Clinical Gastroenterology and Hepatology 2025;23:386–395

REVIEW ARTICLES

The Cost of Inflammatory Bowel Disease Care: How to Make it Sustainable

Johan Burisch,[1,2,3] Jennifer Claytor,[4] Inmaculada Hernandez,[5] Jason Ken Hou,[6,7] and Gilaad G. Kaplan[8]

[1]Gastro Unit, Medical Division, Copenhagen University Hospital - Amager and Hvidovre, Hvidovre, Denmark; [2]Copenhagen Center for Inflammatory Bowel Disease in Children, Adolescents and Adults, Copenhagen University Hospital - Amager and Hvidovre, Hvidovre, Denmark; [3]Department of Clinical Medicine, Faculty of Health and Medical Sciences, University of Copenhagen, Copenhagen, Denmark; [4]Division of Gastroenterology, Mount Sinai Hospital, New York City, New York; [5]Division of Clinical Pharmacy, University of California School of Pharmacy and Pharmaceutical Sciences, La Jolla, San Diego; [6]Center for Innovations in Quality, Effectiveness and Safety (IQuESt), Michael E. DeBakey Veterans Affairs Medical Center, Houston, Texas; [7]Department of Medicine, Section of Gastroenterology and Hepatology, Baylor College of Medicine, Houston, Texas; and [8]Division of Gastroenterology and Hepatology, Cumming School of Medicine, University of Calgary, Calgary, Alberta, Canada

The rising global prevalence of inflammatory bowel diseases (IBDs), such as Crohn's disease and ulcerative colitis, underscores the need to examine current and future IBD care costs. Direct health care expenses, including ambulatory visits, hospitalizations, and medications, are substantial, averaging $9,000 to $12,000 per person annually in high-income regions. However, these estimates do not fully account for factors such as disease severity, accessibility, and variability in health care infrastructure among regions. Indirect costs, predominantly stemming from loss in productivity due to absenteeism, presenteeism, and other intangible costs, further contribute to the financial burden of IBD. Despite efforts to quantify indirect costs, many aspects remain poorly understood, leading to an underestimation of their actual impact. Challenges to achieving cost sustainability include disparities in access, treatment affordability, and the absence of standardized cost-effective care guidelines. Strategies for making IBD care sustainable include early implementation of biologic therapies, focusing on cost-effectiveness in settings with limited resources, and promoting the uptake of biosimilars to reduce direct costs. Multidisciplinary care teams leveraging technology and patient-reported outcomes also hold promise in reducing both direct and indirect costs associated with IBD. Addressing the increasing financial burden of IBD requires a comprehensive approach that tackles disparities, enhances access to cost-effective therapeutics, and promotes collaborative efforts across health care systems. Embracing innovative strategies can pave the way for personalized, cost-effective care accessible to all individuals with IBD, ensuring better outcomes and sustainability.

Keywords: Crohn's Disease; Inflammatory Bowel Diseases (IBD); Ulcerative Colitis.

Inflammatory bowel diseases (IBD) (Crohn's disease [CD] and ulcerative colitis [UC]), affect approximately 7 million people globally.[1] The prevalence of IBD is steadily climbing, approaching 1% in certain industrialized regions, including Europe and North America, within the next decade.[2,3] More patients living with IBD, combined with continuing innovations in IBD therapeutics, diagnostics, and preventative strategies, will inevitably require escalating health care resources. The widening landscape of effectivebiologic and small molecule agents has shifted IBD management toward early, aggressive treatment and treat-to-target approaches.[4,5] These trends place increasing burdens on health care systems and require the development of strategies that ensure the equitable, affordable, and sustainable delivery of IBD care. Herein, we describe the current and future projections of costs of IBD care and discuss measures to foster sustainability and cost reduction.

Current Landscape of IBD Care Costs – The Drivers

Direct Health Care Costs of IBD

Direct health care costs of IBD include ambulatory visits to primary care, specialists (eg, gastroenterologists) and allied health care professionals (eg, dieticians), visits to the emergency department, admissions for hospitalization or surgery, diagnostic investigations (laboratory, radiologic, endoscopy), ancillary products (eg, ostomy appliances, complimentary therapy), and medications[6–8] (Figure 1).

Abbreviations used in this paper: **CD, Crohn's disease; IBD, inflammatory bowel disease; TNF, tumor necrosis factor; UC, ulcerative colitis; U.S., United States; VHA, Veterans Health Administration.**

