WHITE PAPER

Clinical and Managed Care Perspectives in Inflammatory Bowel Disease: Closing the Gap

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In June 2023, as part of the GI ReConnect conference, a multidisciplinary group of 14 experts from across the United States convened to discuss clinical and managed care perspectives on the management of inflammatory bowel disease (IBD). This paper summarizes the key points of these discussions, with the aim of providing an educational foundation for delivering quality care for IBD in an increasingly cost-conscious environment.

GastroIntestinal Health Foundation

IBD Management: An Evolving Landscape in a Cost-Conscious Environment

Crohn's disease and ulcerative colitis (UC) are chronic inflammatory bowel diseases (IBD) characterized by relapsing but progressive courses and a high incidence of complications. These diseases affect approximately 3 million people in the United States,[1] or over 1% of the population,[1,2] with an estimated 70,000 new cases diagnosed each year.[3] Diagnosed commonly before age 35,[3] IBD often leads to a lifetime of chronic symptoms, complications, treatment, and disability that incur high healthcare utilization and cost.

Fortunately, better understanding of the pathophysiology and natural history of IBD have paved the way for medical advances that have improved outcomes and are shifting the care of IBD from the hospital to the community.[4] The introduction of anti-tumor necrosis factor (TNF) therapies at the turn of the 21st century revolutionized the medical management of IBD, leading to improved disease control and clinical outcomes.[5,6] Multiple classes of biologics and targeted small molecule therapies have subsequently been approved for use in IBD, with more than 20 therapies now available to treat patients with these disabling conditions (Figure 1). All of these treatments have distinct features that may make them preferred options for certain populations, such as the safety advantages associated with vedolizumab and ustekinumab or the convenience of oral administration with tofacitinib and upadacitinib.[7–10]

The explosion of new treatment options for IBD has been accompanied by evolving treatment goals and strategies aimed at slowing disease progression with the hope of altering the natural history of the condition.[12,13] The observation that inflammation can persist in the absence of symptoms has led to the realization that treating to symptom resolution alone may leave active disease and is not sufficient to alter long-term remission or complication rates.[14]

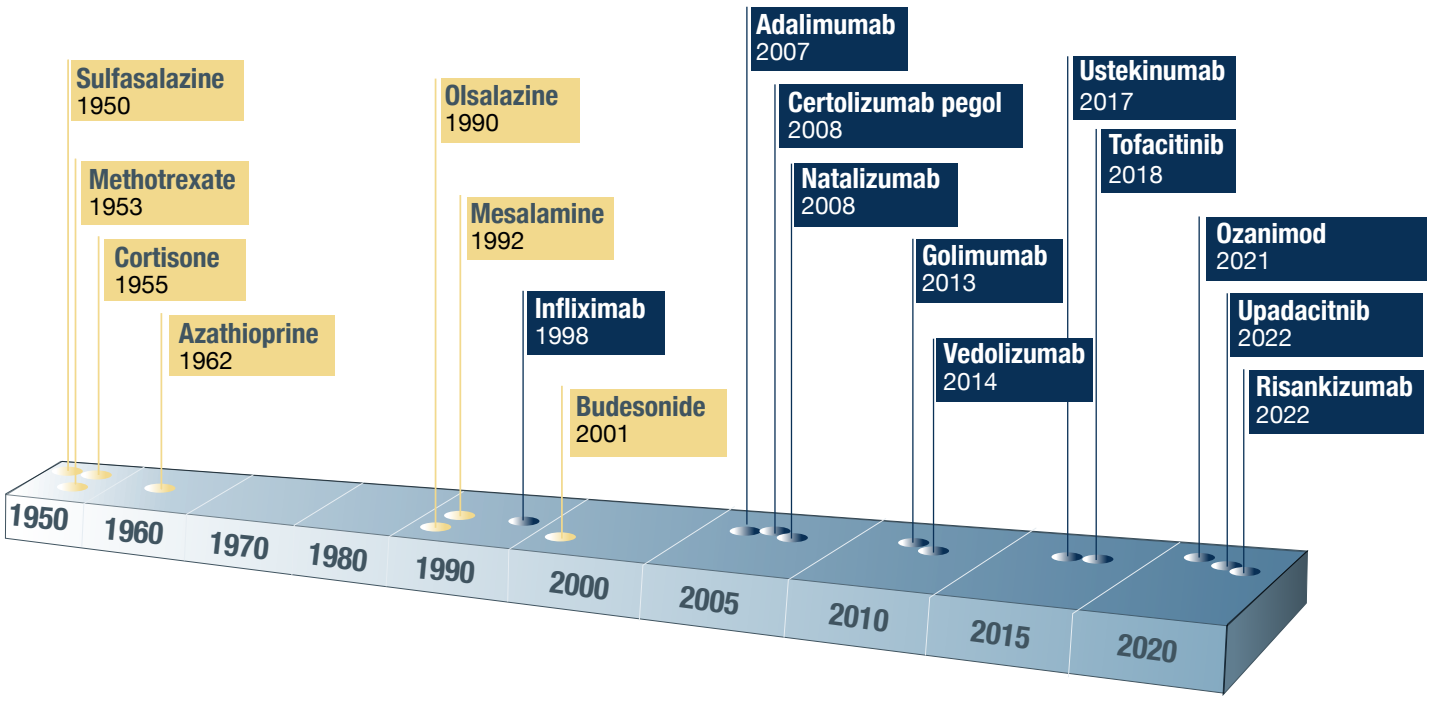


Figure 1. History of medication introduction or approval for IBD in the United States.[11]

