

IBD VIEWPOINTS

Advancing a collaborative prior authorization paradigm in inflammatory bowel disease

August 2024



Tapestry Networks recently engaged payers, self-insured employers, clinicians from health systems and independent gastroenterology practices, patient advocates, and industry representatives to discuss ways in which prior authorization (PA) could evolve to advance high-quality, clinically oriented care in inflammatory bowel disease (IBD) in an era of value and cost containment. Select stakeholders gathered for a December 2023 meeting to further explore how PA can be collaboratively advanced in the short and long term. This *ViewPoints* provides a synthesis of views that arose during participant conversations, supported by external literature when relevant, and will pave the way for additional published perspectives on these topics to be released in 2024.

For a full list of those who contributed insights on these and related topics addressed by the <u>IBD Shared Value Initiative</u>, please see page 18.

This *ViewPoints*¹ highlights the following topics:

Advancing candid dialogue and action on PA in IBD

Considering both transformative and administrative improvements to PA

Case Study: Improving initial PA approval rates at Mayo Clinic

Accelerating a way forward



Executive Summary

"The underlying question of value is this: Are we taking good care of patients or not?" – **Clinician**

The treatment landscape for IBD continues to evolve rapidly. Patients suffering from Crohn's disease and ulcerative colitis—the two chronic disorders comprising IBD—now have a broad range of advanced therapy options to better enable symptom relief and slow disease progression. Additionally, the latest research and standards of care affirm that minimizing disease activity at an early stage with optimized therapy should be the clinical paradigm for IBD.²

However, many gastroenterology (GI) clinicians report that obtaining timely patient access to optimized therapies can be a challenge, in part due to PA policies. In the face of pressure to manage increasing healthcare costs, payers often require PA for a broad range of specialty medications, which means that clinicians must obtain approval before patients can begin a course of treatment. Recently, the role of PA in US healthcare has been debated at state and national levels, with many stakeholders calling for legislation to enable more streamlined PA processes.³

Since 2021, Tapestry Networks has convened a diverse group of stakeholders—including payers, self-insured employers, GI clinicians, patient advocacy organizations, industry representatives, and others—in the IBD Shared Value Initiative, which aims to define and advanced shared value in IBD, a medical subspecialty with significant disease variability and high drug cost.⁴ Following initial discussions on key challenges and opportunities for value-based care (VBC) in IBD,⁵ a group of payers and providers published a consensus-based framework on the necessary elements for value in IBD in the *Journal of Clinical Gastroenterology and Hepatology*.⁶

Following the framework's publication, the IBD Shared Value Initiative has focused on how to enable real-world implementation of some of its specific components. Diverse stakeholders were asked to prioritize specific areas for collaborative discussions and potential design of new approaches, and PA emerged as a pressing topic that the initiative could address (*further details on the prioritization exercise can be found in Appendix 1*). PA is not only relevant for enabling timely access to standard-of-care treatment, but it is also increasingly under debate in the broader healthcare landscape.⁷



Initiative participants highlighted the following factors regarding PA, discussed in more detail in the main body of the document:

- Initiative participants see candid multistakeholder dialogue and action on PA as one of the best ways to implement the key principles identified in the published framework. While other VBC-related issues garnered mixed reactions, stakeholders consistently raised PA as a subject that warranted collaborative discussion, particularly given the dynamic changes facing PA in the healthcare landscape.
- While all agreed on the importance of discussions around PA, stakeholders had diverse and nuanced views about its implementation today. Clinicians and patient advocates stressed that PA should reflect current clinical recommendations more accurately and reduce administrative burdens for care teams. While payers and self-insured employers believe PA will continue to be utilized in IBD for several reasons—including high treatment costs and current variability in patient care—many acknowledged the need to improve the PA process to better enable patient-centered, high-quality care in the subspecialty.
- There are opportunities for collaborative pilots to improve PA. These
 include short-term improvements (for example, streamlining administrative
 processes) and potentially transformative mid- to long-term projects—including
 gold-card variations—to enable sustainable patient access to the right therapy at
 the right time for improved disease outcomes.

The IBD Shared Value Initiative will continue to explore potential avenues for PA innovation to further realize VBC in IBD. One stakeholder was optimistic that progress could be made in the near future: "Operationally, releasing PA would not be hard, so if there's an agreeable way to work [with other stakeholders] and obtain the right data, the results could be worthwhile."



Advancing candid dialogue and action on PA in IBD

"PA should not look the same as it did 15 years ago ... Patients are suffering as a result of antiquated tools." – **Payer**

In electing to focus on PA, several Initiative participants noted that addressing PA "could lead to action and outcomes the quickest." The removal or modification of PA could also serve as a strong alternative incentive for GI and IBD clinicians to deliver value-oriented care, possibly as a complement or alternative to ongoing experiments with value-based payment (VBP) models. One clinician said, "When thinking about barriers to improved patient care, PA continues to persist as a daily hurdle which we spend a lot of time, energy, and resources on." Many payers were open to the notion that PA could be improved: "In many cases, PA is not impacting spend or reducing patient and provider abrasion. We need to develop PA in a way that makes sense for healthcare today."