Most current article

1542-3565
https://doi.org/10.1016/j.cgh.2024.06.049

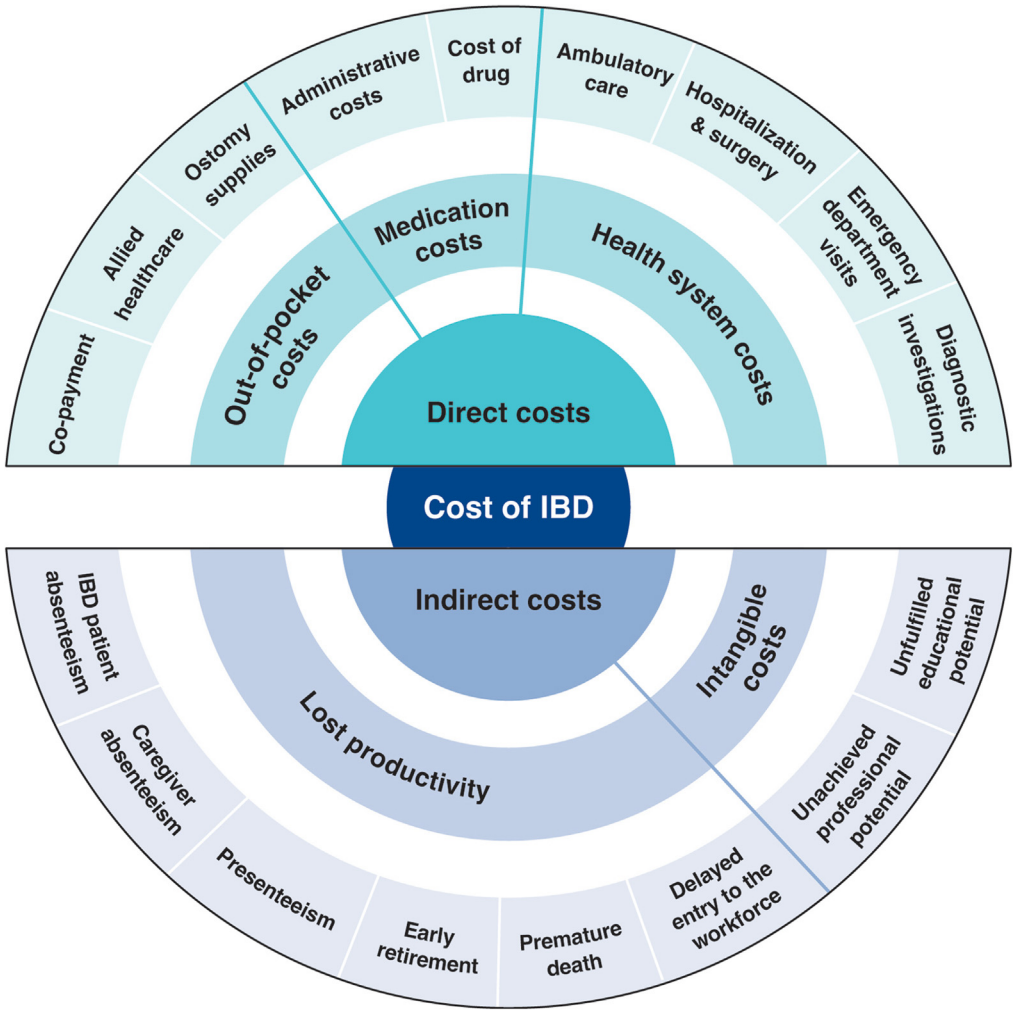

Figure 1. Overall cost of IBD care based on domains of direct and indirect costs. *Allied health care: encompasses a diverse range of specialized professions (ie, dieticians, physical therapists) that collaborate with medical professionals to deliver diagnostic, therapeutic, and support services in patient care.

The *Lancet Gastroenterology & Hepatology* Commission was an international effort to summarize the cost of IBD in high-income regions.[6] The commission estimated that the mean annual direct per person health care cost in 2021 USD was $12,000 for CC and $9,000 for UC.[6] These estimates do not even include disease duration (ie, first years of treatment are typically more expensive than later years), disease severity and phenotypic differences (ie, a small percentage of patients contribute disproportionately to overall health care expenditures),[9] accessibility, penetration, pricing of expensive advanced therapies, or variability in health care infrastructure among regions. Most published studies estimate IBD cost in the era after anti-tumor necrosis factor (TNF) entry, with limited data accounting for increased costs of newer advanced therapies or decreased costs of biosimilars.[6,7]

The per-person annual estimates multiplied by local prevalence data govern annual budget impact analyses per region. For example, the most recent data from the United States (U.S.) estimated that the prevalence of IBD was 0.7% of the population, representing 2.39 million individuals living with IBD.[10] Using the Cost Commission annual average, the annual cost of IBD in the U.S. approximates $50 billion. Regions with specific mean annual estimates can compare their cost with the baseline average from the collective data of high-income settings derived from the Cost Commission. For example, the Crohn's and Colitis Canada 2023 IBD Impact report[11] calculated that the average annual per person cost of IBD in Canada was $10,336 CDN, which translates into a total cost of $3.3 billion CDN,[3,7] given the estimated prevalence of 0.8% (or 330,000 Canadians).

Although variability in annual mean cost was noted in each study, all studies demonstrated a shift over time from costs associated with hospitalizations to costs of medications.[6] In the pre-biologic era, hospitalizations and particularly surgery accounted for more than 50% of direct health care costs of IBD. For example, a population-based inception cohort of patients with IBD in the pre-biologic era in Western European countries and Israel (1993–2004) estimated an annual average cost of IBD of €1,871 per patient, with 53% attributable to hospitalizations.[12] In the pre-biologic era, over 60% of IBD-related costs in the U.S. were related to emergency department visits and hospitalizations, up to $25 billion

annually of direct costs. In 2008, between 27% and 35% of costs were attributed to medications, predominantly 5-ASAs.[13]

Contemporary studies show that the increased penetration of anti-TNF therapies has raised costs of IBD care overall, driven by medication costs.[6] An updated European inception cohort (2010–2015) showed that 75% of patients with CD and 50% of patients with UC were prescribed biologic therapy within 5 years of diagnosis.[14] In Manitoba, the direct health care cost of IBD more than doubled from $3,354 CDN per person per year in 2005 to $7,801 in 2015, largely driven by increased use of anti-TNF therapies.[15] In 2005, 48% of spending was driven by hospitalizations and 34% by medications, compared with 22% and 65% for hospitalizations and medications in 2015, respectively.[15] Recently, costs of administering medications are shifting, with subcutaneous treatments drawing patients from infusion clinics to home-based care. Unfortunately, although home-based infusions reduce infusion-related costs, insurance claims data did not show any significant cost savings with this strategy.[16]

The costs of prescription drugs for IBD vary significantly worldwide, influenced by government regulation of prices and dynamics in the biosimilar market. A particular outlier among high-income countries is the U.S., where manufacturers set prices freely. The lack of nationwide price regulation, coupled with the fragmentation of the U.S. health care system and prolonged market exclusivity periods, result in U.S. drug prices that exceed, on average, international prices by several-fold. With no government negotiation or regulation of drug prices until the recent Inflation Reduction Act, private insurers are left to negotiate directly with pharmaceutical manufacturers via confidential discounts, also known as rebates, which increase opacity in the drug supply chain.[17] Even when insurers are successful at negotiating discounts, patients seldom benefit, as cost-sharing paid at the point-of-sale is based on the full, non-discounted price.[18]

Both hospitalization and surgical rates have decreased over the past 20 years.[19–21] Effective biologic therapies, dysplasia surveillance, and outpatient *Clostridioides difficile* regimens have reduced hospital-related charges.[19,22] Unfortunately, the costs of IBD-related hospitalizations have not fallen as dramatically in the same time span, each costing more today than a decade ago. The biologic era is marked by more complex patients admitted with greater disease severity (eg, medically refractory to biologics, requiring novel agents), decreased access to high-quality care (eg, underserviced area of residence), older age, and a greater burden of comorbidities. Additionally, cost for in-patient care has risen disproportionately to inflation, primarily due to charge inflation in the U.S.[23] Collectively, the rising expense of hospitalization has blunted the cost savings of lower rates of admission. Furthermore, costs may continue to escalate as patients are cycled through multiple ineffective medications, particularly those refractory to biologics, who may require novel agents or dual targeted therapy at higher rates. Although specific interventions, such as early laparoscopic ileocecal resection, may offer cost-effectiveness advantages over treatments like infliximab for ileitis,[24] the overall trend suggests a persistent challenge in managing health care expenses amid evolving treatment landscapes.

Direct health care costs are often viewed separately, paid for by different companies and individuals. However, all costs borne to society are intertwined (Figure 1). The challenge of intertwined costs is that one payer may need to spend more for another payer to save even more. Money spent on drugs that increase direct health care costs are offset in part by lower health care expenditures from reduced hospitalizations and surgeries. Moreover, direct health care expenditures need to be viewed through a lens of indirect costs to an individual and society.

