COLOR OF
GASTROINTESTINAL
ILLNESSES

July 28, 2025

Mr. Andrew York
Executive Director
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Mr. York:

I am again writing on behalf of the Color of Gastrointestinal Illness (COGI) to comment on the Board's ongoing cost review activities. COGI represents black, indigenous and other people of color (BIPOC) who are affected by inflammatory bowel disease (IBD), digestive disorders, gastrointestinal cancer and associated chronic illnesses. As we have stated in letters and opinions, attached, we continue to have deep concerns about the Prescription Drug Affordability Board's (PDAB) process and potential for unintended outcomes.

It has been troubling that the PDAB is unresponsive to the concerns of patients and people with disabilities. To date, we have received no assurances that setting Upper Payment Limits (UPL) will not impact patient access to care, that the affordability review process will not rely on value assessment measures known to discriminate against people with disabilities and serious chronic conditions such as quality-adjusted life years (QALYs) and similar measures, nor that there is a process to handle unintended consequences for patients in a timely and efficient manner. The affordability challenges we face are all too often associated with formulary placement and utilization management that lead patients to experience delays in receiving personalized care. We were very pleased that the NAACP recently passed a resolution as part of its 116th Convention calling on policymakers to reject determinations of care that are based on QALYs, underscoring the implications on health equity that the National Council on Disability and others have been raising consistently for many years.[1]

COGI recently wrapped up its own 5th annual Equity in GI conference, where patients shared their stories. We learned from their stories that what academics may think of as a therapeutic alternative is often not really an alternative for a real-world patient. Patients respond differently to the same

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[1] Not yet published for the public. See https://naacp.org/articles/naacp-previews-116th-national-convention-aiming-empower-community-amidst-adversity#:~:text=June%2016%2C%202025-,NAACP%20Previews%20116th%20National%20Convention%2C%20Aiming%20to%20Empower%20Community%20Amidst,this%20year%20is%20no%20different.%22

medications and often need a particular medication or treatment that uniquely works for them. Forcing patients to take a medication that will fail them before they can access the medication that will optimize their health should not be the goal. If the Board's process exacerbates how payers prefer certain medications and impose barriers to care, whether by preferring the drug selected for a UPL or a so-called therapeutic alternative, we fear the outcome may be fewer options and higher out-of-pocket costs for patients.

Attached are the prior letters we have shared on this issue, as well as an opinion piece that I drafted for Maryland Matters. I hope that the Board will prioritize avoiding use of discriminatory value assessments and advance policies that assure us as patients of a meaningful and enforceable process for addressing any resulting barriers to care in a timely manner.

Thank you for your consideration.

Sincerely,

Melodie N. Blackwell

Melodie C. Narain-Blackwell
President & Founder
Color of Gastrointestinal Illnesses (COGI)

COLOR OF
GASTROINTESTINAL
ILLNESSES

August 26, 2024

Mr. Andrew York
Executive Director
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Mr. York:

I am writing on behalf of the Color of Gastrointestinal Illness (COGI) to comment on the Board's ongoing cost review activities, particularly as it pertains to Skyrizi. COGI represents black, indigenous and other people of color (BIPOC) who are affected by inflammatory bowel disease (IBD), digestive disorders, gastrointestinal cancer and associated chronic illnesses.

Skyrizi is a highly effective and needed treatment for many in our community. One of COGI's key missions is breaking down the barriers preventing people of color from achieving optimal health outcomes. We have serious concerns that the work the PDAB is doing will have the unintended consequence of putting up more barriers for our patients to access Skyrizi and other needed treatments.

Due to the historic perception that people of color are not impacted by gastrointestinal diseases, it often takes far too long for patients in our community to get an accurate diagnosis. Given this delay, it is essential that once we are diagnosed, we are able to quickly and efficiently access the medications we need – additional delays only enhance the disparities in care that patients of color already face. For many patients, Skyrizi is needed to manage conditions like Crohn's disease and others may a different drug. It is imperative to protect patients from unintended consequences for accessing Skyrizi or for encouraging step therapy and prior authorization policies that create barriers to other drugs that treat Crohn's disease or ulcerative colitis.