PA in IBD: What is the state of play today?

Faced with significant and increasing cost pressures, healthcare purchasers and payers frequently use utilization management (UM) strategies for medical services, treatments, and pharmaceutical therapies. In principle, UM tools such as PA "discourage costly low-value services, thereby reducing health care spending without impairing health care quality," especially in areas insurers see as susceptible to this problem.⁸ Within the field of gastroenterology, PA can be required for medical procedures such as endoscopy. For IBD specifically, PA is commonly applied to advanced pharmaceutical therapies such as biologics. Indeed, some IBD specialists report that 94% of referred patients require PA for pharmaceutical treatment.⁹

During the PA process, payers review a patient's clinical and prior treatment history to determine whether to approve a prescribed treatment. As part of PA, some payer policies require patients to undergo step therapy; that is, they require patients to try alternative medications first, and only if those medications fail is approval for the originally proposed medication granted.¹⁰

Overall, patient access to advanced IBD therapies has improved.¹¹ However, some stakeholders believe that the implementation of PA continues to present both clinical and process-related challenges. The former may include step therapy protocols that require steroids, which do not enable long-term remission.¹² Process challenges include delays and administrative burdens, which may affect patient care and clinical teams.



Clinicians and patients emphasized that PA should reflect the current clinical paradigm and decrease administrative burdens

Some stakeholders shared their view that PA policies for IBD continue to be influenced by dated evidence. A clinician said, "The number one drug prescribed for IBD patients is prednisone, and when we ask patients why they're on long-term prednisone and not another treatment, they often cite insurance coverage issues." Indeed, an American Gastroenterological Association study noted that 98% of payer PA policies are inconsistent with clinical guidelines for high-risk ulcerative colitis patients, and 90% are inconsistent with guidelines for moderate- to high-risk Crohn's disease patients. Given the cost of some advanced therapies, a clinician empathized with the financial challenges payers and self-insured employers face, but also noted the need for progress: "Nobody's working with an infinite amount of resources, so I get the rationale for PA. At the same time, it always feels like a fight to get patients access to treatments that are eventually approved anyway, and there must be a way to not make the process as painful as it is for medications that follow guidelines."

Additionally, the frequent requirement of PA for IBD treatment increases the time clinical teams must spend on administrative tasks. While well-resourced IBD centers and private practices with dedicated support staff can achieve a relatively high rate of PA approvals upon initial submission, a survey found that providers still spend up to five hours per week on PAs. A clinician shared that PA takes an emotional and mental toll on clinicians, their teams, and patients: "Providers and patients go through a lengthy shared decision-making process for treatment selection, only to have first- and second-line options denied by insurance. That's exhausting for everyone involved."

When clinical teams work through extended denial and appeal processes, treatment delays of up to 73 days can occur.¹⁵ Delays can contribute to increased healthcare utilization such as emergency room visits, steroid dependence in adult populations, and risk of complications in pediatric populations.¹⁶ Accordingly, to help address patient care and access, as well as increasing rates of provider burnout, GI societies and IBD patient groups are focusing on PA alleviation.¹⁷

Some payers and self-insured employers believe PA could evolve to be of greater value to all

Many payers note that PA has successfully reduced costs and enabled appropriate utilization as healthcare and specialty drug spend continue to rise. As such, there is support in principle for the ongoing use of PA. However, some payers and self-insured employers do see a benefit to more tailored approaches for chronic, variable conditions such as IBD, particularly with care quality in mind. "We're at this point where drugs are



framed as a commodity, not as part of the care pathway, so everyone's pushing towards lower drug costs. We need to rethink PA and have protocols which drive towards a higher quality of care," one self-insured employer opined.

One payer suggested that insurance models need to evolve to "have more flexible PA administration to enable prioritization of provider decision making." Another felt that "payers [need to] take a sledgehammer to the traditional mindset of insurance models and better align with a more sustainable healthcare future." However, speaking candidly, one payer said, "We don't think about utilization management by condition but rather by big cost drivers. Right now, PA is employed at the drug level and not at the disease-specific level ... You could argue it would be better for IBD patients if disease-level policies were created, but based on total cost, I'm not sure IBD is a top 10 priority for many insurers."

These stakeholder views align with trends in the broader healthcare and pharmacy landscape, where there is considerable activity around PA, as detailed in the box below.