Indirect Costs of IBD

Indirect costs are those attributed to an individual with IBD or society as a whole, stemming from the disease limiting the full potential of a person's contribution to oneself or society.[8,25] Indirect costs of IBD predominantly manifest as loss in productivity, as defined by absenteeism (ie, lost wages from missing work), presenteeism (ie, reduced capacity at work), early retirement, premature death, delayed workforce entry, and other intangible costs (not achieving maximal educational or professional accomplishments).[8,25] Indirect costs do not represent money spent by the health system to care for IBD or by the individual with IBD; rather, these costs are lost by the individual or society (Figure 1).

Measurement of indirect costs is abstract, with less published data available and less comprehensive metrics (ie, limiting domains to "absenteeism" or "presenteeism"). In 2023, the Crohn's and Colitis Canada estimated that the indirect cost of IBD in Canada was $1.51 billion CDN based on absenteeism, presenteeism, unemployment, premature death, and caregiving costs.[25] The cost of absenteeism was based on a survey that showed Canadians with IBD missed more than 4.4 days per year as compared with working age adults without IBD.[26] The excess loss of work was estimated to cost $1,080 annually per working-age adult with IBD. In Canada, approximately 150,000 adults were determined to be employed with IBD in 2023,[3] leading to a budget impact analysis of $163 million lost annually to absenteeism.[26]

A national Swedish study used disability pension and sick leave to define the cost of loss of productivity, which estimated that employable adults with IBD cost society on average $22,000 and $14,000 USD in 2020 for CD and UC, respectively.[27] Among children with IBD, absenteeism in their caregivers was estimated to be €6,272 (2021) in the first year of diagnosis.[28] Presenteeism, or working but not at full capacity, has been poorly studied,

with one study from Finland estimating the cost at €640 per year per patient.[29]

Despite these studies, many aspects of indirect costs to individuals with IBD and society are largely unknown, which ultimately results in an underestimation of the actual indirect costs of IBD. For instance, a young individual with IBD may not achieve their full potential by altering their education, delaying their entry into the workforce, or not achieving their career trajectory. Placing a dollar value on loss of aspirational accomplishment is critical, though inherently unquantifiable.

Challenges in Achieving Cost Sustainability: Disparities, Access, and Affordability

Clearly, cost sustainability in IBD health care is a complex goal, challenged by disparities in access to care and treatment affordability, limited access to cost-effective treatment options, and lack of standardized guidelines for cost-effective care delivery. Additionally, underinsurance can significantly impact the quality of care and lead to difficulties in affording necessary treatments.[30] These obstacles to achieving cost sustainability perpetuate inequalities in health care utilization and outcomes.

IBD is increasing in incidence among racial and ethnic minorities globally.[31] Vulnerable populations, including those from low-income or low socio-economic backgrounds and underserved communities, face barriers like limited access to health care facilities, lack of insurance coverage, and financial constraints, hindering their ability to seek timely and appropriate care.[32] Financial toxicity, a term describing the objective financial burden and subjective financial distress, is common among patients with IBD, and is associated with non-adherence to medication and planned health care utilization.[33] In a Canadian study, patients with a lower socioeconomic status had a higher risk of delayed IBD-specific therapy after their diagnosis, as well as a higher risk of long-term non-use of an IBD-specific drug.[34] A subsequent study from Canada showed that individuals of lower socioeconomic status encountered higher rates of hospitalization, prolonged hospital stays, and increased mortality rates, despite comparable access to IBD-specific medications.[35] Studies from the U.S. and the United Kingdom found that people of color were less likely to be prescribed infliximab.[36–38]

Unplanned health care utilization, including emergency department visits and hospitalizations, drives much of the cost in IBD care.[39] American patients insured by Medicaid[40] or without health insurance generate considerable unplanned health care costs.[41] A U.S. study found that 1 in 8 patients with IBD had food insecurity and lacked adequate social support, which was associated negatively with unplanned health care utilization.[42] These data suggest that low-income status conveys an increased risk of not being able to access timely and effective care, to the detriment of long-term health, disease prognosis, and overall cost.

In regions such as South America and Eastern Europe, access to therapies for IBD is more limited,[43–45] which further complicates efforts to achieve cost sustainability. This lack of affordability not only strains health care budgets but also compromises patients' health outcomes, as they may be unable to access the most effective conventional or advanced treatments for their IBD. Variability in health care provision similarly extends to rural areas, whose smaller populations may have limited access to early diagnosis, diagnostic tools, and specialist care.[46]

Practice variability and adherence to guidelines remain key barriers to achieving sustainable care in IBD.[47–49] Suboptimal adherence to international, evidence-based guidelines is an ongoing problem across various aspects of IBD care.[50–52] The absence of standardized guidelines for cost-effective care delivery presents a formidable challenge in achieving cost sustainability.[6] Even when providers adhere to guidelines, patients may defer or skip high-value care due to high out-of-pocket costs. Furthermore, insurance restrictions, such as prior authorizations and fail-first policies, may still limit appropriate adherence to guidelines or access to effective and high-value care, even for patients with adequate insurance coverage.[53,54]

Strategies for Making IBD Care Sustainable

Early implementation of biologic therapies and achievement of deep, endoscopic remission is recommended by guidelines to minimize long-term complications, malignancies, surgeries, and hospitalizations.[55] However, the availability of biologics and infusion centers is often limited outside of high-resource regions, and some studies have shown similar spending without change in hospitalization rates. The U.S. continues to have higher biologic uptake than Canada and Europe, but at substantially greater expense due to ineffective negotiation with pharmaceutical companies. Herein, we will discuss strategies to prevent hospitalization via rigorous medical treatment targets, to streamline price negotiations in non-national payer systems, and to harness preventative care metrics, patient-reported outcomes, and multidisciplinary teams to improve our overall IBD care.

