April 10, 2023

The Honorable Jason Smith
Chairman
Committee on Ways and Means
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Vern Buchanan
Chairman
Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Lloyd Doggett
Ranking Member
Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Smith, Ranking Member Neal, Chairman Buchanan, and Ranking Member Doggett:

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), the American Gastroenterological Association (AGA), the American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE) write on behalf of our members out of concern and desperation. Together, our four societies represent virtually all practicing gastroenterologists in the United States. We have received an increasing number of disturbing reports from our physician members regarding the obstacles and restrictions their patients are experiencing when attempting to gain access to prescribed, lifesaving biologic and small molecule therapies for gastrointestinal (GI) disease and disorders.

Pharmaceutical benefit managers (PBMs), insurance companies, and drug manufacturers have created an elaborate and opaque system to control and manipulate drug prices. Irrespective of this process, newer biologic therapies and small molecules used to treat inflammatory bowel diseases (IBD) are expensive. As a result and in an effort to control costs, insurers and PBMs have implemented a series of roadblocks under the guise of "drug utilization management," increasing administrative costs for physicians, and delaying delivery of medically necessary treatments to patients. The use of utilization management tactics, including "step therapy" (or "fail first" protocols), prior authorization, and insurance company decisions that require patients

to switch biologics when they are stable on current therapy, are all becoming increasingly common with detrimental effects on patients with IBD.

Four recently published stories[1,2,3,4] shine a bright light on the extent to which insurance companies are making health care decisions over the recommendations of treating physicians to the significant detriment of patient health and outcomes. These types of scenarios have become commonplace for physicians who treat children and adults with IBD, which include Crohn's Disease and Ulcerative Colitis. Our medical societies have met in recent years with major insurance companies in an attempt to protect children and adults living with IBD who have been subject to changes in coverage policies and formularies that require patients to switch their biologic medications even though they are currently stable on their authorized treatment. Insurers often make formulary changes without effective communications to patients and providers.

Our societies have made numerous appeals to insurance companies to provide an exception to non-medical switching for patients stable on their approved biologic therapy. When payers have made exceptions, they are typically narrow, require physicians to appeal and seek authorization to keep their patient on existing treatment, or result in greater out-of-pocket costs to patients. The process of reauthorization for patients who are stable on existing therapy is often accompanied by delays and disruption in care.

Drug utilization management protocols also restrict access of new medicines to children and adults. For example, early onset of IBD in children is a risk factor for more severe course of disease and, therefore, requires timely initiation of biologic therapy, often at higher doses than older children and adults. Under the current drug development system, drugs are first tested and approved in adults through expensive clinical trials. After approval in adults, pediatric studies of the same medication are then performed, but such studies can often take a decade or more to complete. For example, the drug vedolizumab, an essential tool in the treatment for Crohn's Disease and ulcerative colitis, was approved by the Food and Drug Administration (FDA) in 2014, but clinical trials in children have yet to be completed. Thus, it is often medically necessary for pediatricians to use these drugs "off label" in children. To quote the American Academy of Pediatrics, "the term 'off-label' does not imply an improper, illegal, contraindicated, or investigational use. Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient." However, insurers and PBMs frequently automatically deny care on the basis of age alone. This constitutes a direct form of discrimination against children that can have terrible consequences for a sick child.

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[1] "I wrote about high-priced drugs for years. Then my toddler needed one." *Washington Post*, Jan. 30, 2023. https://www.washingtonpost.com/wellness/2023/01/30/high-priced-drugs-step-insurance-policies/

[2] "UnitedHealthcare Tried to Deny Coverage to a Chronically Ill Patient. He Fought Back, Exposing the Insurer's Inner Workings." *ProPublica*, Feb. 2, 2023. https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis

[3] Insurance requirements for prior authorization may prompt 'devastating' delays. Lauren Sausser, Kaiser Health News, March 10, 2023. https://www.cnn.com/2023/03/10/health/prior-authorization-khn-partner/index.html

[4] How Cigna Saves Millions by Having Its Doctors Reject Claims Without Reading Them; Patrick Rucker, Maya Miller and David Armstrong March 25, 2023. https://www.propublica.org/article/cigna-pxdx-medical-health-insurance-rejection-claims?utm_medium=social&utm_source=twitter&utm_campaign=TwitterThread

Considerable integration in the PBM industry has compounded the issue. Today, the three biggest PBMs are integrated or owned by a major health insurance provider. Therefore, we support thorough examination of PBM practices by Congress and the Federal Trade Commission. Congressional hearings have largely focused on the role of PBMs and the cost of prescription drugs to consumers. In addition to contracting with PBMs to negotiate prices of prescription drugs, insurance companies use PBMs to design their drug benefits and process claims. PBMs extract discounts on drug prices by increasing volume for preferred manufacturers and suppliers; they do this by restricting patient choice of drugs. The more restrictive the drug formularies are, the bigger the discounts the PBMs extract from drug companies and suppliers.

