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IBD SUMMARY OF THEMES

Exploring pilots to evolve prior authorization for treatments in inflammatory bowel disease

September 2024

In the first half of 2024, Tapestry Networks engaged with payers, self-insured employers, clinicians, patient advocates, and industry representatives to consider how modifications to prior authorization (PA) processes might improve quality of care for inflammatory bowel disease (IBD). These discussions culminated in a virtual June 2024 multistakeholder meeting of the IBD Shared Value Initiative, where participants considered research initiatives and pilots to generate evidence for potentially measurable benefits of PA modification. This *Summary of Themes* provides a synthesis of views that arose during the meeting and in pre- and post-meeting discussions.

For a full list of individuals who contributed insights on these topics, please see Appendix 1 (page 10).

This *Summary of Themes*[1] highlights the following topics:

Background

> *"PA seems to be the easiest and most addressable issue in IBD, and changes there could lead to quick and effective action."*
> — **Self-insured employer**

Patients with Crohn's disease and ulcerative colitis—the two chronic disorders comprising IBD—now have a broad range of advanced drug therapy options to enable symptom relief and slow disease progression, and current standards of care aim to promptly place patients on such treatments to positively alter disease course.[2]

Recent studies from the clinical community have signaled that, in some instances, PA processes for advanced drug therapies can result in treatment delays of up to 73 days and contribute to increases in healthcare utilization, steroid dependence, and risk of complications.[3] For clinical teams, extended denial and appeal processes add notable administrative burdens, and there is evidence to suggest that some clinicians prescribe less-efficacious therapies to avoid such processes.[4] At the same time, some well-resourced academic centers with specialty pharmacy teams are able to achieve relatively high rates of approvals for initially prescribed drugs, leading to questions around how PA might be better streamlined for all.[5]

From the purchaser perspective, both payers and self-insured employers continue to use PA to help manage spending in an era of cost containment and rising specialty drug prices. In principle, PA and other utilization management approaches "discourage costly low-value services, thereby reducing health care spending without impairing health care quality."[6]

However, some recognize the need for more tailored and sustainable PA approaches for chronic, variable conditions like IBD, where effective disease management can reduce high-cost utilization such as emergency department visits and inpatient hospitalizations.[7] As other methods to drive quality and contain costs (e.g., value-based payment models) remain challenging to design for small subspecialty populations, some stakeholders are interested in exploring how PA modification could be used as an incentive to drive value and quality. Such considerations also come at a time when PA processes are being examined closely at the state and federal level, and public interest in the issue remains high.[8]

Against this backdrop, Tapestry Networks convened payers, self-insured employers, clinicians, patient advocates, and industry members in June 2024 to brainstorm approaches to evolving PA in this subspecialty. Participants were asked to consider two specific concepts:

- **Exploratory studies**, potentially in collaboration with health systems, to shed light on the role of PA removal and its link to predefined outcomes (e.g., clinical remission)
- **Practical pilots** where self-insured employers might consider the impact of PA modification or removal for qualifying practices

Key points from the discussion, as well as insights contributed during pre- and post-meeting conversations, are detailed below.

Obtaining PA insights from health systems

While stakeholders anticipate potential benefits from modifying or removing PA requirements in IBD care, many agree on the need to build an evidence base to better measure these benefits and develop criteria for when and how PA modification might yield positive outcomes for relevant stakeholders. One purchaser reflected, *"I would gladly remove PA for providers here in this meeting because you're doing the right thing for patients. But I don't know that removing PA for all IBD clinicians will be helpful."*

In earlier discussions of the IBD Shared Value Initiative, stakeholders suggested that some healthcare systems–particularly those that have worked to align clinical and technological processes across relevant teams (e.g., provider, pharmacy, health plan, pharmacy benefits manager) to enable the collection and evaluation of data throughout a patient's care journey–might be well positioned to explore the benefits of PA modification in IBD. During the June meeting, Nebraska Medicine was discussed as an illustrative example of a health system with integrated datasets.

Nebraska Medicine: Tapping into a unique dataset and care infrastructure

Nebraska Medicine is an academic, integrated-delivery network with a well-established in-house specialty pharmacy team. It is also a self-insured employer with a distinct benefit design: employees who receive therapy from Nebraska Medicine's specialty pharmacy are exempted from PA for all specialty medications, including IBD therapies.