A Focus on Cost-effectiveness in Settings With Limited Resources

Early treat-to-target paradigms lead to durable, steroid-free remission and improved disease outcomes for patients with IBD.[56] However, there are no guidelines as to when biologic medications can be de-escalated or withdrawn while preventing morbidity,

hospitalization, or need for surgery. The IBD Emerging Nations Consortium describes low biologic uptake in Asia (4% in UC, 13% in CD), greater reliance on thiopurines, and substantially lower direct drug-related costs in Asia than in Europe or North America ($1,051–$3,755, compared with $5,938–$10,484 and $8,053–$13,212). This group recommended discontinuing any biologic within 2 years after initiation, presenting findings that only 32% of patients relapsed at 2 years of follow-up (fewer still, if only considering patients in deep remission).[57] Other lower-cost and evidence-based treatments recommended for low-risk patients include dietary therapy, initial surgery for CD, fecal microbiota transplant for UC, and complimentary therapies. Still, these recommendations take aim at high direct drug, procedural, and monitoring costs without maximizing disease control or indirect, patient-reported outcomes; therefore, they are primarily considerations for resource-limited areas.[57]

Promise of Biologics to Reduce Direct Costs

Using a "top-down" clinical paradigm, guidelines suggest starting biologic medications early to induce remission of moderate-to-severe IBD, thereby reducing risk of complications, surgeries, and hospitalizations and improving quality of life.[55,58] A randomized controlled trial demonstrated a clear benefit in steroid-free and surgery-free remission among patients randomized to top-down vs step-up care (79% vs 15%; $P < .0001$).[58] Still, under 20% of private insurance companies in the U.S. permit the use of first-line biological therapy.[59] Studies have been mixed as to whether the cost savings from hospitalizations and surgeries outweigh the exorbitant costs of biologic medications. A systematic review suggested that biologics were cost-effective in CD for a maximum duration of 2 years.[60] A Canadian group showed increased direct costs over the past decade, with anti-TNF therapies alone now representing 70% of total CD costs and 60% of total UC costs.[15] However, a prospective Danish study with 10-year follow-up showed that biologic use to implement early disease control led to lower direct costs at 10 years. Indirect costs (ie, education, workplace achievement, taxes paid, and sick days taken) were high but not higher than the general population, possibly related to the social support from welfare provisions in Denmark.[61] Such clear data are difficult to obtain in the U.S. due to multi-payer systems and obscure pricing incentives used to reduce market competition from biosimilars.

Biosimilars: Promises, Untapped Possibilities, and Legal Thickets

Biosimilars are clinically comparable, nearly identical versions of molecularly complex biologics that can be marketed after originator biologics lose patent exclusivity. Infliximab biosimilars were introduced first in Europe, taking up 13% of the market share at 2 years and 52% by 5 years.[62] Denmark, availing itself of its universal health system, achieved a remarkable 95.1% adalimumab biosimilar uptake within 4 months, cutting costs by 82.8%.[63]

In the U.S., biosimilar entry and uptake have been relatively modest. This difference is explained by the early lack of regulatory environment, prevention of biosimilar entry by originator manufacturers through several legal approaches, and reimbursement dynamics. First, U.S. biosimilar entry was delayed by the lack of a U.S. Food and Drug Administration regulatory framework. The Biologics Price Competition and Innovation Act established a regulatory framework for the approval of biosimilars. However, biosimilar entry was delayed by several approaches employed by manufacturers of originator biologics to extend market exclusivity periods. A good example is that of Humira (adalimumab). After original patent expiry in 2016, the market entry of adalimumab biosimilars was delayed by 7 years via 165 additional patents that granted additional protected years. This practice has been dubbed a "patent thicket" because of the dense obfuscation of hundreds of patents pertaining to the same product. In addition to slowing the approval process for other novel patents, pharmaceutical companies have been appending "terminal disclaimers" to these patents, meaning the follow-on patents expire when the original patent does. Thus, companies aiming to manufacture biosimilars must design around hundreds of complex, frequently litigated patents. Most patent thickening occurs within the year prior to the original patent's expiration. Among 12 biologics nearing biosimilar competition, 271 patents were filed, 48% of which included terminal disclaimers regarding subtle tweaks on mode of treatment and formulation. In 2022, a bipartisan group of senators attempted to eliminate the use of terminal disclaimers[64]; this practice is already illegal in Europe.

After actual market entry, biosimilar market uptake in the U.S. has been hindered by market dynamics related to the reimbursement of products. Although manufacturers of originator small molecule drugs do not compete with generics after loss of exclusivity, manufacturers of originator biologic products offer confidential discounts to payers, out-competing biosimilars. For example, while the list price for infliximab more than doubled in 2007 to 2018, increased confidential discounts negotiated between manufacturers and insurers actually resulted in decreased net prices.[65] Similar trends have been observed for self-administered biologic products.[66]

The financial Incentives associated with these discounting and reimbursement practices differ across payers, which explains the wide variability of biosimilar uptake across payers in the U.S. For instance, the Veterans Health Administration (VHA) has encouraged

biosimilar switching by designating them for preferred use in the national formulary. However, the VHA is a closed system, the only one in the U.S. with a national formulary. Although these VHA efforts have been more effective than non-VHA academic settings, still only 38% of veterans were switched to biosimilar infliximab within 4 years of launch, despite a potential 81% cost savings.[67] This unrealized potential was attributed to poor provider and patient awareness, poor acceptance of interchangeability, and supply chain limitations.[68,69] The Kaiser Permanente system, the largest integrated delivery system in the U.S., has been more successful at biosimilar adoption.[70] Across the remaining market, however, biosimilars have seen modest adoption, as payers often favor originator biologics with higher list prices and higher discounts than biosimilars. This is particularly the case of Medicare, the largest purchaser of drugs in the U.S.[71] The passage of the Inflation Reduction Act in 2022 should yield savings to Medicare, although medications with a biosimilar available may be exempt. The biologic therapy ustekinumab is 1 of 10 selected products for negotiation in the first year of implementation of the program, which will be expanded to provider-administered drugs in 2028. This Act includes 2 additional drug-related provisions that are relevant to U.S. patients covered under Medicare. First, out-of-pocket costs for self-administered products will be limited at $2,000 per year, which will bring financial relief for patients using self-administered biologic therapies; and second, manufacturers will have to pay back to Medicare increases in prices above inflation, which is expected to slow down post-launch price increases.

Using Teams and Technology to Prevent Hospitalizations

Severe disease, high cost of medications, health care-related anxiety, and low resilience all worsen IBD symptoms. The notion of an "IBD Medical Home" is based on primary care models of patient-centered medical homes under the Affordable Care Act (2010). IBD medical homes integrate a team of physicians, psychologists, social workers, dieticians, and dedicated nurses who proactively monitor high-risk patients, aiming to capture flare symptoms and psychosocial stressors before the patient requires emergent care.

