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MD PDAB January 29, 2024 Meeting | Draft Supply Chain Report HealthHIV Comments

Scott Bertani [redacted] Wed, Jan 24, 2024 at 4:27 PM
To: comments.pdab@maryland.gov

On behalf of HealthHIV, we are writing in efforts to provide a landscape overview of the "*HIV ecosystem*"—especially in the context of the initiatives undertaken by the Maryland Prescription Drug Affordability Board (PDAB). This overview is supplemented by an analysis of the shifting dynamics of Medicare Part D, the impact of the Inflation Reduction Act (IRA) on the accessibility and affordability of HIV treatments, and crucial insights derived from the Supply Chain Report, as mandated by Health General Article § 21-2C-07.

Our objective is to offer insights and pragmatic recommendations specifically tailored to address the critical issue of drug affordability within the ecosystem of HIV treatment and prevention. This is key to our commitment to ensuring Maryland's residents have full access to essential HIV medications. In exploring the details of pharmaceutical pricing, distribution, and access, the Supply Chain Report becomes a significant tool, shedding light on the PDAB's process for reviewing HIV medication affordability and patient protections.

Consequently, this letter seeks to highlight critical concerns including the PDAB's tangible impact—be it intentional, unintentional, or unforeseen—on prescription drug costs, the intricate challenges of negotiating drug prices, the disparity in coverage across various insurance plans, and the ramifications of Utilization Management within publicly funded healthcare programs.

Furthermore, we are incorporating strategic advocacy elements, including the promotion of patient-centric healthcare plans, the critical reevaluation of Utilization Management practices, the necessity of inclusive policy making, and an examination of the financial and clinical ramifications of transitioning between HIV medications. In particular, our analysis of the Ryan White Program highlights the distinct challenges encountered across various public health insurance frameworks, offering a layered understanding of the unique obstacles and cost implications faced by different patient groups.

The Critical Role of PDAB in Prescription Drug Costs: PDAB's potential in reducing prescription drug costs is in line with broader healthcare objectives. However, its impact on specific insurance frameworks, particularly employer-sponsored and high-deductible health plans, brings complex challenges to the forefront. These predominantly revolve around issues such as limited drug formularies and high coinsurance rates, significantly affecting the adherence to and efficacy of HIV medications. Targeted interventions and regulations are crucial in addressing these challenges to ensure comprehensive care for individuals living with HIV.

Objectives and Challenges of Maryland's PDAB: Maryland's PDAB is pivotal in enhancing prescription drug affordability. Its multifaceted objectives include reviewing drug prices, establishing payment limits for costly drugs, and monitoring market trends. The Board's commitment to policy recommendations and stakeholder engagement reflects Maryland's dedication to healthcare accessibility.

However, several critical considerations and potential limitations of PDAB's operations need acknowledgment:

1. **Scope and Authority Limitations:** Maryland's PDAB mainly focuses on broader drug price control, potentially limiting its direct influence on specific formulary decisions and cost-sharing structures, particularly in private insurance plans. This underscores the critical role of regulatory agencies in ensuring alignment with PDAB's objectives.
2. **Complexities in Drug Price Negotiations:** Negotiating lower drug prices is intricate and may not immediately result in reduced out-of-pocket expenses for patients, a complexity heightened in the context of HIV treatments.
3. **Variability in Employer-Sponsored Plans:** Disparities in coverage and cost-sharing among these plans can lead to unequal access to essential HIV medications, impacting patient health outcomes.

4. **Challenges in High-Deductible Plans:** The PDAB is at the forefront of advocating for innovative insurance models, like value-based designs, where the patient's cost-sharing is more closely aligned with the value of the medications. Ongoing monitoring and reporting on the impact of high-deductible plans, and providing valuable data to inform and support further policy changes or interventions, rather than their price, is particularly beneficial for managing chronic conditions such as HIV.

5. **Potential Indirect Consequences on Drug R&D:** Efforts to reduce drug prices may inadvertently hinder the research and development of new drugs, including those for HIV treatment.

6. **Time Lag in Impact of Price Negotiations:** Individuals reliant on HIV medications might not see immediate benefits from price negotiations, vital for their health and HIV transmission prevention.

Expanding on HIV-Specific Concerns: The PDAB's cost review process might inadvertently prioritize HIV medications in a way that restricts access or leads to negative pricing alterations. The actions of the PDAB can significantly influence pharmaceutical companies' pricing strategies, impacting how employer-sponsored health plans cover HIV medications. This necessitates careful consideration to prevent unintentional restrictions on essential HIV treatments.