In parallel, data have demonstrated that early treatment can mitigate long-term complications, while conversely, delays in diagnosis and/or treatment are associated with higher risk of complications.[15,16] Accordingly, treatment paradigms are shifting to emphasize early intervention and top-down strategies, treat-to-target, and tight control approaches aimed at achieving early and long-lasting remission of both clinical symptoms and endoscopic inflammation (ie, deep remission).[17] Risk stratification and prognostication are important in determining initial therapies, with early aggressive treatment recommended for patients at risk for an unfavorable disease course and a more conventional step-up approach used for those with fewer risk factors for progression.[15,18–20]

The Pharmacoeconomic Burden of IBD

The advances in IBD management have occurred across an environment of increasing health care costs in the United States. Health care spending in the US, which now accounts for over 18% of gross domestic product, continues to outpace the growth of the economy.[21,22] Indeed, total national health expenditures in 2021 reached $4.3 trillion, or $12,914 per person, reflecting an increase of more than 500% in spending since 1970.[22]

The high public health burden associated with the care of IBD has been well documented, with significant costs compared with other chronic diseases (Figure 2)[23] and non-IBD controls.[24] In a study designed to estimate the lifetime incremental costs of IBD, a Markov model was used to simulate expected treatment costs from diagnosis to death based on administrative claims data from 2008 to 2015.[23] Analysis of these data estimated expected lifetime total costs of $498 billion and $377 billion in 2016 US dollars for patients with prevalent Crohn's disease and UC, respectively. Not surprisingly, lifetime costs are particularly high for patients who received a diagnosis of IBD at a younger age (<11 years). Outpatient costs accounted for the highest proportion of total incremental cost in both conditions, followed by inpatient and pharmacy costs (Figure 3).

Other studies evaluating the annual costs of care for IBD confirm the high and rising cost of caring for the disease. A systematic review of studies assessing the financial burden of IBD reported that patients with IBD incurred direct, out-of-pocket annual costs ranging from $7,824 to $41,829, with the cost of Crohn's disease considerably higher than that of UC.[25] In an analysis of data from 52,782 patients with IBD in the Optum Research Database from 2007 to 2016, patients with IBD incurred more than 3 times higher direct costs of care compared with non-IBD

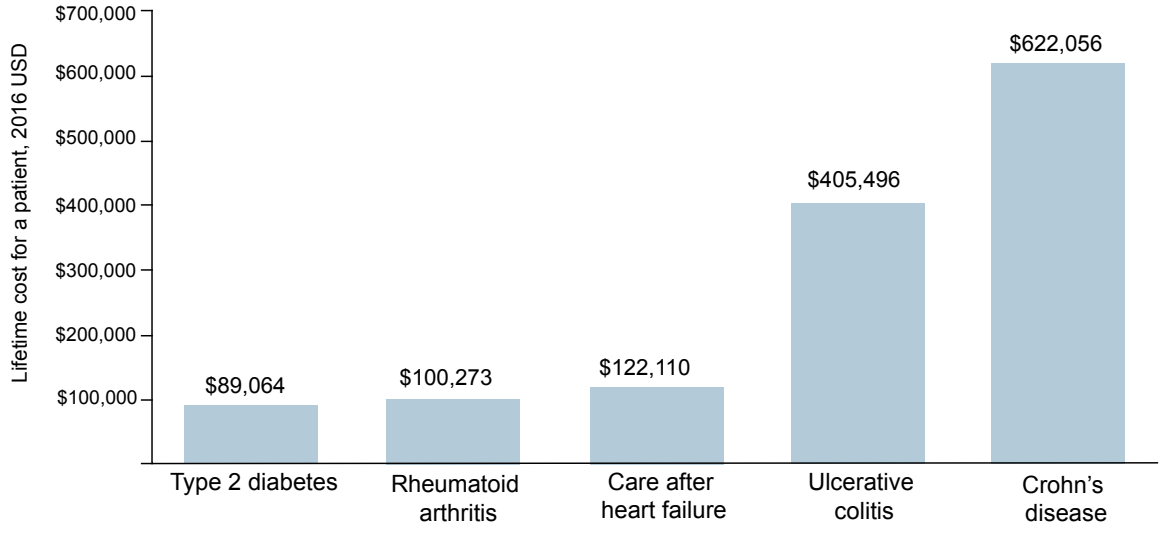


Figure 2. Comparison of published lifetime estimates for a patient across different diseases.[23]