This model was deployed by the University of Pittsburgh Medical Center in partnership with a regional private insurer. Implementation of their University of Pittsburgh Medical Center Total Care–IBD program resulted in 47.3% fewer emergency department visits, 35.9% hospitalizations, and $2,500 savings per patient per year.[72] Quality of life and symptom control also improved. Low quality of life and use of opiates or steroids preceding enrollment predicted hospitalization, prompting focus on targets for early intervention in the psychosocial domain.[73] The University of California Los Angeles targeted "value-oriented care," adding work productivity and activity assessments to regular patient-reported clinical inventories collected. Illinois piloted a proprietary patient symptom index called "SONAR" to capture flares prior to their onset.[74] Still, a single-center randomized controlled trial showed no difference in charges per patient between usual care and a patient-oriented intervention arm, which used a care coordinator for proactive monitoring and individualized multidisciplinary care. This intervention improved patient symptom scores, but both arms over the study period had decreased costs, leaving the true cost-effectiveness of such interventions unclear.[75]

Mount Sinai Hospital demonstrated that early access to such multidisciplinary care among patients just diagnosed with IBD reduced steroid courses and improved clinical remission.[76] Multiple centers dedicate inpatient hospital services to the exclusive care of patients with IBD, coordinating with a dedicated nurse who follows proactively after discharge, reducing costs related to longer hospital stays.[77] These interventions can be particularly effective in reinforcing preventative care guidelines (ie, vaccines, tuberculosis screens, hepatitis B checks), although the data are mixed as to whether electronic medical record-based interventions and dedicated care coordinators consistently reduce steroid course prescriptions.[78] Ongoing cycles of innovation and process to improve quality are central to any true IBD Medical Home.

Outside the U.S., a Canadian telemedicine program saved $47,565 in costs while reducing time to specialist establishment.[72] A Dutch pragmatic, multicenter, randomized controlled trial demonstrated the utility of a nurse-driven telemedicine program that drew upon personalized treatment plans, patient-reported outcome inventories, and health questionnaires, to identify early and intervene upon patients at risk for hospitalization of flare, while not overwhelming the need for gastrointestinal physician visits.[79] This program resulted in lower mean annual costs of €612/patient without changing quality-adjusted life-years.[80] Clearly, multidisciplinary care teams leveraging technology and patient-reported outcomes hold great promise to reduce direct and indirect costs, while putting the patient at the forefront.[81]

Conclusions

As the prevalence of IBD continues to increase, so will the financial burden it places on health care systems across the world. Addressing the increasing direct and indirect costs to patients, their families, and society demands a comprehensive strategy, tackling disparities, access barriers, and cost-effectiveness of therapeutics. It will also require policy reforms that improve access to IBD care (Table 1). Achieving these goals requires actions from health care providers, payers, and regulators. Figure 2 summarizes measures that could be

Table 1. Proposed Policy Reforms to Improve Access to IBD Care and Treatment

Reform prior authorization processes	Regulate the prior authorization process, prevent unnecessary delays through the development of policies that limit pharmacy and provider administrative burden and limit the time window where insurers can decline coverage.
Limitation of utilization management tools	Limit the number of unique products onto which insurers can impose utilization management tools within regulated markets.
Ensure access to manufacturer patient assistance programs	Advocate for policies that limit insurers' ability to prevent patients from benefiting from manufacturer patient assistance programs (copayment accumulators).
Address uninsured populations	Call for comprehensive measures to address health care coverage gaps and provide access to affordable health care services and medications, facilitating excellent longitudinal medical care for all patients with IBD, regardless of insurance status, socioeconomic background, comorbid substance use disorder or psychiatric illness, or ethnic, racial, or other minority status.
Enhance transparency in drug pricing	Advocate for policies that promote transparency in drug pricing, including disclosure requirements for manufacturers and insurers.
Introduce value-based reimbursement structures	Foster the deployment of formulary and benefit design structures that are based on value (ie, where cost-sharing and utilization management tools are not guided by drug costs alone, but also by value only but rather by value in a given patient population).
Support eHealth expansion	Advocate for the expansion of eHealth services and reimbursement policies to improve access to care for patients with IBD, particularly those in underserved or rural areas.
Invest in IBD research and education	Call for increased funding for research on IBD prevention, treatment, and management, as well as public education initiatives to raise awareness of IBD and the available resources.

IBD, Inflammatory bowel disease.

implemented by clinicians and to help in reducing costs. By embracing innovative approaches and collaborative efforts across health care systems, we can advance towards a future where personalized, cost-effective care is accessible to all individuals living with IBD, ensuring better outcomes and greater sustainability.

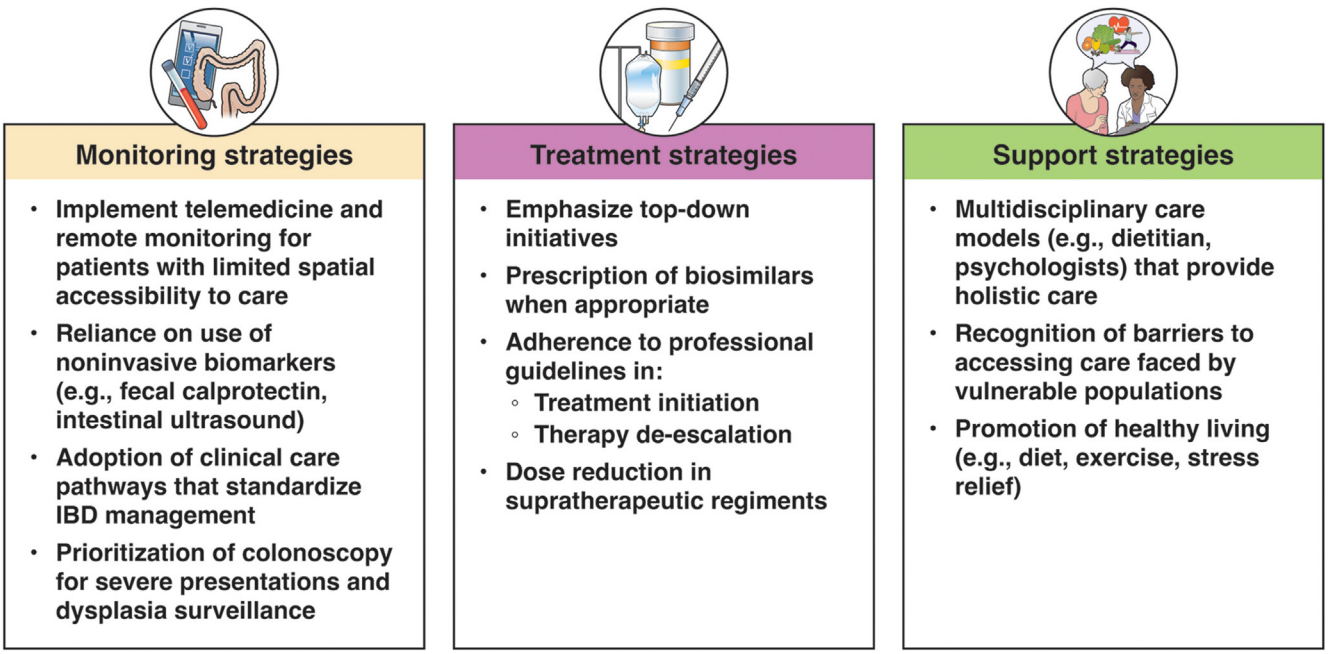

Figure 2. Strategies for cost reduction in the clinical treatment of IBD.