Therefore, we have real concerns that the PDAB's actions related to Skyrizi may lead to the drug being unavailable to patients in Maryland and/or may lead to more aggressive utilization management being employed by insurers on competitor products that some of our patients also need. This outcome would be a significant step back in the push for health equity. We urge the PDAB to carefully consider this reality as it moves forward with cost reviews and proposed upper payment limits.

We support the intent to help patients access the care they need – which is only possible if the Board meaningfully engages and listen to patients. We have been consistently concerned that the Board's processes for cost reviews are not centered on the patients and people with disabilities impacted by its decisions. As a small patient advocacy organization, we do not know how our engagement makes a difference or how the information we provide to the Board may be used in its decisions. With a process that values our input, COGI stands ready to help the Board conduct its work in a patient-centered manner.

We are pleased to be working with the Ensuring Access through Collaborative Health (EACH) Coalition on a new survey for patients that elicits information about their challenges accessing affordable medications. When that survey becomes available, we look forward to sharing it with patients in an effort to get reliable information to the Board about the real-world experiences of patients.

Thank you for your consideration of our comments.

Sincerely,

Melodie C. Narain-Blackwell

Melodie C. Narain-Blackwell
President & CEO
Color of Gastrointestinal Illnesses (COGI)

COLOR OF
GASTROINTESTINAL
ILLNESSES

February 4, 2025

Senator Pamela Beidle
Chair
3 East Miller Senate Office Building
Annapolis, Maryland 21401

Delegate Joseline A. Pena-Melnyk
Chair
240 Taylor House Office Building
Annapolis, Maryland 21401

Senator Antonio Hayes
Vice Chair
3 East Miller Senate Office Building
Annapolis, Maryland 21401

Delegate Bonnie Cullison
Vice Chair
241 Taylor House Office Building
Annapolis, Maryland 21401

Dear Chair Beidle, Vice Chair Hayes, Chair Pena-Melnyk and Vice Chair Cullison:

I am writing on behalf of the Color of Gastrointestinal Illness (COGI) to share my concerns about SB357 and HB424 requiring the Prescription Drug Affordability Board to establish a process for setting upper payment limits for all purchases and payor reimbursements of prescription drug products in the State that the Board determines have led or will lead to affordability challenges. As the founder and CEO of COGI, I can attest to my personal experience and the experiences of so many patients that we represent that access to affordable care is the most important challenge we face. We are very concerned that the PDAB has ignored concerns shared by patients, has no plans to meaningfully engage patients and has failed to communicate how patients will be protected from egregious utilization management strategies because of UPLs.

I founded COGI based on my own personal experience. I have been on 16 medications, from pills to injections to suppositories. I started having rectal bleeding at the age of 13, yet was not diagnosed with Crohn's disease until 2018 after a 30-year journey. And even with diagnosis, I did not get an advanced therapy prescribed, Skyrizi, until December, 2023. That medication changed my life. Yet, I also recognize that I have a progressive disease and my health has been forever impacted by a delayed diagnosis and delayed prescribing of the advanced therapy I needed.

Based on my experience and so many like me, it is imperative that the activities of the PDAB do not result in patients experiencing furthers delays in receiving the drugs needed to achieve the outcomes that matter most to them and that evidence demonstrates to be most effective for them based on their personal characteristics. These drugs do not have the same impact on different patients and we should be making sure patients and their physicians are not being steered by payers into prescribing decisions.

The Board has failed to provide any information on how patients will be protected from adverse formulary placement and utilization management strategies in response to an upper payment limit (UPL) that will make patient access to affordable care that much more challenging. In August, 2024, COGI sent a letter to the Board expressing concerns about its ongoing cost review activities, particularly as it pertains to Skyrizi. COGI represents Black, indigenous and other people of color (BIPOC) who are affected by inflammatory bowel disease (IBD), digestive disorders, gastrointestinal cancer and associated chronic illnesses. Skyrizi is a highly effective and needed treatment for many in our community.

Our letter expressed serious concerns about health equity and access to care.[1,2] Yet, upon review of the Board's website, we noticed that our comment letter was not posted. It is not clear to me that it was ever shared with the Board or its advisory committee. And it was not mentioned in the Board or advisory committee proceedings. It was posted at a point long after consideration of Skyrizi.