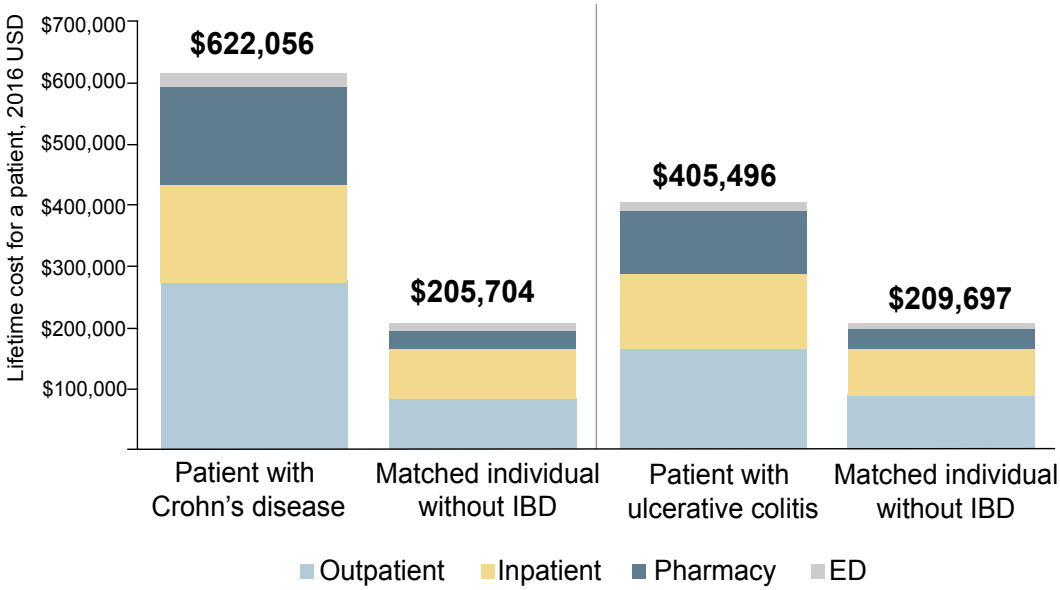


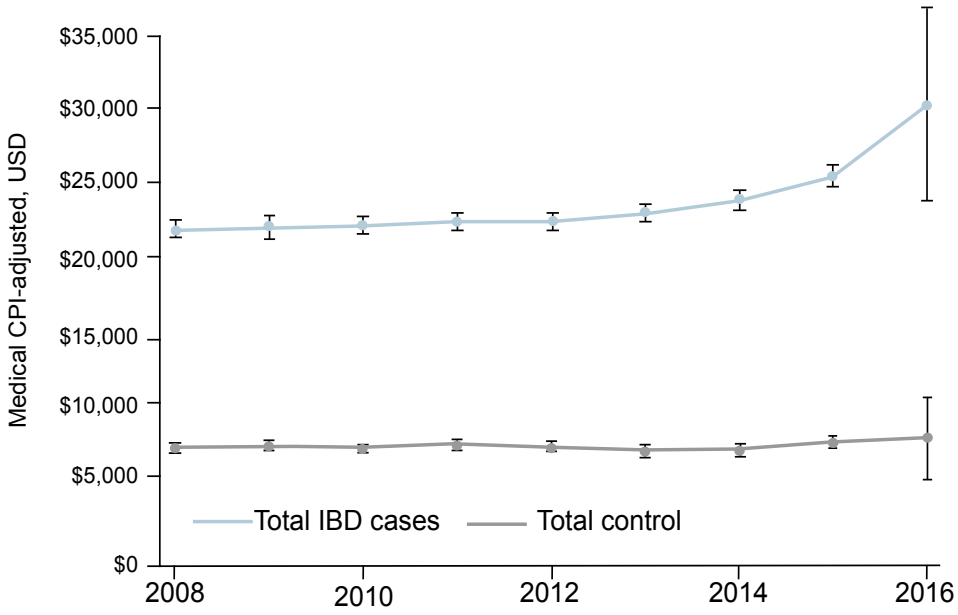
Figure 3. Average lifetime cost and incremental cost for a patient with Crohn's disease and a patient with ulcerative colitis.[23]
ED, emergency department; USD, US dollars.

controls ($22,987 vs $6956 per-member per year paid claims) and more than twice the out-of-pocket costs.[24] Trend analysis of these data indicated that despite stable costs before the year 2012, all-cause IBD costs increased significantly after 2013 (**Figure 4**). Similarly, a study of a nationally representative sample of patients with IBD (N=641) found that median total annual health care expenditures for IBD nearly doubled from 1998 to 2015.[26]

The economic burden of IBD reflects both the direct costs of managing the disease and the indirect costs related to the effects of the disease on the economic productivity of patients and their caregivers.[25,27] These costs, in turn, are driven by multiple factors that drive the total cost of the disease (**Figure 5**).[27] Overall, higher costs of care have been associated with Crohn's disease than UC, and with patients with active disease or severe symptoms than those in remission or with low symptom burden.[25,28] As with other chronic diseases, most of the total IBD health care burden is attributed to a minority (25% to 30%) of patients,[29] with pharmacy costs, anemia, mental health disorders, and ED visits recognized as key cost drivers among these patients.[24] The increased proportion of spending attributed to pharmacy costs represents a shift from the historical drivers of inpatient admissions and surgeries, and likely reflects the introduction of and increasing use of biologics in clinical practice.[26]