Recent developments around PA

- Proposed legislation on transparency for pharmacy benefit managers (PBMs)¹⁸
- Fragmentation of health plan services amongst self-insured employers and payers¹⁹
- Enactment of state gold-card laws that remove PA for some providers (e.g., as implemented in Texas)²⁰
- Emergence of new insurance and specialty pharmacy business models that seek to promote transparency and optimized treatment outcomes on behalf of clients like self-insured employers

Although state and federal bodies have evaluated UM and PA historically, some believe the current level of interest among lawmakers presents an opportunity for the Initiative. One participant said, "I've been on the Hill many times, and there is more interest on PA today than I can remember. We can utilize that momentum to push things along with a multistakeholder group." Some payers also favor a collaborative effort at this time, with one noting, "UM and PBMs have been under fire recently, and it would be a great time to talk with others about how they can be innovative to add value and enable the best care possible."

Within IBD, some clinicians are already exploring new ways of working with insurance partners in a local fashion. For example, some report negotiating the waiver of all PA requirements from an individual local payer following demonstration of clinical and cost-



related outcomes compared to other practices. However, stakeholders noted there remains a need to refine and implement such concepts at scale for clinicians, payers, patients, industry, and others.

Considering transformative and administrative improvements to PA

With these insights and developments in mind, select stakeholders from the IBD Shared Value Initiative gathered in December 2023 to explore opportunities for multistakeholder collaboration on PA. Ahead of the meeting, stakeholders evaluated a list of concepts adapted from proposals from the Crohn's and Colitis Foundation (CCF) and the American Heart Association Prior Authorization Learning Collaborative for their applicability to PA innovation.²¹

Potential transformative approaches

Potential Option	Involved Stakeholders	Approach
Relax PA under performance-based arrangements	Payer, self-insured employer, PBM, health system, clinicians	Waive or modify PA for therapies that adhere to care pathways or other benchmarks, defined collaboratively across stakeholders, with ongoing evaluation (e.g., gold-card program variations, sometimes referred to as dynamic gold carding).
Advance value- based drug contracts	Payer, self-insured employer, PBM, developers	Modify PA requirements for approval, enabling greater patient access. Increased costs from therapy could be offset by innovative agreements with drug developers.

Approaches targeting administrative improvements

Potential Option	Involved Stakeholders	Approach
Address current systems' pain points	Payer, self-insured employer, PBM, health system, clinicians	PA criteria design: Collaboratively update PA criteria, with input from IBD specialists, to enable consideration of evidence-based recommendations and payer utilization requirements. Process design: Standardize templates for PA to clarify the information necessary from the clinicians for approval.



Approaches targeting administrative improvements (continued)

Potential Option	Involved Stakeholders	Approach
Reward PA success	Payer, self-insured employer, PBM, clinicians	Traditional gold-card program: Clinicians who regularly receive approval for therapies may be exempt from PA for a certain time, with intermittent evaluations for renewal of program. Sunset program: Eliminate PA for regularly approved drug therapies.
Leverage technologies to support process improvements	Payer, self-insured employer, PBM, health system, clinicians	Electronic PA (ePA): Enable PA forms to be filled and sent online more easily (vs. paper-based methods). Develop or improve online portal for payer-provider for communication (vs. fax or telephone). Automated PA: Based on evidence-based algorithms, automatically screen PA with AI and/or real-time pharmacy benefit checks. Ensure provision of clear rationale for approvals or denials (caveat: algorithms must be well defined, given challenges associated with automatic AI-driven denials observed in IBD).

Of note, while PA modifications under value-based contracts and payment models are a potential avenue for change, this option was not initially prioritized for discussion given that VBP models involving risk transfer are limited in IBD, as discussed in Appendix 1. That said, one stakeholder suggested that PA challenges may be better addressed within VBP models: "For payers, removal of PA will increase cost, and total cost of care needs to be lowered somewhere else. Practices can only be incentivized to evaluate total costs if they're under a value-based contract."

Stakeholders are keen to further assess transformative pilots, especially those based on "gold-card" concepts

Many stakeholders expressed an interest in considering transformative pilots to improve PA in IBD, particularly gold-card program variations (dynamic gold carding) that enable modifications to PA based on measurable performance metrics. Payers and self-insured employers highlighted the importance of such metrics for IBD: "We'd like to find a path towards continual measurement to see providers who have historically and continuously performed well and reward those performers with some type of PA relaxation." Another agreed that there could be value in a "provider-focused gold-carding program ... with a



[PA] pathway for those providers that we know are providing that high-quality care."

In conversation on how to identify or benchmark those providing robust care, one clinician noted that practice participation in IBD Qorus (a quality improvement initiative from CCF) has enabled improved outcomes such as reduced ER visits, leading some to wonder if the IBD Qorus program could be utilized for performance benchmarking relevant to PA.

Some stakeholders also voiced interest in a pragmatic sunset program whereby PA could be eliminated for regularly approved drug therapies. "If 90% of a provider's prescriptions for a certain medication are approved, then it seems the PA hurdle is just creating cost on the payer side. I think there's an opportunity for payers to partner with us to redesign this," one clinician opined. A self-insured employer also expressed curiosity in "understanding the impact of a sunset program because there could be high value proposition to enhance member experience."