References

1. GBD 2017 Inflammatory Bowel Disease Collaborators. The global, regional, and national burden of inflammatory bowel disease in 195 countries and territories, 1990-2017: a systematic analysis for the Global Burden of Disease Study 2017. Lancet Gastroenterol Hepatol 2020;5:17–30.
2. Dorn-Rasmussen M, Lo B, Zhao M, et al. The incidence and prevalence of paediatric- and adult-onset inflammatory bowel disease in Denmark during a 37-year period: a nationwide cohort study (1980-2017). J Crohns Colitis 2023;17:259–268.
3. Coward S, Benchimol EI, Bernstein CN, et al. Canadian Gastro-Intestinal Epidemiology Consortium (CanGIEC). forecasting the incidence and prevalence of inflammatory bowel disease: a Canadian nationwide analysis. Am J Gastroenterol 2024; 119:1563–1570.
4. Peyrin-Biroulet L, Sandborn W, Sands BE, et al. Selecting Therapeutic Targets in Inflammatory Bowel Disease (STRIDE): determining therapeutic goals for treat-to-target. Am J Gastroenterol 2015;110:1324–1338.
5. Thompson W, Argáez C. Early biologic treatment versus conventional treatment for the management of Crohn's disease: a review of comparative clinical effectiveness and cost-effectiveness. Ottawa: Canadian Agency for Drugs and Technologies in Health, 2019.
6. Burisch J, Zhao M, Odes S, et al. The cost of inflammatory bowel disease in high-income settings: a Lancet Gastroenterology & Hepatology Commission. Lancet Gastroenterol Hepatol 2023;8:458–492.
7. Kuenzig ME, Coward S, Targownik LE, et al. The 2023 impact of inflammatory bowel disease in canada: direct health system and medication costs. J Can Assoc Gastroenterol 2023;6:S23–S34.
8. Garaszczuk R, Yong JHE, Sun Z, et al. The economic burden of cancer in Canada from a societal perspective. Curr Oncol 2022; 29:2735–2748.
9. Limsrivilai J, Stidham RW, Govani SM, et al. Factors that predict high health care utilization and costs for patients with inflammatory bowel diseases. Clin Gastroenterol Hepatol 2017; 15:385–392.e2.
10. Lewis JD, Parlett LE, Jonsson Funk ML, et al. Incidence, prevalence, and racial and ethnic distribution of inflammatory bowel disease in the United States. Gastroenterology 2023;165:1197–1205.e2.
11. Windsor JW, Kuenzig ME, Murthy SK, et al. The 2023 Impact of Inflammatory Bowel Disease in Canada: executive summary. J Can Assoc Gastroenterol 2023;6:S1–S8.
12. Odes S, Vardi H, Friger M, et al. European Collaborative Study on Inflammatory Bowel Disease. Cost analysis and cost determinants in a European inflammatory bowel disease inception cohort with 10 years of follow-up evaluation. Gastroenterology 2006;131:719–728.
13. Kappelman MD, Rifas-Shiman SL, Porter CQ, et al. Direct health care costs of Crohn's disease and ulcerative colitis in US children and adults. Gastroenterology 2008;135:1907–1913.
14. Burisch J, Vardi H, Schwartz D, et al; Epi-IBD group. Health-care costs of inflammatory bowel disease in a pan-European, community-based, inception cohort during 5 years of follow-up: a population-based study. Lancet Gastroenterol Hepatol 2020; 5:454–464.
15. Targownik LE, Kaplan GG, Witt J, et al. Longitudinal trends in the direct costs and health care utilization ascribable to inflammatory bowel disease in the biologic era: results from a Canadian population-based analysis. Am J Gastroenterol 2020; 115:128–137.
16. Giese-Kim N, Wu M, Dehghan M, et al. Home infliximab infusions are associated with suboptimal outcomes without cost savings in inflammatory bowel diseases. Am J Gastroenterol 2020;115:1698–1706.
17. Hernandez I, Hung A. A primer on brand-name prescription drug reimbursement in the United States. J Manag Care Spec Pharm 2024;30:99–106.
18. Dickson S, Gabriel N, Hernandez I. Changes in net prices and spending for pharmaceuticals after the introduction of new therapeutic competition, 2011-19. Health Aff (Millwood) 2023; 42:1062–1070.
19. King JA, Underwood FE, Panaccione N, et al. Trends in hospitalisation rates for inflammatory bowel disease in western versus newly industrialised countries: a population-based study of countries in the Organisation for Economic Co-operation and Development. Lancet Gastroenterol Hepatol 2019;4:287–295.
20. Chen Y-M, Chen YJ, Ho W-H, et al. Classifying chest CT images as COVID-19 positive/negative using a convolutional neural network ensemble model and uniform experimental design method. BMC Bioinformatics 2021;22:147.
21. Tsai L, Nguyen NH, Ma C, et al. Systematic review and meta-analysis: risk of hospitalization in patients with ulcerative colitis and Crohn's disease in population-based cohort studies. Dig Dis Sci 2022;67:2451–2461.
22. Murthy SK, Begum J, Benchimol EI, et al. Introduction of anti-TNF therapy has not yielded expected declines in hospitalisation and intestinal resection rates in inflammatory bowel diseases: a population-based interrupted time series study. Gut 2020;69:274–282.
23. Hartman M, Martin AB, Whittle L, et al; National Health Expenditure Accounts Team. National health care spending in 2022: growth similar to prepandemic rates. Health Aff (Millwood) 2024; 43:6–17.
24. Ponsioen CY, Groof EJ de, Eshuis EJ, et al; LIR!C study group. Laparoscopic ileocaecal resection versus infliximab for terminal ileitis in Crohn's disease: a randomised controlled, open-label, multicentre trial. Lancet Gastroenterol Hepatol 2017;2:785–792.
25. Kuenzig ME, Im JHB, Coward S, et al. The 2023 Impact of Inflammatory Bowel Disease in Canada: indirect (individual and societal) and direct out-of-pocket costs. J Can Assoc Gastroenterol 2023;6:S16–S22.
26. Kuenzig E, Lebenbaum M, Mason J, et al. Costs of missed work among employed people with inflammatory bowel disease: a cross-sectional population-representative study. Int J Popul Data Sci 2022;7:S546.
27. Khalili H, Everhov ÅH, Halfvarson J, et al; SWIBREG Group. Healthcare use, work loss and total costs in incident and prevalent Crohn's disease and ulcerative colitis: results from a nationwide study in Sweden. Aliment Pharmacol Ther 2020; 52:655–668.
28. Klomberg RCW, Aardoom MA, Kemos P, et al; PIBD-SET Quality consortium. High impact of pediatric inflammatory bowel disease on caregivers' work productivity and daily activities: an international prospective study. J Pediatr 2022;246:95–102.e4.
29. Rankala R, Mattila K, Voutilainen M, et al. Inflammatory bowel disease-related economic costs due to presenteeism and absenteeism. Scand J Gastroenterol 2021;56:687–692.
30. Berinstein JA, Cohen-Mekelburg SA, Steiner CA, et al. Variations in health care utilization patterns among inflammatory bowel disease patients at risk for high medical service utilization enrolled in high deductible health plans. Inflamm Bowel Dis 2021;27:771–778.