The Impact of Utilization Management in Medicaid: Utilization Management (UM) in Medicaid, especially for dual-eligible individuals, presents a complex scenario that can disrupt medication continuity and lead to administrative burdens and potential adverse health outcomes. The application of UM techniques, like step therapy and prior authorization, requires cautious implementation to not impede access to vital medications.

Maryland's Potential Influence on HIV Treatment Accessibility and Therapy Innovation: There is a risk that the cost review process may target HIV medications, restricting access or leading to unfavorable pricing structures. Additionally, a focus on cost containment could deter pharmaceutical companies from investing in innovative HIV therapies, impacting the advancement of HIV treatment options.

Advocating for a Balanced and Comprehensive Approach: A comprehensive strategy encompassing the following aspects is necessary:

1. **Patient-Centric Healthcare Plans:** The development of healthcare plans that prioritize HIV medication coverage, reduce out-of-pocket expenses, and enhance access is essential. Within the HIV care ecosystem, PDABs play a critical role by implementing patient-centric healthcare plans. These plans are particularly important as they ensure that HIV medications are accessible and affordable. It's noteworthy that affordability varies depending on whether patients are covered by employer-sponsored insurance or public health programs. This addresses a significant barrier to continuous and effective treatment for those who do incur out-of-pocket costs.

   By focusing on HIV medication coverage and striving to minimize out-of-pocket expenses, particularly for those who face such costs, these healthcare plans recognize the unique challenges of individuals living with HIV. This approach promotes better adherence to treatment regimens and, consequently, enhances overall health outcomes.

   The emphasis on patient-focused plans is especially crucial in HIV care, as it provides patients with more autonomy and control over their treatment choices. Aligning healthcare strategies with the individual needs and circumstances of each patient is key to effective disease management and improving their quality of life.

2. **Reevaluating Utilization Management practices**. Despite the critical need for reevaluating Utilization Management (UM) practices, progress in reforming these protocols to ensure timely access to essential treatments has been disappointingly slow. Current UM practices often create bureaucratic delays and hurdles, impeding the swift approval and delivery of necessary medications, particularly for chronic conditions like HIV. The lack of significant advancement in streamlining UM processes continues to place undue stress on patients and healthcare providers, compromising the efficiency of treatment regimens. This stagnation in reforming UM underscores a pressing need for systemic change to prioritize patient well-being and expedite access to life-saving treatments, a goal that remains unfulfilled in the current healthcare framework, but is something that the PDAB can undertake.

3. **Inclusive Policy Making:** Inclusive policy making in HIV care necessitates the involvement of representatives not just from the patient community, but also from key healthcare sectors such as Maryland Department of Health (MDH), AIDS Drug Assistance Programs (ADAPs), and entities involved in the 340B

Drug Pricing Program, as well as Health Center Programs under Section 330 and HIV prevention initiatives under Section 318.

Collaboration with professionals from MDH and the ADAP world is essential, as these experts bring a wealth of experience in managing statewide health initiatives and possess deep insights into the medication needs and challenges faced by People Living with HIV (PWH).

Engaging representatives from the HIV state level and community based HRSA covered entity 340B and 330 programs to the policy-making table is essential, given the significant role these programs play in offering affordable medications and comprehensive healthcare services to underserved communities. Their involvement ensures that policy decisions are grounded in the practical realities of resource distribution and patient accessibility at the community level. It's important to recognize that the details of Section 318 funding, including the allocated amounts and specific supported programs, can change annually in response to legislative developments, public health demands, and shifts in federal budgeting. By including these varied perspectives, we can develop more comprehensive and effective policies. This approach not only centers around patient needs but also aligns seamlessly with the operational aspects of healthcare provision and the unique funding structures integral to HIV treatment and prevention.

4. **Fostering Innovation in HIV Treatment:** Supporting policies that encourage ongoing research and development in HIV therapies is essential for continued advancement in treatment options.
5. **Incorporating Research into Policy Decisions:** Utilizing real-world (patient-level) research and findings to inform policy decisions, with a focus on the impact of financial barriers on medication adherence.
6. **Targeted Subsidy Programs for HIV Medications:** Advocating for and facilitating targeted subsidy programs to reduce out-of-pocket costs for patients under high-deductible health plans or those with employer-sponsored insurance that lacks comprehensive coverage.
7. **Mandatory Inclusion of Comprehensive HIV Drug Formularies:** Implementing policies requiring comprehensive HIV drug formularies in all health insurance plans to ensure access to a wide range of HIV medications.
8. **Incentivizing Research and Development of HIV Medications:** Proposing incentives for the research and development of new HIV medications to encourage innovation while ensuring affordability.
9. **Uniformity in Coverage Across Healthcare Platforms:** *Emphasizing the Significance of the Six Protected Classes within Medicare at the PDAB Level***.** Highlighting the importance of these classes as a model for potential carve-outs in PDAB's drug affordability reviews is crucial. These classes—antiretrovirals, antidepressants, antipsychotics, anticonvulsants, immunosuppressants for transplant rejection, and antineoplastics—are critical for treating serious conditions. Medicare's policy mandating coverage of all or substantially all drugs in these classes acknowledges the unique needs of patients dependent on these medications and serves as a crucial precedent for PDABs. Considering these principles, PDABs can develop a nuanced, patient-centric approach in controlling prescription drug prices by identifying critical drug classes where cost-containment measures should be carefully balanced with maintaining broad access. This approach ensures continued access to effective treatments and upholds shared clinical decision-making, crucial for populations with complex health needs like those living with HIV.