Clinicians are conducting pilots to address PA's administrative burden

At present, clinicians are addressing system pain points primarily by leveraging the use of new technologies. For example, some GI clinicians have invested in AI-enabled platforms to navigate PA telephone calls and reduce hold times for staff. Some specialty centers are streamlining internal clinical, workflow, and communication processes for greater consistency of information for PA. The result has been an increase in initial PA approval rates for injectable and oral therapies "from 50% to 90%." This second initiative is discussed in detail in the case study below.

More broadly, some health systems are also trying to optimize treatment selection and maintenance in IBD and other immunological conditions such as rheumatoid arthritis by aligning clinical data, disease activity questionnaires, and outcomes tracking—specifically, time to therapy and time to reach therapeutic goals—across provider, specialty pharmacy, and policy teams. Such programs aim to proactively identify opportunities for achieving value during a patient's course of treatment, such as by determining how frequently a patient needs to schedule a clinic visit or when a treatment dose can be increased or decreased. These types of initiatives may be more possible in integrated systems that provide greater visibility into clinical and pharmacy data.

While these administrative-focused projects have had favorable outcomes, some stakeholders raised concerns about their applicability to other sites of care, where there remains a clear need for innovative PA approaches: "The providers who need oversight don't have the right resources or are not paying attention, which is how we ended up with this onerous utilization management system in the first place. How can we create solutions given that all GI providers are not the same?"



Case Study

Improving initial PA approval rates at Mayo Clinic

Author: Jami Kinnucan, MD, Frank Farraye, MD, Michael Picco, MD, Jana Al Hashash, MD, Sheena Crosby, PharmD

Background

With the increasing availability of advanced therapies and their central role in managing IBD, leading IBD providers are giving more attention to the role of PA in patients' access to treatment, particularly as clinicians have observed that some patients must undergo suboptimal treatments (e.g., use of steroids) and consequent poor outcomes while waiting for therapy approvals.²² Additionally, survey results indicate that PA contributes significantly to clinician administrative burden and burnout, with models estimating that providers issuing IBD prescriptions spend a weighted average of 138 hours per provider per year on PA, costing an estimated \$300 million annually in provider time, even prior to including contributions from support staff (e.g., pharmacists).²³

Various templates for PA appeals and letters of medical necessity exist in the public domain to support clinicians in making PA requests, including for IBD.²⁴ However, those templates are stand-alone downloadable resources that are not fully integrated into clinical and pharmacy workflows, and many of them focus on denials and appeals as opposed to proactively improving initial submittals.

Program rationale and goals

Against this backdrop, in 2021, Mayo Clinic began an initiative to improve PA success. The goal was to have its clinicians identify and successfully prescribe optimal therapeutic treatments, as determined through provider-patient shared decision making. Previously, prescription workflows varied at Mayo, and detailed patient information relevant to a PA for the order (e.g., medication history) was not consistently and seamlessly made available to internal pharmacists. Pharmacy staff would instead receive a simple automated PA request for a drug order and delve deeply through charts to find more detailed data as directed to properly place a submittal to a payer.

The initiative began after Mayo's internal specialty pharmacy team observed that certain IBD physicians had greater success in securing authorization for drug therapy from initial PA submittals than their colleagues. The pharmacy team partnered with the successful IBD physicians to glean best practices from their PA processes and design an approach that could be used broadly across the health system—namely, an easy-to-use PA request tool for clinicians and pharmacists embedded within Mayo's electronic medical



record (EMR) system.

The overarching goal of the effort was to help providers with denial remediation—that is, to improve their *initial* PA approval rate, thereby reducing time spent managing denials. The approach implemented by the Mayo team proactively addresses a broad variety of reasons why payers commonly deny requests for advanced therapies in an initial submission. In Mayo's examination of its previous PA process, staff observed that missing information on diagnosis, disease severity, and prior medications were the most common reasons for denials.

Implementation

Mayo pharmacy team members used SmartPhrase functions within Epic to create a PA request informational checklist embedded within the daily clinical workflow that physicians could use to communicate detail relevant for a PA with the centralized Mayo pharmacy team.

PA encounter process

In this process, a physician creates a PA encounter separate from the clinical encounter within the EMR, and then uses the SmartPhrase tool created by the team to add detail necessary for a PA approval in a consistent fashion. The creation of a PA encounter generates an automatic PA request, and when an advanced therapy is placed within that request, the system generates a work queue line item for the central pharmacy team. The pharmacy team can scan the PA encounter and review the information ahead of electronically submitting an official request through a platform such as Availity and CoverMyMeds®.

Physician creates PA encounter Pharmacy team Pharmacy team PA encounter reviewś PA submits PA to causes phamacy and uses payer via team to receive encounter details SmartPhrase to an automatic PA to inform PA eletronic portal add PA-related request request (e.g., Availity) detail

Figure 1. Denial remediation process



SmartPhrase tool content

The SmartPhrase tool developed by Mayo is designed to address all possible reasons for denial up front. The box below highlights the tool's embedded drop-down links.