Estimates of indirect costs associated with IBD vary considerably,[25] with one study reporting annual indirect costs of up to $312 million. Presenteeism has been identified as the most prevalent contributor to the indirect costs of IBD, an important reality given that this condition affects predominantly younger working-age adults.[25] Analysis of data from 1543 patients in the CorEvitas' IBD Registry, a longitudinal pharmacovigilance registry of US adults with IBD, indicated that although work impairment increased with IBD severity, impairments in work productivity due to fatigue, pain, and anxiety/depression were present even among patients with remission.[28] Financial distress is common among patients with IBD, and has been significantly associated with lower education level, lower household income, public insurance, comorbid illness, IBD severity, and food insecurity.[25]

Figure 4. Longitudinal trends in all-cause costs of IBD.[24]
CPI, Consumer Price Index.



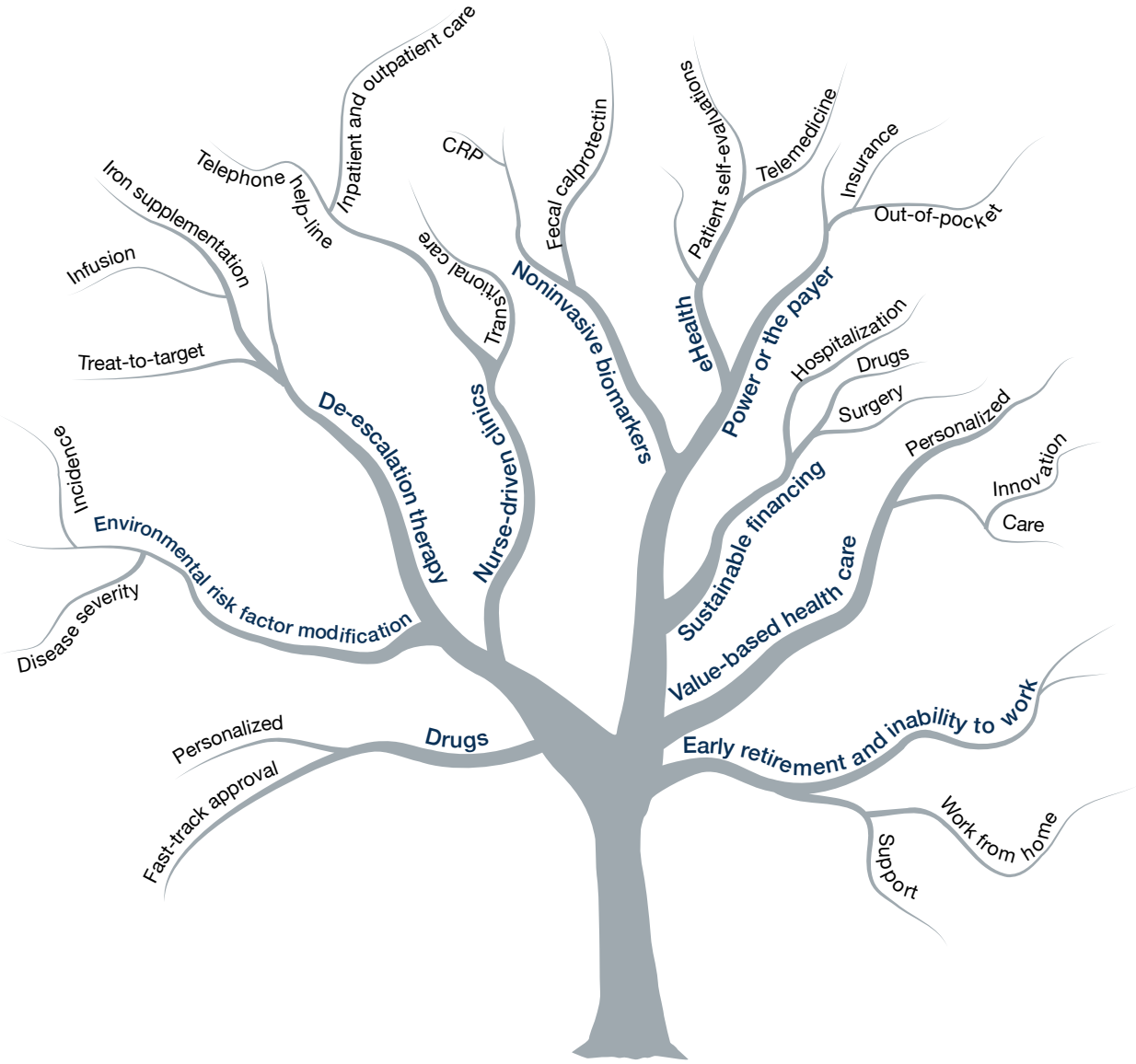


Figure 5. Drivers of direct and indirect cost in IBD.[27]

Delivering Quality Care in IBD: The Role of Clinical Practice Guidelines

The increasing cost of managing IBD in the face of unsustainable cost growth in US health care underscores the need for collaboration between key stakeholders from the health care, payer, industry, and government sectors to deliver high-quality, high-value care for patients and their families.[24,26,27] Developing evidence-based clinical guidelines is one strategy for standardizing and reducing variability of care, with the hope of improving the appropriateness and outcomes of treatment while controlling costs.[27] Additionally, guidelines influence policy, with strong recommendations having the potential for incorporation into quality improvement initiatives or affecting insurance reimbursement.[30]

How are guidelines developed?