Recently, the Nebraska Medicine specialty pharmacy team has been working to drive quality of care across multiple disease areas. In IBD specifically, the team is capturing baseline and ongoing patient disease activity with the Simple Clinical Colitis Activity Index and Harvey Bradshaw Index every three months. While these measures may not be optimal for every patient, they do enable patient assessments to be completed electronically or over the phone without a physical exam. Subsequently, the frequency of clinic visits and prescribed medications are adjusted as needed and in collaboration with clinicians to achieve *"low disease activity or remission as quickly as possible."*

From this process and its care delivery to IBD patients broadly, the health system can obtain robust data for Nebraska Medicine patients and its employees with IBD. As a result, the Nebraska Medicine specialty pharmacy team is keen to consider how such data could generate insights of benefit for the broader IBD community.

The June multistakeholder discussion around Nebraska Medicine's novel plan design and data yielded several takeaways:

- **Participants were excited about the potential insights Nebraska Medicine's data could provide on PA in IBD.** The absence of PA requirements for Nebraska Medicine employees combined with the granular level of data available for IBD patients means that Nebraska Medicine may be primed to generate foundational evidence on the benefits of PA removal. One clinician summarized, *"We need hard data to progress PA, and Nebraska Medicine has both clinical disease activity and claims information, which would give us the clearest information on PA."* Stakeholders believed that in a comparative analysis, the health system's employees could serve as a built-in control group against patients on other health plans with PA requirements, and clinicians in particular highlighted the potential value of such an analysis.
- **Time to treatment and disease activity are two measures of interest from various candidates that Nebraska Medicine might readily explore.** Stakeholders considered a list of potential measures of interest that could be explored by leveraging Nebraska Medicine's unique dataset (see table below). While PA-associated treatment delays have been linked to patient complications and increases in healthcare utilization, stakeholders noted that the health system could evaluate the benefits from a lack of treatment delay—or shorter time to treatment—especially in correlation with disease activity. *"If [Nebraska Medicine] could show that shorter time to get on a drug is associated with better outcomes, that would be a clear way to demonstrate why patients should not have the barrier of PA in place,"* one clinician said. A payer echoed this sentiment, stating that *"outcomes data in relation to time to treatment would be highly influential on potential PA removal."*

Table 1. *Illustrative measures addressed in June how*

Stakeholder	Potential measures of interest
Patient	• Time to treatment • Patient reported outcomes • Clinical remission or disease activity
Clinician	• Time spent on PA/admin burden
Self-insured employer/payer	• Employee productivity • Time to treatment/member satisfaction • Administrative cost of PA • Healthcare utilization • Total cost of care (TCOC)

- **Measuring and comparing total cost related to PA remains challenging.** Participants said that quantifying the impact of PA on TCOC would be ideal, especially as purchasers utilize value levers to improve outcomes at lower cost. Yet many also recognized the inherent difficulty of capturing the financial benefit of PA removal: *"What we would be trying to measure is the savings obtained from patients not ending up in the emergency department or in the hospital without PA in play; accurately measuring that is almost impossible."* Furthermore, while Nebraska Medicine may have the necessary data points to closely model the cost implications for its employees, it does not have claims data for a comparison group of patients. *"Normally, hundreds and hundreds of patients are needed to see differences in TCOC, and we don't have claims data from other payers to reach those numbers,"* a participant explained.

In addition to considering the benefit of Nebraska Medicine data to inform community learning about PA and its role in IBD, stakeholders also discussed whether its approach as a self-insured health system could be replicated elsewhere. Purchasers expressed uncertainty about this point: *"This is a fascinating example, but it's a self-contained system and not many purchasers can control as much as [Nebraska Medicine]. I'm not sure this can be scalable."* Furthermore, some noted that plans are likely to focus on *"bigger cost drivers in specialty, such as site of care"* when considering new ways of working.