We acknowledge that policies included in the *Inflation Reduction Act* have the potential to lower the prices of biologic products and, perhaps eventually, will obviate the need for prescription drug utilization management tools, but this will take time and our patients simply cannot wait.

In many respects, by virtue of their integration, investigation into PBMs puts insurance companies under the microscope as well. However, the growing and egregious use of utilization management practices by PBMs, which is being endorsed by the insurance companies with which they are contacted or affiliated, are having detrimental effects on patient care and safety. Our societies call for the investigation and oversight of insurance companies who control and direct treatment coverage decisions for their enrollees and their use or endorsement of utilization management practices that result in denials of or delays to medically necessary care, and we ask Congress to enact common sense legislation — such as the *Safe Step Act* (S. 652) — this year that prioritizes patient care and safety over insurance company profits.

The recently published final rule by the Centers for Medicare and Medicaid Services (CMS) to put guardrails in place for prior authorization processes used by Medicare Advantage plans does not include prior authorization and step therapy for Part B drugs, which include biologics used by IBD patients.[5] Likewise, a proposed rule that would automate and standardize the prior authorization process across public and private payers and require more timely reviews and more transparency is a good step in the right direction; however, this proposed rule also excluded Part B drugs, which are crucial for our patients' care and long-term management.[6] It is clear congressional intervention is needed to prioritize the interests of patients living with IBD and other diseases and disorders that require treatment with biologic and small molecule therapies.

Evidence of Patient Harm

A retrospective study of 190 pediatric patients with IBD published in *Pediatrics* found that prior authorization and complicated prior authorizations (requiring appeal, step therapy, or peer-to-peer review) did not deter the use of certain medications, but were associated with 10.2-day and 24.6-day delays in biologic initiation time, respectively. This is clinically significant because

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[5] Medicare Program: Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, etc. Posted by the Centers for Medicare&Medicaid Services on April 5, 2023. https://public-inspection.federalregister.gov/2023-07115.pdf . This document is scheduled to be published in the Federal Register on 04/12/2023 and available online at federalregister.gov/d/2023-07115, and on govinfo.gov.

[6] Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard. Posted by the Centers for Medicare&Medicaid Services on Dec 20, 2022https://www.regulations.gov/document/CMS-2022-0204-0001

delays in care in IBD increase the risks of penetrating complications, future need for surgery, and corticosteroid-related toxicities, including growth failure, fractures, thromboembolism and infections.[7] The study concluded there is roughly one potentially avoidable health care utilization outcome for every eight patients requiring prior authorization.

Many insurance companies use "step therapy," or "fail first," protocols where treatment with an older, less effective, but cheaper medication is required before use of a more expensive medication. In IBD, step therapy may require documented nonresponse to an older agent, known to be inferior with a worse adverse effect profile, before a biologic can be prescribed.[8] These insurance companies are dictating medical care and clinicians are being forced to prescribe medications that they do not feel are appropriate. Equally problematic is that the majority of these policies are inconsistent with current evidence-based IBD treatment guidelines.[9]

It is common for patients who are doing well on their therapy to receive a denial of care by an insurance company that changes the patient's treatment as biologic products move on and off formulary. Switching of biologic therapies, particularly in pediatric patients, have been associated with adverse patient outcomes.

Patients, in particular children, may also require higher doses of a biologic than those approved by the FDA; yet, insurance companies are increasingly rejecting dosing of medications above their FDA approved dose. This type of scenario was detailed in a recently published story about UnitedHealthcare's refusal to approve off-label or higher dosing regimens for a patient with a severe case of ulcerative colitis.[10]

An abstract will be presented at a major GI scientific conference this May with the results of a nationwide survey of 373 gastroenterologists regarding the effect of prior authorization for biologics to treat IBD on patient outcomes, medical decision making and provider burden.[11] Of the respondents, 97 percent reported prior authorizations somewhat-to-greatly worsen care, with 82 percent reporting that prior authorizations moderately-to-greatly limit their ability to provide optimal care. The vast majority of physicians (83%) reported that prior authorizations delayed biologic initiation and contributed to a hospitalization or surgery. Ninety-five percent reported the clinical burden of prior authorization has increased over the past five years. The administrative burden is important to highlight as this is likely contributing to the burnout crisis the medical field is currently experiencing.