Before the advent of evidence-based medicine,[31] clinical practice guidelines were developed through informal consensus of experts. Beginning with the Delphi method in the 1960s, a number of formal consensus methods were introduced that aimed to obtain the most reliable of consensus of a group of experts and minimize bias.[32,33] With the emergence of evidence-based medicine in the 1980s,[30] the emphasis on clinical practice guidelines has increasingly shifted toward how they are developed, with a focus on multidisciplinary input that is based on a systematic review of published research and that explicitly links the recommendations to the supporting evidence.[34]

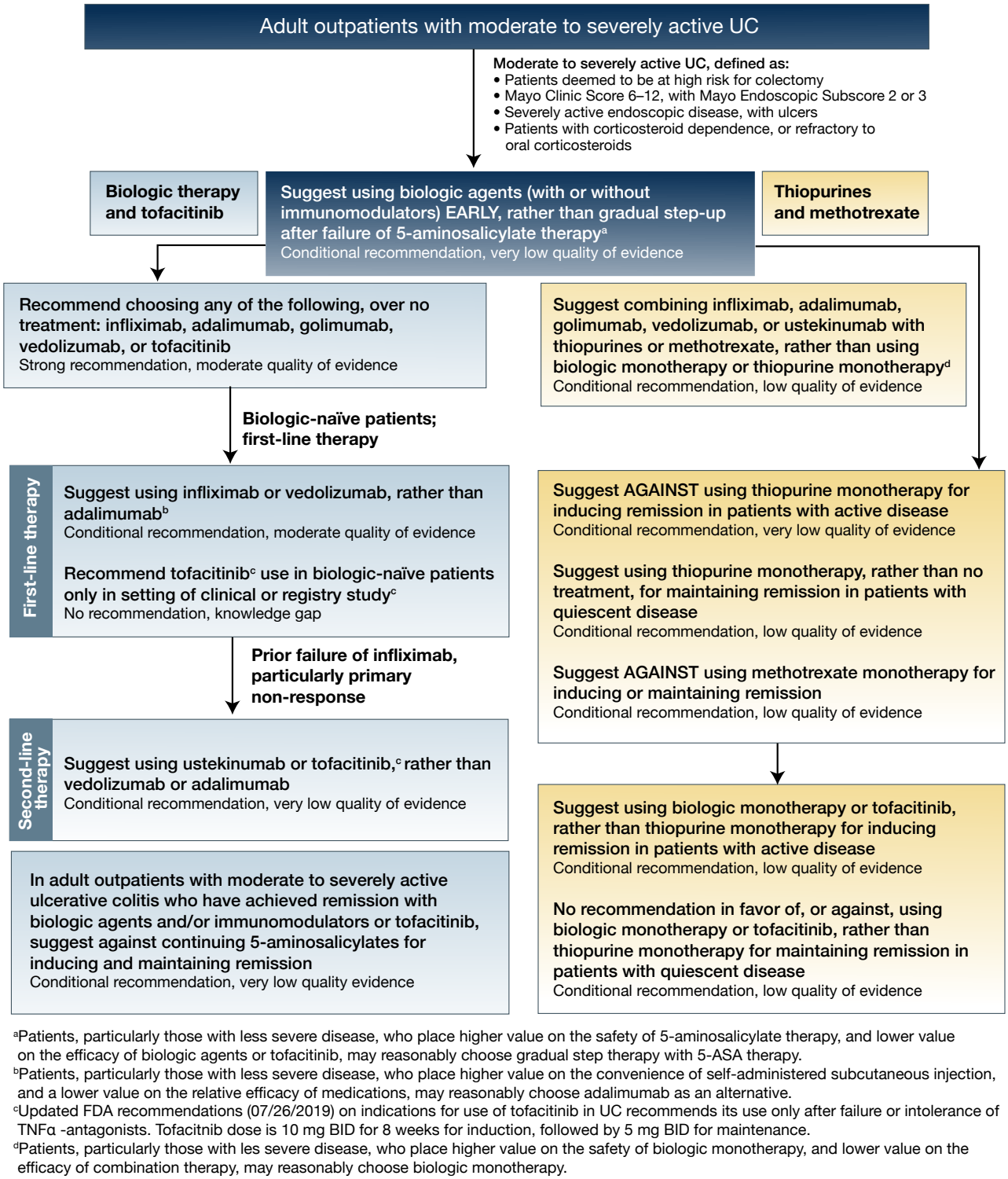
Today, the process of developing clinical practice guidelines begins with identifying and refining the topic, determining the clinical questions that will be addressed, and defining the composition of the guidelines panel.[34–36] The next key step is conducting a systematic review of the evidence, with the literature identified according to an explicit search strategy and then evaluated against consistent methodologic standards.[34] Appraising the quality of evidence is critical to determine the degree to which studies are susceptible to bias, and thus the degree of support they provide for the strength of recommendations. In addition to bias, other factors that can decrease the quality of evidence include inconsistency, indirectness, and imprecision.[35] Many classification schemes exist for assessing levels of evidence, with most employing a hierarchical approach based on the type of data generated.