Despite these caveats, many stakeholders still saw benefit in further exploring how Nebraska Medicine could share or publish its data—particularly on time to treatment and disease activity—to further inform thinking on PA, not just in IBD but in other *"major specialty disease states as well."*

Advancing self-insured employer PA pilots

Payers and self-insured employers currently face external scrutiny about the value and efficiency of PA processes while also grappling with the complexity of value-based care models and the imperative to effectively manage healthcare costs. In some states, legislation has compelled the establishment of "gold-card" programs—programs that remove PA requirements for providers who meet certain criteria. For example, providers in Texas can have future PA waived based on a 90% or higher prior PA approval success rate.[9]

However, questions remain around how PA removal could be more meaningfully tied to high-quality care—in other words, "dynamic gold-card" concepts, where removal of PA requirements could be linked to baseline and ongoing measurement of beneficial patient outcomes. One employer said, *"PA is about whether I trust the provider to Ndo the right thing, so with PA removal, there has to be some way of verifying trust."* As such, meeting participants considered how a dynamic gold-card program, which would modify PA requirements for providers who demonstrate quality, could be implemented.

Of note, numerous companies and initiatives have worked to improve care quality in IBD and could offer potential quality benchmarks for gold-card initiatives. IBD Qorus, a program from the Crohn's and Colitis Foundation, aggregates longitudinal patient- and clinician-reported outcomes from over 60 clinical sites nationally to establish quality-improvement interventions and good practices, which have yielded lower urgent-care utilization and steroid and opioid use.[10] SonarMD and Trellus Health, two IBD-focused digital health platforms, partner with health plans and clinics to provide ongoing patient risk stratification and monitoring to reduce emergency room visits and hospitalizations. More broadly, Embold Health and Surest are developing networks of high-quality providers based on proprietary measures.

With these quality initiatives in mind, stakeholders at the June meeting provided the following reflections on gold-card program opportunities in IBD:

- **Self-insured employers may have the greatest interest in gold-card programs for IBD given the importance of factors such as member satisfaction and productivity.** Employers and other payers are grappling with the challenges of designing and managing risk-bearing agreements with third-party vendors in specialty care. Comparatively, one participant said, *"turning off PA is a simple operational procedure that avoids complicated contracting"* in the eyes of some employers. As such, these employers see the upside of testing how modifying or removing PA can drive improvements in *"clinically oriented patient access and care outcomes."*
- **That said, scale in IBD remains an issue for employers, though some solutions and programs could serve as a useful aggregator.** Even for large, self-insured

employers, the relatively low prevalence of IBD means pilots can be difficult to design: *"Our patients are so distributed that even in the most concentrated markets, there are still not many covered lives with IBD. It's hard to see how a pilot can be expanded to a meaningful population size."* Some noted that initiatives such as IBD Qorus *"could have sufficient numbers"* to achieve meaningful scale and believed that such partnerships may warrant further consideration. However, scale can also be challenging for providers given the diversity of payers and plans: *"Clinical sites work with a lot of different payers, so, practically, how would we implement gold-carding from just one payer?"* Therefore, within a single employer-based pilot, PA removal may not sufficiently reduce the total administrative burden for a provider, though there may be potential patient and purchaser benefits to explore.

- **While quality improvement is important, purchasers noted the need for robust quality *standards* to more confidently consider gold-card initiatives in IBD.** In disease areas such as oncology, purchasers have established networks of *"high-performing providers or centers of excellence*" based on quality benchmarks, which subsequently enable the utilization of various incentives, such as increased rates of reimbursement. However, in IBD, some purchasers noted that further exploration was required for specific measures or features of quality that could be more clearly demonstrated and relied on to inform a dynamic gold-carding method.

Additional PA pilot concepts

While stakeholder discussions during the meeting focused on purchaser gold-carding in relation to provider quality, there may be other viable approaches to dynamic PA modification. The following concepts were offered post-meeting as potential alternatives:

- **Front-end claims-based PA.** This dynamic gold-card approach based on a claims-derived metric would allow select IBD patients to skip the PA process. With an appropriate metric (which would need to be identified and agreed-upon by relevant stakeholders), purchasers could waive PA, with the goal of better enabling therapy optimization to avoid costly utilization, such as hospitalization. There is precedent for this in diabetes, where, as one stakeholder described, *"patients with prescriptions of GLP-1s can skip the PA process with a diabetes diagnosis and fills of other diabetes-related drugs from claims data."*
- **Removal of up front PA with increased back-end utilization management.** Purchasers would agree to remove PA up-front for select IBD therapies to potentially reduce time to therapy and decrease provider administrative burdens. In exchange, purchasers would closely evaluate expected outcomes at predefined periods of time to evaluate effectiveness of therapy, potentially under value-based drug contracts with manufacturers. *"This would essentially be an aggressive utilization-management*

strategy to get patients to therapy quickly but also drive them away from the same therapies if they're not working in an appropriate amount of time," a purchaser said.