Checklist content

- ✓ The drug and dosage requested
- ✓ Whether the indication is on or off label
- ✓ The diagnostic/lab requirements a payer may require (e.g., tuberculosis status)
- ✓ Prior treatments and reasons for any treatment discontinuation
- ✓ Potential contraindications to alternative treatments
- ✓ A linked electronic template for a letter of medical necessity that the physician can quickly complete, tailored for specific drugs and scenarios with supportive literature

Mayo physicians emphasized the value of including an array of templated letters of medical necessity in connection to the PA request. Mayo's letter templates include links to a repository of relevant literature references for specific drugs and various scenarios—e.g., a patient needing a new drug, a renewal, or dose management. The templates and literature references are regularly updated by the pharmacy team but once created, can be repeatedly used across similar patient scenarios. Such letters are necessary when, for example, a treatment is off-label, and the templates make it easy to include comments on a patient's level of severity, which may be relevant in specific cases, such as when an advanced therapy is requested for a patient who has not first failed mesalamine or steroids.

Discussion

Mayo's denial remediation program offers several benefits for IBD clinicians. First, it has already demonstrated meaningful impact. Mayo's initial PA submittal success rate has significantly improved from 50% to 90% within 6 months of program implementation. Furthermore, when appeals do occur, the new workflow creates a central information repository for rapid access to relevant patient information and referenced literature. Given the program's success, Mayo has scaled the approach internally for different therapies across their entire GI practice, in rheumatology, and in other areas. The workflow serves to not only save pharmacy, physician, and payer time managing denials and appeals, but also helps patients initiate a drug of choice more quickly.

Second, the approach's initial and ongoing investment requirements are likely to be



minimal for many IBD specialty centers as well as independent practices that use an established EMR system. In Mayo's experience, building the approach required no additional technology budget or IT staff time, although creating the new workflow and the SmartPhrase tool required coordination and time across clinical team members and specialty pharmacy staff. Additional time was also required to secure buy-in from and train other clinicians on the approach once the initial workflows were created. In a practice without a dedicated pharmacy team, coordination with another clinical team member who leads PA workflows would be required. On an ongoing basis, Mayo data shows that templates require 3-5 minutes of physician time per patient to complete when completed during a clinical encounter with a patient.

Initial setup	Ongoing implementation
Time: Centralized pharmacy team/licensed practical nurse/PA submittal staff time for: SmartPhrase tool creation	Time: • 3-5 minutes per patient investment of physician time
 Workflow change adaptation (awareness of new PA encounter detail) Creation of a repository of literature to use in templated letters of medical necessity Physician buy-in and training to develop and implement the workflow in partnership with pharmacy/support staff 	Ongoing training and roll- out, dependent on practice size
IT infrastructure:	
 An EMR with options for rapidly customizable tools (SmartPhrase in Epic or dot phrases in other vendors' EMRs) Electronic platform (ideally) through which a pharmacy team member/other staff can issue the PA submittal based on information gathered from the PA encounter tool 	

The Mayo approach to denial remediation does come with limitations. An investment of 3-5 minutes per patient drug order may be challenging for busy physicians to make and may require changes to current workflows, despite the benefits of saving time spent on denials and appeals on the back end. More broadly, the process aims to address a narrow set of challenges associated with current PA processes, i.e. denial processes and the time they require, and does not fundamentally transform PA. The process also does not provide physicians and their ancillary team members with a comprehensive solution for the entirety of the PA process. For example, the approach does not, at present, provide an overall dashboard to track the status of outstanding PAs, a resource some believe would be very helpful. Electronic PA submittal tools like Availity are starting to prove helpful with PA tracking, but such tools do not always encompass therapies delivered via both pharmacy and medical benefit channels. However, Mayo's approach is pragmatic, completely managed within the clinical center, and allows practices to manage clinical team time and place patients on recommended treatment regimens sooner, thereby reducing the potential impact of treatment delays.



Accelerating a way forward

Moving forward, Tapestry will continue to work with stakeholders from the IBD Shared Value Initiative on the above issues, focusing especially on pilots that are capable of starting small and generating foundational evidence for innovative PA programs. The overarching goal is to advance PA and ensure timely, patient-centered treatment that adheres to the latest clinical guidelines. In the interim, the case study from Mayo Clinic included in this document offers an existing model for improving patient access to treatment and reducing the administrative burden of PA denials.

About Tapestry Networks

Since 2004, <u>Tapestry</u> has been the premier firm for building collaboration platforms with leaders of the world's foremost organizations. Tapestry Networks brings senior leaders together to learn and to shape solutions to today's most pressing challenges. We are a trusted convener of board directors, executives, policymakers, and other stakeholders, connecting them with information, insight, and each other. Top experts join our discussions to learn from the leaders we convene and to share their knowledge. Our platforms help educate the market, identify good practices, and develop shared solutions. We call this the power of connected thinking.