Another letter from COGI and 37 other organizations to the Board specifically commented on the draft UPL Plan and also seems to have been ignored, as none of the concerns it raised were addressed in the revised plan nor was it posted on the website as a letter considered by the Board until long after the meeting.[3] For this process to be trusted and credible, the Board cannot simply hope to get this right and ignore the real-world experiences of patients that are the source of our legitimate questions and concerns.

To date, the Maryland Prescription Drug Affordability Board (PDAB) has ignored the pleas of so many in the patient and disability communities for reassurances that their affordability review process will not use discriminatory value assessments that devalue people with disabilities and serious chronic conditions. Instead, we are aware that the Board is being supported by entities that are on record supporting the use of value assessment measures that are barred by federal law under Section 504 of the Rehabilitation Act. The Board has explicitly invited and referenced input from the Institute for Clinical and Economic Review and the Program on Regulation, Therapeutics and Law (PORTAL), both entities supported by Arnold Ventures which has a long history of supporting the generation and use of value assessments that utilize discriminatory measures.[4,5] Federal law bars use of "any measure, assessment, or tool that discounts the value of life extension on the basis of disability" by an entity receiving federal financial assistance, including Medicaid.[6] It also bars denying care based on "bias or stereotypes about a patient's disability."[7] The final rule explains, "Methods of utility weight generation are subject to section 504 when they are used in a way that discriminates."[8] Therefore, any reference to measures such as quality-adjusted life years (QALYs) or equal value of life year gained (evLYG) are contrary to federal law.

To help meaningfully engage patients, we were pleased to work with the Ensuring Access through Collaborative Health (EACH) Coalition on a new survey for patients that elicits real-world information about their challenges accessing affordable medications. We do not have reassurances that the PDAB will meaningfully incorporate this data into its decisions.[9] For now, real-world information is not being

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[1] Borum ML. Racial and Ethnic Disparities in Inflammatory Bowel Disease. Gastroenterol Hepatol (N Y). 2023 May;19(5):281-283. PMID: 37799459; PMCID: PMC10548245.

[2] Liu JJ, Abraham BP, Adamson P, Barnes EL, Brister KA, Damas OM, Glover SC, Hooks K, Ingram A, Kaplan GG, Loftus EV, McGovern DPB, Narain-Blackwell M, Odufalu FD, Quezada S, Reeves V, Shen B, Stappenbeck TS, Ward L. The Current State of Care for Black and Hispanic Inflammatory Bowel Disease Patients. Inflamm Bowel Dis. 2023 Feb 1;29(2):297-307. doi: 10.1093/ibd/izac124. PMID: 35816130; PMCID: PMC10210746.

[3] http://www.pipcpatients.org/uploads/1/2/9/0/12902828/maryland_pdab_comments_final.pdf

[4] ICER submissions at https://pdab.maryland.gov/Pages/cost_review_process.aspx

[5] PORTAL presentation at https://pdab.maryland.gov/documents/stakeholders/2023/havard_med_brigm_prst.pdf

[6] Section 504 of the Rehabilitation Act, final regulations at 84.57.

[7] Section 504 of the Rehabilitation Act, final regulations at 84.56.

[8] 45 CFR Part 84 at 40102.

[9] https://eachpic.org/pic-launches-patient-created-survey-on-drug-affordability-and-access/

considered, and with it the real-world consequences for patients who consistently face barriers to care imposed by payer utilization management strategies.

We support the legislative intent to help patients afford and access the care they need. We do not support the activity of a PDAB to conduct affordability reviews that are discriminatory and that fails to address the tough questions being asked by patients. As it stands, the PDAB does not protect patients or advance health equity. Therefore, we urge the legislature to oppose this bill. Instead, the legislature should be restricting the impact of the PDAB until it provides reassurances that patients are meaningfully engaged and protected against discrimination, with safeguards in place against unintended consequences for patient access to care. In our experience, when payers do not cover the drugs we need, they do not become more affordable – only less.

Thank you for your consideration of our comments.