31. Aniwan S, Harmsen WS, Tremaine WJ, et al. Incidence of inflammatory bowel disease by race and ethnicity in a population-based inception cohort from 1970 through 2010. Therap Adv Gastroenterol 2019;12:1756284819827692.
32. Barnes EL, Loftus EV Jr, Kappelman MD. Effects of race and ethnicity on diagnosis and management of inflammatory bowel diseases. Gastroenterology 2021;160:677–689.
33. Nguyen NH, Khera R, Dulai PS, et al. National estimates of financial hardship from medical bills and cost-related medication nonadherence in patients with inflammatory bowel diseases in the United States. Inflamm Bowel Dis 2021;27:1068–1078.
34. Melesse DY, Targownik LE, Singh H, et al. Patterns and predictors of long-term nonuse of medical therapy among persons with inflammatory bowel disease. Inflamm Bowel Dis 2015; 21:1615–1622.
35. Bernstein CN, Walld R, Marrie RA. Social determinants of outcomes in inflammatory bowel disease. Am J Gastroenterol 2020; 115:2036–2046.
36. Jackson JF 3rd, Dhere T, Repaka A, et al. Crohn's disease in an African-American population. Am J Med Sci 2008;336:389–392.
37. Nguyen GC, Laveist TA, Harris ML, et al. Racial disparities in utilization of specialist care and medications in inflammatory bowel disease. Am J Gastroenterol 2010;105:2202–2208.
38. Farrukh A, Mayberry JF. Apparent discrimination in the provision of biologic therapy to patients with Crohn's disease according to ethnicity. Public Health 2015;129:460–464.
39. Nguyen NH, Khera R, Ohno-Machado L, et al. Annual burden and costs of hospitalization for high-need, high-cost patients with chronic gastrointestinal and liver diseases. Clin Gastroenterol Hepatol 2018;16:1284–1292.e30.
40. Axelrad JE, Sharma R, Laszkowska M, et al. Increased healthcare utilization by patients with inflammatory bowel disease covered by Medicaid at a tertiary care center. Inflamm Bowel Dis 2019;25:1711–1717.
41. Rubin DT, Feld LD, Goeppinger SR, et al. The Crohn's and Colitis Foundation of America survey of inflammatory bowel disease patient health care access. Inflamm Bowel Dis 2017; 23:224–232.
42. Nguyen NH, Khera R, Ohno-Machado L, et al. Prevalence and effects of food insecurity and social support on financial toxicity in and healthcare use by patients with inflammatory bowel diseases. Clin Gastroenterol Hepatol 2021;19:1377–1386.e5.
43. Putrik P, Ramiro S, Kvien TK, et al; Working Group. 'Equity in access to treatment of rheumatoid arthritis in Europe.' Inequities in access to biologic and synthetic DMARDs across 46 European countries. Ann Rheum Dis 2014;73:198–206.
44. Péntek M, Lakatos PL, Oorsprong T, et al; Crohn's Disease Research Group. Access to biologicals in Crohn's disease in ten European countries. World J Gastroenterol 2017;23:6294–6305.
45. Balderramo D, Quaresma AB, Olivera PA, et al. Challenges in the diagnosis and treatment of inflammatory bowel disease in Latin America. Lancet Gastroenterol Hepatol 2024;9:263–272.
46. Cyr ME, Etchin AG, Guthrie BJ, et al. Access to specialty healthcare in urban versus rural US populations: a systematic literature review. BMC Health Serv Res 2019;19:974.
47. Jackson BD, Cruz P De. Quality of care in patients with inflammatory bowel disease. Inflamm Bowel Dis 2019;25:479–489.
48. Massuger W, Moore GTC, Andrews JM, et al. Crohn's & Colitis Australia inflammatory bowel disease audit: measuring the quality of care in Australia. Intern Med J 2019;49:859–866.
49. Kaazan P, Li T, Seow W, et al. Assessing effectiveness and patient perceptions of a novel electronic medical record for the management of inflammatory bowel disease. JGH Open 2021; 5:1063–1070.
50. Reddy SI, Friedman S, Telford JJ, et al. Are patients with inflammatory bowel disease receiving optimal care? Am J Gastroenterol 2005;100:1357–1361.
51. Jackson BD, Con D, Liew D, et al. Clinicians' adherence to international guidelines in the clinical care of adults with inflammatory bowel disease. Scand J Gastroenterol 2017;52:536–542.
52. Schoepfer A, Bortolotti M, Pittet V, et al. The gap between scientific evidence and clinical practice: 5-aminosalicylates are frequently used for the treatment of Crohn's disease. Aliment Pharmacol Ther 2014;40:930–937.
53. Constant BD, Long MD, Scott FI, et al. Insurer-mandated medication utilization barriers are associated with decreased insurance satisfaction and adverse clinical outcomes: an Inflammatory Bowel Disease Partners Survey. Am J Gastroenterol 2024.
54. Yadav A, Foromera J, Feuerstein I, et al. Variations in health insurance policies regarding biologic therapy use in inflammatory bowel disease. Inflamm Bowel Dis 2017;23:853–857.
55. Turner D, Ricciuto A, Lewis A, et al; International Organization for the Study of IBD. 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 2021;160:1570–1583.
56. Colombel JF, Panaccione R, Bossuyt P, et al. Effect of tight control management on Crohn's disease (CALM): a multicentre, randomised, controlled phase 3 trial. Lancet 2017; 390:2779–2789.
57. Banerjee R, Raghunathan N, Pal P. Managing inflammatory bowel disease: what to do when the best is unaffordable? Lancet Gastroenterol Hepatol 2023;8:396–398.
58. Noor NM, Lee JC, Bond S, et al; PROFILE Study Group. A biomarker-stratified comparison of top-down versus accelerated step-up treatment strategies for patients with newly diagnosed Crohn's disease (PROFILE): a multicentre, open-label randomised controlled trial. Lancet Gastroenterol Hepatol 2024; 9:415–427.
59. Anderson KL, Anand R, Feuerstein JD. Insurance companies' poor adherence to guidelines for moderate-to-severe ulcerative colitis/Crohn's disease management. Am J Gastroenterol 2024.
60. Pillai N, Dusheiko M, Maillard MH, et al; Swiss IBD Cohort Study Group. The evolution of health care utilisation and costs for inflammatory bowel disease over ten years. J Crohns Colitis 2019; 13:744–754.
61. Lo B, Vind I, Vester-Andersen MK, et al. Direct and indirect costs of inflammatory bowel disease: ten years of follow-up in a Danish population-based inception cohort. J Crohns Colitis 2020;14:53–63.
62. Chen AJ, Gascue L, Ribero R, et al. Uptake of infliximab biosimilars among the Medicare population. JAMA Intern Med 2020;180:1255–1256.
63. Jensen TB, Kim SC, Jimenez-Solem E, et al. Shift from adalimumab originator to biosimilars in Denmark. JAMA Intern Med 2020;180:902–903.
64. Tu SS, Goode R, Feldman WB. Biologic patent thickets and terminal disclaimers. JAMA 2024;331:355–357.