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This work was funded and supported by Pfizer Inc. No direct funding, honoraria, or consulting fees were provided to clinicians or payers for participating in the Initiative. The sponsor had an opportunity to review this document's content before publication but did not play a role in authorship.



Appendix 1:

Prioritizing a focus area for a multistakeholder forum

Although PA was the Initiative's final choice for a focal topic, stakeholders also considered three other VBC-related topics highlighted in the coauthored framework publication—VBP, holistic risk stratification, and health equity. Although those topics were ultimately not selected, the points raised in discussion of them are of great value for understanding the issues involved in VBC and choosing a focus going forward.

VBP remains relevant but faces notable challenges

VBP models comprise a range of incentives that aim to achieve high-quality care and improved patient outcomes at lower or contained costs. Changes to reimbursement based on provider performance and transfer of financial risk to clinicians managing patient care are two examples of incentives utilized today. Despite evidence showing that value-oriented incentive structures might help support IBD medical homes, integrated care, and remote patient monitoring—all of which can have a positive impact on disease control and patient satisfaction—stakeholders are uncertain how VBP should progress in these areas due to several challenges:

- There may be insufficient scale in IBD to advance VBP models. The relatively small population of IBD patients means that it can be difficult for payers and providers who experiment with new models "to prove value-based savings are worthwhile." Recognizing this reality, some clinicians have expanded participation in VBP to conditions across GI: "It's hard to achieve savings with an IBD focus—there's low prevalence, and there's not much you can do to reduce cost. You need to take on accountable care across all of GI."
- Fee-for-service remains dominant across GI. VBP payment models have a limited track record in GI, in part because of ongoing fee-for-service incentives. For many GI clinicians, at least in the views of one stakeholder, fee for service "is lucrative ... there's no reason to take on risk."
- The interest in specialty models may be cooling. Even for large disease areas such as oncology, some stakeholders note that there is "significant complexity behind standing these models up." One payer shared that there is now "a lot of push and pull within internal strategy teams on whether what we're doing is actually working."

Despite the many challenges interviewees cited for VBP models, some payers and self-insured employers are still implementing alternative approaches and incentives to improve value for relevant GI providers and patients. Upside-only arrangements, where providers receive performance-based benefits such as increased per-member-per-month payments, have "gained traction amongst the specialist community." A clinician



shared a recent example: "Last year, our data showed that a small number of GI patients were responsible for a quarter of costs for a single payer. As a result, we renegotiated our contract and entered an upside shared-savings arrangement to closely monitor those patients." Some payers are incentivizing "providers to keep close engagement with patients who miss clinic appointments to avoid costly emergency department visits," while others are providing administrative support for medical benefit management to high-quality, but resource-limited, clinics. Many stakeholders believe these alternative approaches and incentives could be implemented in IBD, but given the complications inherent in VBP approaches, some were doubtful about the benefits of prioritizing it.

Holistic risk stratification continues to be utilized unevenly

Holistic risk stratification, which includes a thorough assessment of a patient's clinical presentation and psychosocial factors, is identified as a key principle of VBC in the published framework. Interviewees considered risk stratification's importance in IBD today and its potential to be advanced via a multistakeholder forum.

Some underscored that risk stratification techniques in IBD are emerging as an important practical intervention in care delivery. For example, IBD Qorus has published on the role that a simple list of high-risk patients played in successfully impacting practices' ability to manage patient costs.²⁵ Optimal ways to stratify baseline and ongoing patient risk progression is a topic of ongoing research in IBD, and pilots that employ such approaches in service to VBC are in "early stages." Diverse stakeholders are enthusiastic about the promise of such approaches, citing results from analogous diseases like rheumatoid arthritis.

Additionally, clinicians and payers are increasingly utilizing more sophisticated large-scale analytics—with databases built in-house or in partnership with third-party vendors—to improve patient care and identify risk factors that affect the total cost of care. Although VBC is the primary reason for employing these data tools, some stakeholders acknowledged that the tools also offer short-term commercial advantages in the form of sales of data to third parties.

In short, some participants believe the emerging research and experiences in this area indicate that risk stratification may have valuable lessons for the Initiative, but because the implementation of risk stratification is only in early stages and has been uneven, with diverse short-term interests at play, several stakeholders felt the Initiative's attention should be directed elsewhere.

Health equity may require more upstream focus

Historically, IBD was considered to be more prominent in younger, white populations, though recent epidemiological studies reveal incidence in more diverse and older populations.²⁶ Given that health equity is an increasingly urgent issue for many organizations—particularly large, self-insured employers with diverse demographics—



stakeholders considered whether the Shared Value Initiative could make an impact in this area. Some stakeholders raised specific issues that may warrant further consideration and investment, including holistic care education, inclusive data collection methodologies, and new partnerships between academic institutions and community sites of care.