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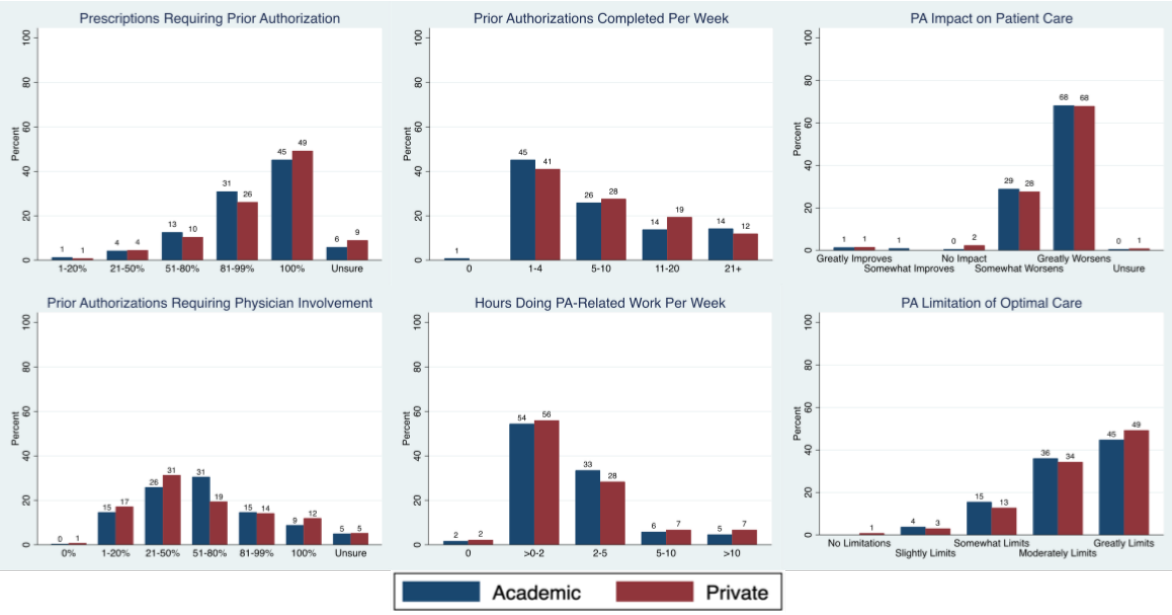
[7] Constant BD, de Zoeten EF, Stahl MG, et al. Delays Related to Prior Authorization in Inflammatory Bowel Disease. Pediatrics. 2022;149(3):e2021052501

[8] Kahn SA, Bousvaros A. Denials, Dilly-dallying, and Despair: Navigating the Insurance Labyrinth to Obtain Medically Necessary Medications for Pediatric Inflammatory Bowel Disease Patients. J Pediatr Gastroenterol Nutr. 2022 Oct 1;75(4):418-422. doi: 10.1097/MPG.0000000000003564. Epub 2022 Jul 15. PMID: 35836325.

[9] Ibid.

[10] "UnitedHealthcare Tried to Deny Coverage to a Chronically Ill Patient. He Fought Back, Exposing the Insurer's Inner Workings." ProPublica, Feb. 2, 2023. https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis

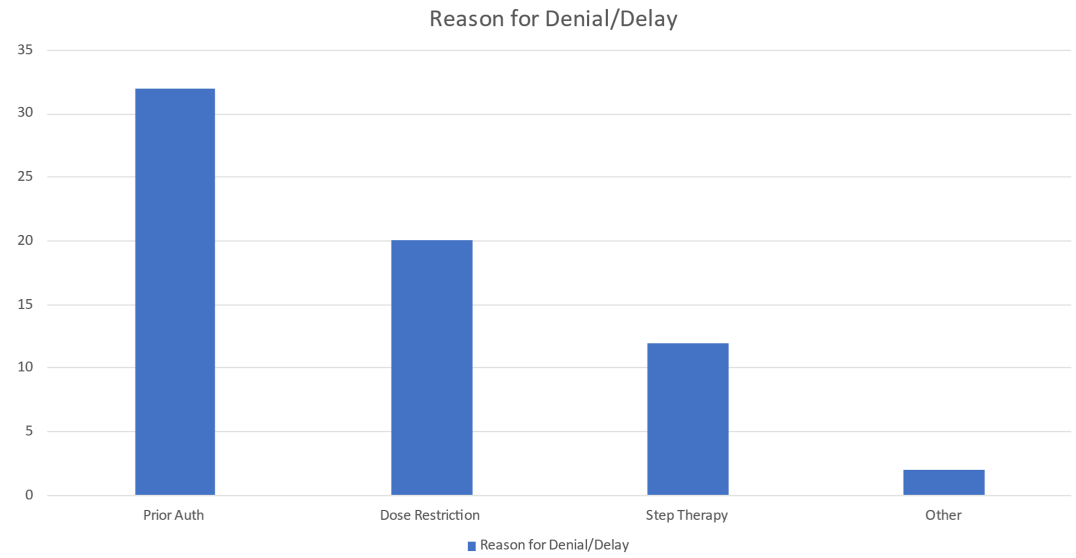
[11] Constant BD, Albenberg L, Mitchel E, et al. Prior Authorizations for IBD Biologics Delay Therapy, Impact Decision Making, and Lead to Serious Adverse Events: 2022 Nationwide Provider Survey. 2023 Digestive Disease Week Annual Meeting, Chicago, IL, USA.



Prior Authorizations for IBD Biologics Delay Therapy, Impact Decision Making and Lead to Serious Adverse

In an effort to better document the use of prior authorization, step therapy and other utilization control tactics in pediatric IBD patients on an ongoing basis, physician members of NASPGHAN and Improve Care Now (ICN) recently created a survey to be completed by physicians every time there is an issue with a payor or PBM, for example a denial, delay of care, or extra administrative time. The survey is still open and results will eventually be published.

Of the physician responses collected to date, the median delay of medication approval was 19 days. Twenty-three percent reported their patient had an adverse outcome due to delay, and 22 percent of patients had a hospitalization or extended length of hospital stays. In the majority of cases, treatment was eventually approved. However, delays and denials occurred across all major insurance companies, as well as Medicaid and TRICARE.



Survey results collected between March 8-23,

The commentary being collected through the survey highlights the suffering pediatric patients are needlessly enduring as a result of insurance company tactics. Examples include:

- 17-year-old girl in Massachusetts was hospitalized and received IV antibiotics and endoscopy after insurance company-induced prior authorization delays. Access to treatment delayed by 20 days.

- 17-year-old male in New York denied coverage to prescribed biologic therapy because he had not first "failed" on steroids or immunomodulating agents. The patient's quality of life was impacted and resulted in a four-day hospitalization. Coverage of the prescribed biologic was eventually approved. Access to treatment delayed by 60 days.

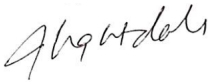
- 15-year-old male in California was in remission with current biologic administered every four weeks for two years. The patient has a complicated history of fistulas and developed antibodies to two other biologics. At the beginning of 2023, his insurance company denied his every four-week treatment. The physician made multiple attempts to contact the insurance company and a letter of medical necessity was written with no reply. At the time of the report, the patient was still waiting approval for treatment at four-week intervals.

- 13-year-old female in Washington required prior authorization for her physician-recommended treatment. Delays in approval resulted in deterioration of the patient's condition. The prior authorization peer-to-peer review was scheduled for seven days after initial denial with no option to expedite it. Due to significant anemia and fatigue, the patient collapsed, falling and hitting her head. The result was hospitalization and subsequent admission where her recommended treatment was ultimately initiated. Treatment delayed by 18 days.

While the examples above highlight how children are being hurt by these policies, adult patients face similar challenges, including when they require doses at higher levels or at more frequent levels than approved by the FDA. When insurers deny a medically necessary therapy, the physician practice spends an extraordinary amount of time modifying orders, completing prior authorizations, conducting peer-to-peer reviews, and writing letters of medical necessity which detracts from the care of other patients. Prior authorization, step therapy and other utilization controls result in unnecessary delays in patient care, often with deleterious effects to the patient's overall health, while shifting costs onto physicians who are uncompensated for the administrative time and staff required for authorization and appeals when coverage of a prescribed treatment is initially denied.

Our societies request an opportunity to meet with you in an effort to work toward increased oversight of insurance companies and polices that will protect IBD patients by ensuring that insurance plan policies do not delay or deny access to medically necessary care. For more information and to schedule a meeting, please contact Camille Bonta at cbonta@summithealthconsulting.com or (202) 320-3658.

Sincerely,



Jenifer Lightdale, MD
President
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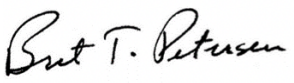

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