65. San-Juan-Rodriguez A, Gellad WF, Good CB, et al. Trends in list prices, net prices, and discounts for originator biologics facing biosimilar competition. JAMA Netw Open 2019;2:e1917379.
66. Ferris LK, Gellad WF, Hernandez I. Trends in list and net prices of self-administered systemic psoriasis therapies manufactured by US-based pharmaceutical companies. JAMA Dermatol 2020; 156:1136–1138.
67. Baker JF, Leonard CE, Re V Lo, et al. Biosimilar uptake in academic and Veterans Health Administration settings: influence of institutional incentives. Arthritis Rheumatol 2020;72:1067–1071.
68. Gibofsky A, Evans C, Strand V. Provider and patient knowledge gaps on biosimilars: insights from surveys. Am J Manag Care 2022;28:S227–S233.
69. Jacobs I, Singh E, Sewell KL, et al. Patient attitudes and understanding about biosimilars: an international cross-sectional survey. Patient Prefer Adherence 2016;10:937–948.
70. Lang MB, Awsare S, Joyce K, et al. How lawmakers can achieve savings from biosimilars: lessons from Kaiser Permanente. Heal Aff Forefr, 2023. Available at: https://www.healthaffairs.org/content/forefront/lawmakers-can-achieve-savings-biosimilars-lessons-kaiser-permanente. Accessed June 6, 2024.
71. Kozlowski S, Flowers N, Kwist A, et al. Uptake and competition among biosimilar biological products in the US Medicare fee-for-service population. J Gen Intern Med 2022;37:4292–4294.
72. Regueiro M, Click B, Anderson A, et al. Reduced unplanned care and disease activity and increased quality of life after patient enrollment in an inflammatory bowel disease medical home. Clin Gastroenterol Hepatol 2018;16:1777–1785.
73. Szigethy EM, Allen JI, Reiss M, et al. White Paper AGA: the impact of mental and psychosocial factors on the care of patients with inflammatory bowel disease. Clin Gastroenterol Hepatol 2017;15:986–997.
74. Kosinski LR, Brill J, Regueiro M. Making a medical home for IBD patients. Curr Gastroenterol Rep 2017;19:20.
75. Berinstein JA, Cohen-Mekelburg SA, Greenberg GM, et al. A care coordination intervention improves symptoms but not charges in high-risk patients with inflammatory bowel disease. Clin Gastroenterol Hepatol 2022;20:1029–1038.e9.
76. Ungaro RC, Ho M, Stanley S, et al. Sa1761. An interdisciplinary care program for recently diagnosed inflammatory bowel disease patients is associated with increased clinical remission rates and lower steroid use. Gastroenterology 2020;158:S413.
77. Sack C, Phan VA, Grafton R, et al. A chronic care model significantly decreases costs and healthcare utilisation in patients with inflammatory bowel disease. J Crohns Colitis 2012;6:302–310.
78. Fudman DI, Perez-Reyes AE, Niccum BA, et al. Interventions to decrease unplanned healthcare utilization and improve quality of care in adults with inflammatory bowel disease: a systematic review. Clin Gastroenterol Hepatol 2022; 20:1947–1970.e7.
79. Jong MJ de, Meulen-de Jong AE van der, Romberg-Camps MJ, et al. Telemedicine for management of inflammatory bowel disease (myIBDcoach): a pragmatic, multicentre, randomised controlled trial. Lancet 2017;390:959–968.
80. Jong MJ de, Boonen A, Meulen-de Jong AE van der, et al. Cost-effectiveness of telemedicine-directed specialized vs standard care for patients with inflammatory bowel diseases in a randomized trial. Clin Gastroenterol Hepatol 2020;18: 1744–1752.
81. Patel KB, Turner K, Alishahi Tabriz A, et al. Estimated indirect cost savings of using telehealth among nonelderly patients with cancer. JAMA Netw Open 2023;6:e2250211.

Correspondence
Address correspondence to: Johan Burisch, MD, PhD, DMSC, Gastrounit, Medical Division, Hvidovre Hospital, Kettegårds alle 30, DK-2650 Hvidovre, Denmark. e-mail: johan.burisch@regionh.dk.

Conflicts of interest
These authors disclose the following: Johan Burisch reports personal fees from AbbVie; grants and personal fees from Janssen-Cilag; personal fees from Celgene; grants and personal fees from MSD; personal fees from Pfizer; grants and personal fees from Takeda; grants and personal fees from Tillots Pharma; personal fees from Samsung Bioepis; grants and personal fees from Bristol Myers Squibb; grants from Novo Nordisk; personal fees from Pharmacosmos; personal fees from Ferring; and personal fees from Galapagos. Inmaculada Hernandez reports consulting fees from Bristol-Myers Squibb and Pfizer. Jason Ken Hou has received research funding from Redhill Biosciences, Janssen, Abbvie, Celgene, Genentech, Eli Lilly, Lycera, and Pfizer Inc; and has served as a consultant for Eli Lilly. Gilaad G. Kaplan has received honoraria for speaking or consultancy from AbbVie, Amgen, Janssen, Pfizer, and Takeda; has received grants for research from Ferring and for educational activities from AbbVie, Bristol Myers Squibb, Ferring, Fresenius-Kabi, Janssen, Pfizer, Takeda. He shares ownership of a patent (Treatment of Inflammatory Disorders, Autoimmune Disease, and PBC. UTI Limited Partnership, assignee. Patent WO2019046959A1. PCT/CA2018/051098. 7 Sept. 2018). The remaining authors disclose no conflicts.

Funding
Jason Ken Hou is supported by a grant from VA Health Services Research and Development (IIR 19-045); he is also supported in part with resources at the VA HSR&D Center for Innovations in Quality, Effectiveness, and Safety (#CIN 13-413), at the Michael E. DeBakey VA Medical Center, Houston, Texas.