After the quality of the evidence is assessed, recommendations are developed and graded to differentiate those based on strong evidence from those based on weak evidence.[34] This information is intended to provide the user with an estimate of the group's confidence that following the recommendation will produce the desired health outcome.[36] As with levels of evidence, many classification schemes have been developed for grading recommendations. The GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach is commonly used to grade the strength of recommendations and has been adopted as the standard by many guideline developers and organizations, including the American Gastroenterological Association (AGA) and the American College of Gastroenterology (ACG).[33,37,38] The GRADE approach typically grades the strength of recommendations as either strong or weak, also known as conditional or discretionary.[30,35] While the GRADE approach acknowledges that expertise is required to interpret any form of evidence, it considers that opinion is an interpretation of rather than a form of evidence.[35]

Once recommendations are developed and graded, the guidelines are then made available for public policy evaluation. Lastly, the guidelines are submitted for peer review and published.

Overview of IBD guidelines

Multiple international and national clinical practice guidelines are available to guide clinicians in various aspects of IBD management.[12,20,37,39–41] Clinical guidelines for the management of Crohn's disease and UC have been published by both the ACG[12,20] and the AGA.[37,41,42] Consistent with evolving management approaches in IBD, both the ACG and the AGA recognize clinical and endoscopic remission (ie, mucosal healing) as important goals of treatment.[12,20,37,41] Although specific recommendations vary, IBD guidelines have evolved toward an individualized, risk-stratified approach, with the



[a]Patients, particularly those with less severe disease, who place higher value on the safety of 5-aminosalicylate therapy, and lower value on the efficacy of biologic agents or tofacitinib, may reasonably choose gradual step therapy with 5-ASA therapy.
[b]Patients, particularly those with less severe disease, who place higher value on the convenience of self-administered subcutaneous injection, and a lower value on the relative efficacy of medications, may reasonably choose adalimumab as an alternative.
[c]Updated FDA recommendations (07/26/2019) on indications for use of tofacitinib in UC recommends its use only after failure or intolerance of TNFα -antagonists. Tofacitnib dose is 10 mg BID for 8 weeks for induction, followed by 5 mg BID for maintenance.
[d]Patients, particularly those with les severe disease, who place higher value on the safety of biologic monotherapy, and lower value on the efficacy of combination therapy, may reasonably choose biologic monotherapy.

Figure 6. AGA clinical decision support tool for treatment of moderate to severely active UC.[37]

early integration of biologic therapy for high-risk patients.[7,15,20,37,41] Importantly, the AGA guidelines recommend early introduction of biologic therapies in patients with moderate to severe disease, rather than delaying their use until after failure of conventional therapies (ie, 5-aminosalicylates and/or corticosteroids)(Figures 6 and 7).[37,41] This change reflects the potential that using minimally effective agents for a prolonged duration allows for continued inflammation and the development of tissue