However, while all stakeholders affirmed the importance of addressing health equity, several of those involved in the IBD Shared Value Initiative felt that the narrow focus of their respective organizational roles and purviews might limit their ability to make a difference. For example, one payer said, "For Medicaid patients with IBD, the state is restrictive on what we can do with treatment, so that's an equity issue that is out of our hands." Others believe that health equity would be best impacted through research and development efforts already in progress, such as "diversifying clinical trial enrollment" or "understanding how treatment approaches should differ amongst populations." As a result, stakeholders voiced a strong preference for the Initiative to select a different area in which it might have an impact.



Appendix 2: Participants

An asterisk after a name indicates a participant in the December 2023 meeting; other participants contributed high-level insights on PA and related topics.

AffirmedRx: Kristin Stadler, Head of Growth Strategy
AT&T: Luke Prettol, Principal Benefits Strategy Consultant*
Brown University: Samir Shah, Clinical Professor of Medicine*

Capital Digestive Care: Michael Weinstein, President*

Color of Gastrointestinal Diseases: Melodie Narain-Blackwell, President and Founder; Latonia Ward, Former

Director of Community and Culture

Crohn's & Colitis Foundation: Cassie Ray, Director of Advocacy*; James Testaverde, Senior Director, Patient

Education and Support; Alandra Weaver, Vice President, Clinical Quality and Research Innovation

CVS: Joe Couto, Senior Director, Specialty Program Outcomes and Evaluations*

Elevance: Isaac Burrows, Director, Payment Innovation Design; Erin Smith, Vice President, Payment Innovation

Strategy*

Geisinger Health Plan: Phil Krebs, Director, Medical Policy and Clinical Guidelines*

GI Alliance: Paul Berggreen, Chief Strategy Officer

Highmark Inc: Matt Fickie, Senior Medical Director; Bob Wanovich, Vice President, Ancillary Provider Strategy and

Management

Mass General Brigham: Mark Sanderson, Head of Analytics of Value-Based Care

Mayo Clinic: Jami Kinnucan, Senior Associate Consultant*

Mount Sinai Hospital: Laurie Keefer, Director for Psychobehavioral Research, Division of Gastroenterology

Nebraska Medicine: Sarah Kuhl-Padgett, Director, Community-based Pharmacy Services*; Kyle Skiermont, Senior

Vice President, Operations

Oshi Health: Sameer Berry, Chief Medical Officer*

Pfizer: Debanjali Mitra, Value and Access Strategy Team Lead*; Craig Singewald, Senior Director, US Market

Access Lead, Inflammation and Immunology (initiative sponsor)

Promise Bio: Assaf Kacen; Co-founder and Chief Technology Officer; Ronel Veksler, Cofounder and Chief

Executive Officer

Purchaser Business Group on Health: Emma Hoo, Director of Value-Based Purchasing

Rubicon Founders: David Johnson, Clinical Operating Partner

Saratoga Schenectady Gastroenterology Associates: Arthur Ostrov, Gastroenterologist

Sepsis Alliance: Paul Epner, Board Member

SonarMD: Larry Kosinski, Founder and Chief Medical Officer

Stephens Insurance: Rich Krutsch, Senior Vice President, Employee Benefits*

Surest: Marcus Thygeson, Emeritus Chief Health Officer

TFA Analytics: Emily Cane, Manager, Clinical Programs; Torrie Fields, Managing Partner

The Pharmacy Group: Perry Cohen, Chief Executive Officer Vantris Oncology: Joe O'Hara, Strategic Business Consultant VIVIO Health: Bhargav Raman, Vice President, Clinical Product Walmart: Mike Jansen, Senior Director of Health and Wellbeing