- **Removal of PA based on care pathway.** PA removal could be triggered by adherence to care and treatment pathways, which would enable providers to prescribe appropriate treatment without requiring drug-specific PA approvals. This concept would need refinement and further development with clinical experts.
- **Gold-card virtual clinics with existing risk-based contracts.** Given the robust data and insights that purchasers can glean from some third-party vendors (e.g., virtual clinical providers) that already take on financial risk, removing PA for those vendors may be a feasible way to easily assess the impact of PA on patient outcomes within the context of an established contractual relationship.

Building a foundation for change

Moving forward, Tapestry will continue to work with stakeholders from the IBD Shared Value Initiative to tangibly explore the potential benefits and limitations of PA modification or removal. Initially, health systems such as Nebraska Medicine could advance the community's understanding of the overall impact of PA on IBD patients, which could have further relevance for self-insured employers and payers for practical pilots as they consider opportunities for approaches like the "dynamic gold-card" concepts outlined above. The initiative will also continue to serve as a learning forum for diverse stakeholders to address challenges and new approaches to getting the right drug to the right patient at the right time in a US healthcare system still grappling with the transition from volume to value. Overall, there remains strong interest in additional brainstorming among participants and commitment to ongoing cross-stakeholder dialogue.

About Tapestry Networks

Since 2004, Tapestry 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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Appendix 1: Participants

AT&T: Luke Prettol, Principal Benefits Strategy Consultant
Cedars-Sinai Medical Center: Gil Melmed, Co-Director, Clinical Inflammatory Bowel Disease
Crohn's & Colitis Foundation: Cassie Ray, Director of Advocacy; Alandra Weaver, Vice President, Clinical Quality and Research Innovation; James Testaverde, Vice President, IBD Qorus Implementation; Taylor Weyers, Research Coordinator, Program Engagement
Dartmouth-Hitchcock Medical Center: Corey Siegel, Section Chief, Gastroenterology and Hepatology
Elevance: Isaac Burrows, Director, Payment Innovation Design
Geisinger Health Plan: Phil Krebs, Director, Medical Policy and Clinical Guidelines
Nebraska Medicine: Sarah Kuhl-Padgett, Director, Community-based Pharmacy Services; Randy Moore, Clinical Pharmacy Manager; Anthony Donovan, Pharmacist Program Coordinator
Pfizer *(initiative sponsor)*: Debanjali Mitra, Access Strategy and Pricing Franchise Lead; Craig Singewald, Senior Director, US Market Access Lead, Inflammation and Immunology
Purchaser Business Group on Health: Emma Hoo, Former Director of Value-Based Purchasing
Stephens Insurance: Rich Krutsch, Former Senior Vice President, Benefits Strategy
Tapestry Networks: Lindee Goh, Managing Director; Elizabeth Shaughnessy, Executive Director; Joel Ang, Senior Associate; Ashley Vannoy, Project and Event Manager
University of California San Diego: Siddharth Singh, Assistant Professor of Medicine

Endnotes

[1] *Summary of Themes* reflects the 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] 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.

[4] S. G. Salzbrenner, et al., "Influence of Prior Authorization Requirements on Provider Clinical Decision-Making," *American Journal of Managed Care* 29, no. 7 (2023), 331.

[5] David Choi, et al., "Delays In Therapy Associated with Current Prior Authorization Process for the Treatment of Inflammatory Bowel Disease," *Inflammatory Bowel Diseases* 29, no. 10 (2023), 1658–1661.

[6] 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.

[7] Lawrence R. Kosinski and Joel V. Brill, "The Impact of Cascading Accountability on Specialty Practices: Time for a Nested Solution," *Clinical Gastroenterology and Hepatology* 21, no. 2 (2023), 260–263.

[8] Tanya Albert Henry, "9 States Pass Bills to Fix Prior Authorization," *AMA News Wire,* March 8, 2024.

[9] Andis Robeznieks, "New Physician 'Gold Card' Law Will Cut Prior Authorization Delays," *AMA News Wire,* Sept 15, 2021.

[10] Christopher V. Almario, et al., "Health Economic Impact of a Multicenter Quality-of-Care Initiative for Reducing Unplanned Healthcare Utilization Among Patients with Inflammatory Bowel Disease," *American Journal of Gastroenterology* 116, no. 12 (2021), 2459–2464.