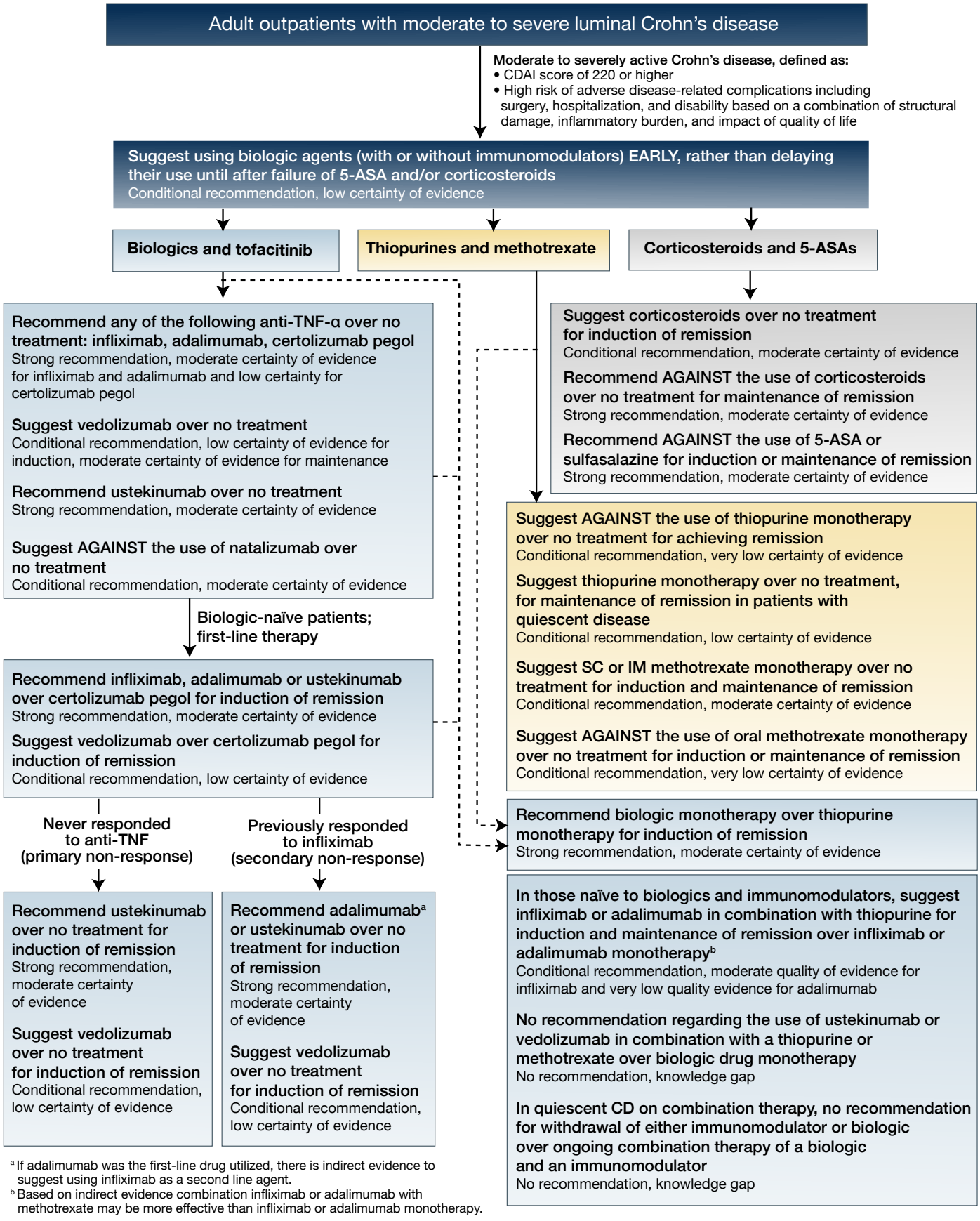


Figure 7. AGA clinical decision support tool for treatment of moderate to severely active Crohn's disease.[41]

Are IBD guidelines being followed?

Although IBD guidelines favor the early use of biologics in appropriate patients,[37,41] recent evidence indicates that the most effective therapies are being used in a small proportion of patients.[45] Using claims data from 44,379 adult patients with IBD, <1% of patients with UC and <5% of patients with Crohn's disease were initially treated with biologics.[45] Significantly fewer patients followed treatment pathways that included biologic therapies compared with nonbiologic therapies (6% vs 94% for UC; 19% vs 81% for Crohn's disease, both $P<0.05$). Initiation of therapy with 5-aminosalicylates was associated with longer time until biologic initiation (median of 616 and 486 days for Crohn's disease and UC, respectively) compared with other pharmacologic therapies (Figure 8).

Similarly, data from an international survey involving 1368 patients with CD, 1030 patients with UC, and 654 physicians indicated that while up to half of patients reported ever being treated with an anti-TNF agent, <20% had received an anti-integrin or ustekinumab, and only 5% had received a JAK