Endnotes

- ¹ ViewPoints reflects the network's use of a modified version of the Chatham House Rule whereby comments are not attributed to individuals or organizations. Quotations in italics are drawn from conversations with participants in connection with the meeting.
- ² Dan Turner et al., "STRIDE-II: An Update on the Selecting Therapeutic Targets in Inflammatory Bowel Disease (STRIDE) Initiative of the International Organization for the Study of IBD (IOIBD): Determining Therapeutic Goals for Treat-to-Target Strategies in IBD." Gastroenterology 160, no. 5 (2021), 1570–1583.
- ³ Tanya Albert Henry, "9 States Pass Bills to Fix Prior Authorization," American Medical Association, March 8, 2024
- ⁴ Lawrence Kosinski et al., "<u>Financial Volatility of Inflammatory Bowel Diseases vs Other Chronic Gastrointestinal Diseases—Using the Beta Coefficient to Categorize GI Disorders.</u>" *Inflammatory Bowel Diseases* 26, no. Supplement_1 (2020), S49.
- ⁵ Inflammatory Bowel Disease Shared Value Initiative, <u>Laying the Foundation for Greater Value in Inflammatory Bowel Disease</u>
 <u>Care</u> (Waltham: Tapestry Networks, 2021).
- ⁶ IBD Shared Value Initiative Author Group, "Principles to Advance Value in Inflammatory Bowel Disease: A Collaborative Payer–Provider Framework." Clinical Gastroenterology and Hepatology 21, no. 12 (2023), 3011–3014.
- ⁷ "CMS Interoperability and Prior Authorization Final Rule," Centers for Medicare and Medicaid Services, January 17, 2024.
- ⁸ Aaron L. Schwartz et al., "Measuring the Scope of Prior Authorization Policies: Applying Private Insurer Rules to Medicare Part B," *JAMA Health Forum* 2, no. 5 (2021), e210859.
- ⁹ David K. Choi et al., "Role and Impact of a Clinical Pharmacy Team at an Inflammatory Bowel Disease Center," *Crohn's & Colitis* 360 5, no. 2 (2023), otad018.
- ¹⁰ Shubha Bhat et al., "Advocating for Patients with Inflammatory Bowel Disease: How to Navigate the Prior Authorization Process," Inflammatory Bowel Diseases 25, no. 10 (2019), 1621–1628.
- ¹¹ Parambir S. Dulai et al., "Market Access Analysis of Biologics and Small-Molecule Inhibitors for Inflammatory Bowel Disease among US health Insurance Policies," *Digestive Diseases and Sciences* 64, no. 9 (2019), 2478–2488.
- ¹² Codey Pham et al., "Patterns of Steroid Use Among a Real-World National Cohort of Veterans with Inflammatory Bowel Disease," Gastroenterology 164, no. 4 (2023), S101–S102.
- ¹³ Abhijeet Yadav et al., "Variations in Health Insurance Policies Regarding Biologic Therapy Use in Inflammatory Bowel Diseases," *Inflammatory Bowel Diseases* 23, no. 6 (2017), 853–857.
- ¹⁴ Brad D. Constant et al., "Prior Authorizations Delay Therapy, Impact Decision-Making, and Lead to Adverse Events in Inflammatory Bowel Disease: 2022 Provider Survey," *Clinical Gastroenterology and Hepatology* 22, no. 2 (2024), 423–426.
- ¹⁵ Elizabeth A. Spencer et al., "<u>Barriers to Optimizing Inflammatory Bowel Disease Care in the United States</u>," *Therapeutic Advances in Gastroenterology*, 16 (2023), 17562848231169652.
- ¹⁶ David K. Choi et al., "<u>Delays in Therapy Associated with Current Prior Authorization Process for the Treatment of Inflammatory Bowel Diseases</u>," *Inflammatory Bowel Diseases* 29, no. 10 (2023), 1658–1661.
- ¹⁷ "AGA Supports Reducing Prior Authorization Burdens That Delay Patient Access to Care," American Gastroenterology Association. Accessed April 30, 2024.
- ¹⁸ Leigh Feldman et al., "<u>Pharmacy Benefit Manager Reform: What's on the Horizon? (December 2023 Update)</u>," McDermott Consulting, December 21, 2023.



- ¹⁹ Anastassia Gliadkovskaya, "<u>Mark Cuban Cost Plus Drug Company Announces First Health Plan Partner, Capital Blue Cross</u>," *Fierce Healthcare*, October 6, 2022.
- ²⁰ Andis Robeznieks, "New Physician 'Gold Card' Law Will Cut Prior Authorization Delays," American Medical Association, September 15, 2021.
- ²¹ Mitchell A. Psotka et al., "Streamlining and Reimagining Prior Authorization Under Value-Based Contracts: A Call to Action from the Value in Healthcare Initiative's Prior Authorization Learning Collaborative," *Circulation: Cardiovascular Quality and Outcomes* 13, no. 7 (2020), e006564.
- ²² Lauren Loeb et al., "Prior Authorization of Biologics in the Management of Inflammatory Bowel Disease," Inflammatory Bowel Diseases 29, no. 9 (2023), e37.
- ²³ Brad D. Constant et al., "Prior Authorizations Delay Therapy, Impact Decision-Making, and Lead to Adverse Events in Inflammatory Bowel Disease: 2022 Provider Survey," Clinical Gastroenterology and Hepatology 22, no. 2 (2024), 423–426.
- ²⁴ "Appeal Letters," Crohn's & Colitis Foundation. Accessed May 1, 2024.
- ²⁵ Christopher V. Almario et al., "<u>Health Economic Impact of a Multicenter Quality-of-Care Initiative for Reducing Unplanned Healthcare Utilization among Patients with Inflammatory Bowel Disease,</u>" *American Journal of Gastroenterology* 116, no. 12 (2021), 2459–2464.
- ²⁶ Joyce W. Y. Mak et al., "<u>Development of the Global Inflammatory Bowel Disease Visualization of Epidemiology Studies in the 21st Century (GIVES-21)</u>," *BMC Medical Research Methodology* 23, no. 1 (2023), 129.