treatment: single versus multiple tablet regimen comparison among US Medicaid beneficiaries. *AIDS Res Ther*. 2020;17(1):12. Published 2020. doi.org/10.1186/s12981-020-00268-1

[49] Hines DM, Ding Y, Wade RL, Beaubrun A, Cohen JP. Treatment Adherence And Persistence Among HIV-1 Patients Newly Starting Treatment. *Patient Prefer Adherence.* 2019;13:1927-1939.

[50] Sax PE, Eron JJ, Frick A, et al. Patterns of Adherence in Bictegravir- and Dolutegravir-based Regimens. Poster presented at: Conference on Retroviruses and Opportunistic Infections; March 8-11, 2020; Boston, Massachusetts.