Sincerely,

Melodie N. Blackwell

Melodie Narain-Blackwell

Founder and CEO

Color of Gastrointestinal Illnesses (COGI)

Health

Commentary

It’s time to hit pause on the PDAB

Melodie Narain-Blackwell

April 10, 2025 1:16 am

A pharmacist counts out pills for a prescription in this 2024 file photo. (Photo by Senior Airman Thomas Karol/U.S. Air Force)

I had hoped voices like mine – a Black woman with Crohn’s disease – would still have impact in the state of Maryland. Yet, there seems to be little concern that Maryland’s Prescription Drug Affordability Board may reduce access to care for those already experiencing health disparities. The legislature created the board to make drugs more affordable – though to whom is still an open question.

I founded a nonprofit representing patients like me, Color of Gastrointestinal Illnesses, based on my own personal experience. I have been on 16 medications, from pills to injections to suppositories. I started having rectal bleeding at age 13, yet was not diagnosed with Crohn’s disease until 2018, after a 30-year journey. And even with diagnosis, I did not get an advanced therapy prescribed until five years later.

That medication changed my life. Yet, I also recognize that I have a progressive disease and my health has been forever impacted by a delayed diagnosis and delayed prescribing of the advanced therapy I needed.

Based on my experience and so many like me, I worry the activities of the Maryland Prescription Drug Affordability Board will exacerbate existing health disparities. In this age of personalized medicine, clinicians can prescribe treatment based on evidence of clinical effectiveness based on personal characteristics. Drugs do not have the same impact on different patients, and policies should not allow physicians to be steered by payers into prescribing decisions. Insurers are not doctors.

Your opinion matters

Maryland Matters welcomes guest commentary submissions at editor@marylandmatters.org.

We suggest a 750-word limit and reserve the right to edit or reject submissions. We do not accept columns that are endorsements of candidates, and no longer accept submissions from elected officials or political candidates.

Opinion pieces must be signed by at least one individual using their real name. We do not accept columns signed by an organization. Commentary writers must include a short bio and a photo for their bylines.

Views of writers are their own.

Patients face a flurry of threats to our access to health care in Congress right now, giving state policymakers an opening to slide past us what they might call policy tweaks or simple data collection to inform payer decisions.

Yet, any patient that has fought for coverage of their treatment knows that the policies governing payers really matters. What sounds good to save the system money does not translate into affordability and access for patients and people with disabilities. Adding to the insult, the Maryland legislature passed legislation to expand the reach of the state's Prescription Drug Affordability Board to the commercial insurance market.

We all want drugs to be accessible and affordable. Patients like me are literally fighting for their lives to achieve policies that allow them to receive care prescribed by their doctors without the barriers of utilization management, such delayed treatment due to prior authorizations, step therapy forcing patients to fail on a treatment before accessing what their doctors prescribe, and nonmedical switching at the pharmacy to a different drug.

Patients pay for the mistakes of insurers that impose their judgement about medical treatment – based largely on cost effectiveness and not clinical effectiveness – in the form of costly adverse medical events or by having to pay out-of-pocket for denied care they know they need.

When patients have raised concerns that this Board's decisions may trigger insurers to change their formularies and raise costs to patients, there has been no serious consideration of the issue other than a commitment to monitor and study it. We all know what that means – nothing.

We have also shared concerns individually and as coalitions that the board's work may conflict with the laws governing disability nondiscrimination, which bars their use of measures of cost effectiveness known to devalue people with serious, disabling and chronic conditions like mine. In response, a board member bluntly stated it was better to have more data than less and expressed intent to collect data using the quality-adjusted life year (QALY) measure to value treatments.

The board did not acknowledge the QALY is known to devalue disabled lives and is barred from use by federal law to make decisions in programs such as Medicaid. It was developed for the purpose of rationing care in other countries, which does not bode well for the disproportionate share of people of color that have disabling conditions or older adults.

The National Council on Disability is an independent federal agency advising Congress and the states on disability policy. It has consistently recommended against use of QALYs and similar measures, including by reference to other countries.

The question now is whether the board will pause its work and listen to people like me about what really drives our affordability challenges.

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