Of note—The Financial and Clinical Implications of Switching HIV Medications: It's important to note that while UM techniques can be applied to the six protected classes, CMS requires Medicare Part D plans to provide all beneficiaries with access to "all or substantially all" drugs in these classes. This requirement protects patients who depend on these drugs to maintain their health and ensures broad access without undue restrictions. Therefore, UM must be implemented with caution and oversight to prevent reduced access to essential medications for vulnerable patient populations.

To that, switching HIV medications involves additional clinical monitoring and incurs costs, particularly impacting patients under the Ryan White Program. This program serves as a safety net for those not covered by other insurance plans. Switching medications involves not just adjusting to a new regimen but also additional (interim) clinical monitoring, including viral load labs.

Laboratory tests and medical appointments incur extra costs and require extensive coordination—and are not inconsequential. For Ryan White Program participants, these changes can translate into a greater financial and logistical burden compared to those on more comprehensive insurance plans. Despite being crucial in providing access to HIV care and treatment, the Ryan White Program operates with limited resources, and additional strain from medication switches can stretch its capacity, potentially impacting care quality. This scenario highlights a disparity where the burden of cost and the challenge of maintaining optimal health outcomes disproportionately falls on those navigating more complex health and socio-economic scenarios.

Therefore, PDABs and healthcare policy-makers need to consider these implications when making decisions about formulary changes or implementing UM protocols. Policies must be tailored to minimize the frequency and impact of medication switches, especially for vulnerable populations reliant on programs like Ryan White. This approach ensures continuity and stability in HIV care and upholds equity and fairness in healthcare access.

Comparative Cost Implications on Ryan White Program and Other Public Health Insurance Plans: The additional costs associated with switching HIV medications, such as increased laboratory tests and clinical monitoring, impose a significant burden on the Ryan White Program. However, these costs must be compared with those borne by other public health insurance plans like Medicare or Medicaid. Interestingly, the financial impact on the Ryan White Program may, in some cases, be less than the costs incurred by Medicare or Medicaid. This can be attributed to the varied structures and funding mechanisms of these programs. Medicare and Medicaid, with broader beneficiary bases and complex reimbursement models, might face higher overall costs when beneficiaries switch HIV medications. These costs arise not only from medical aspects like laboratory tests but also from administrative processes inherent in these larger systems. In contrast, the Ryan White Program, while resource-limited, often has more streamlined processes and targeted resource allocation, resulting in more cost-effective management of medication switches, despite the additional clinical burdens.

However frequent, any medication change can strain the ("Payer of Last Resort") Ryan White Program's limited resources. It highlights the need for PDABs and policymakers to evaluate the broader financial implications of their decisions across various healthcare programs—and the seamless coordination of that activity. Ensuring policy changes do not disproportionately impact any single program, especially those catering to vulnerable populations like Ryan White, is crucial. Balanced policy decisions should aim to distribute financial and administrative burdens more evenly across the healthcare spectrum, including larger programs like Medicare and Medicaid, to maintain equitable healthcare access and the integrity of HIV treatment across all patient groups.

In conclusion, HealthHIV appreciates the opportunity to contribute to this crucial dialogue. We recognize the complexities involved in balancing patient protections, affordability, and access—while safeguarding innovation in HIV medication and healthcare provision. Our aim is to work collaboratively with the Maryland Prescription Drug Affordability Board, healthcare policymakers, and other stakeholders to develop and implement policies that effectively address these challenges. By focusing on practical patient protection solutions and evidence-based approaches to UM, we strive to enhance the quality of care for those with HIV—and those of the Six Protected Classes of Medicare. We are eager to continue this partnership, thank you for your attention to our analysis, and look forward to contributing further to this important work.

Sincerely,

Scott D. Bertani

Scott D Bertani, MNM (He/Him)

Director of Advocacy

[redacted]

[redacted]

National Coalition for LGBTQ Health

https://healthlgbt.org/