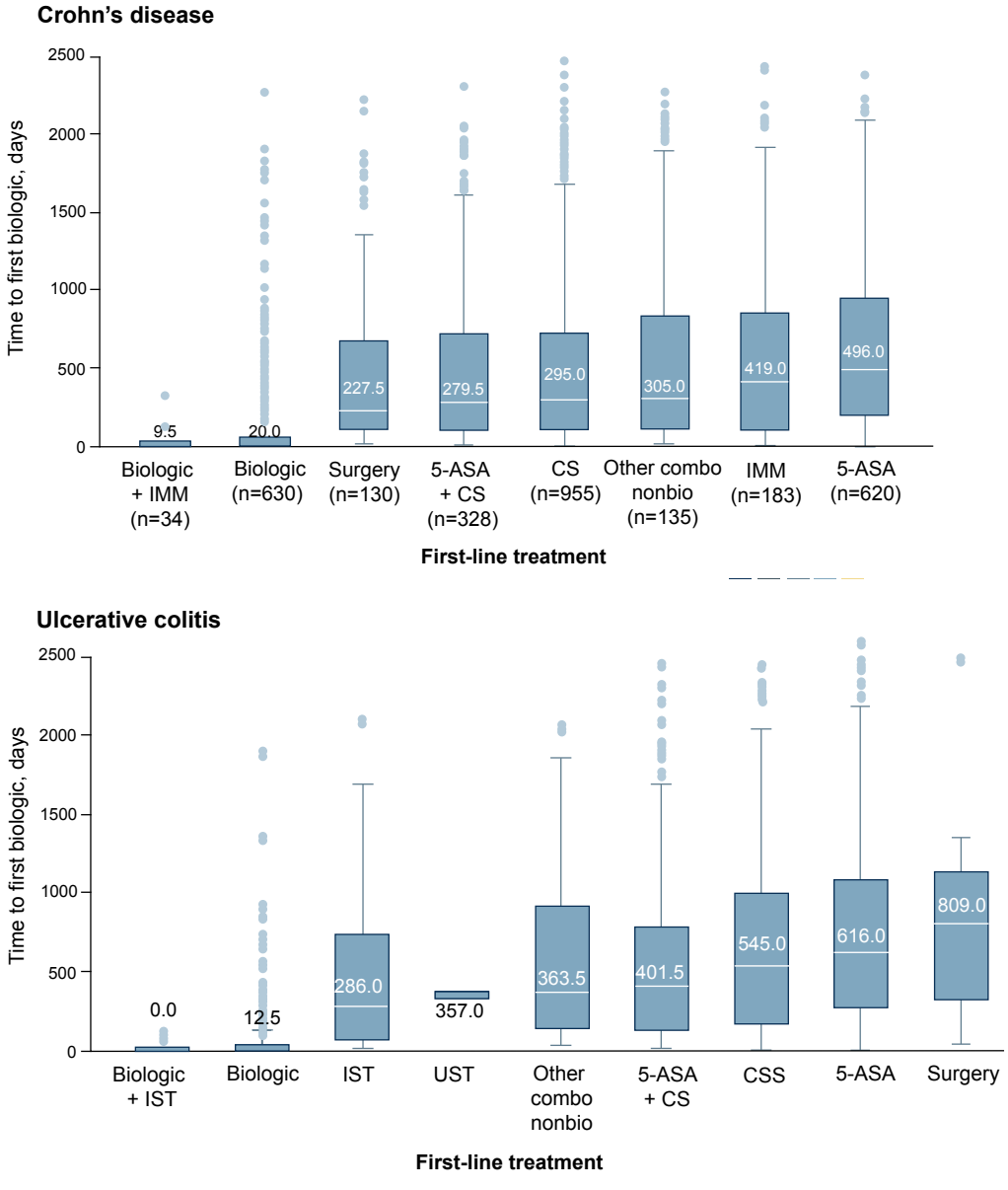


Figure 8. Time to first biologic therapy for patients with IBD, by first-line treatment.[45]
ASA, aminosalicylate; CS, corticosteroid; IMM, immunomodulator; IST, immunosuppressant therapy; other combo nonbio, other combination with a nonbiologic.

inhibitor (Figure 9).[46] Another analysis of data from 325 patients with IBD at a US tertiary care center indicated that providers without specific IBD interest and training were 2.5 times less likely to prescribe biologics than dedicated IBD providers (OR=0.42, 95% CI 0.15–0.79; *P*=0.007).[47]

In addition to suboptimal use of advanced therapies, significant variation in guideline adherence and the quality of IBD care has been described in multiple studies.[48–50] A retrospective analysis of insurance claims data highlighted a number of indicators of potential unsuccessful or suboptimal therapy among a large population of IBD patients enrolled in a commercially managed care health plan.[51] In addition to frequent dose and treatment changes with all therapy classes, prolonged corticosteroid use, hospitalization, and/or surgery were noted in a considerable proportion of patients (Figure 10). Other evidence indicates that patients continue to be treated late in their disease course, despite growing evidence of the benefit of early intervention with advanced therapies.[49]

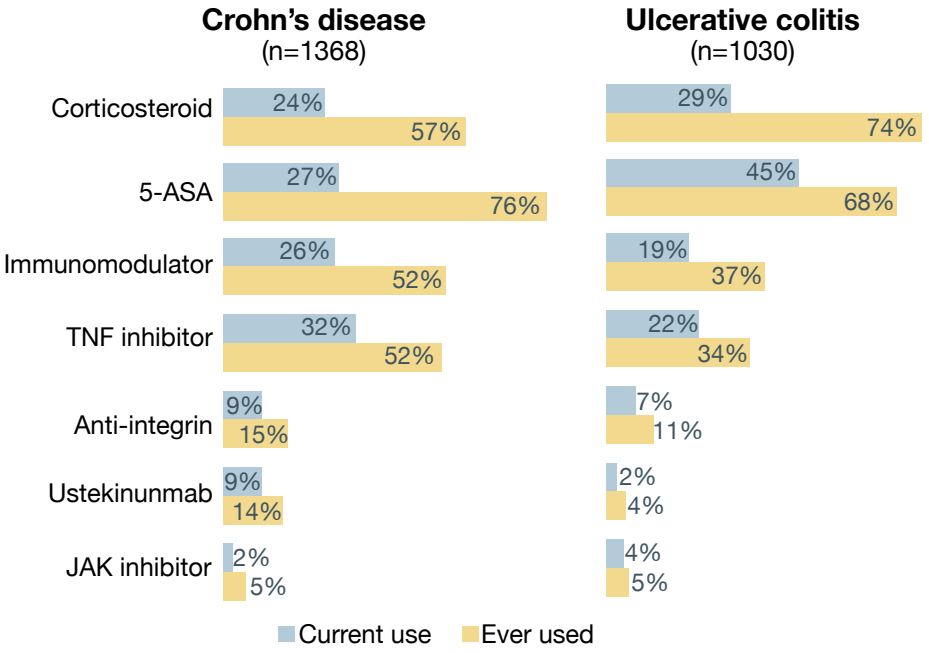


Figure 9. Biologic use among patients with IBD.[46]
ASA, aminosalicylate; JAK, januse kinase; TNF, tumor necrosis factor.

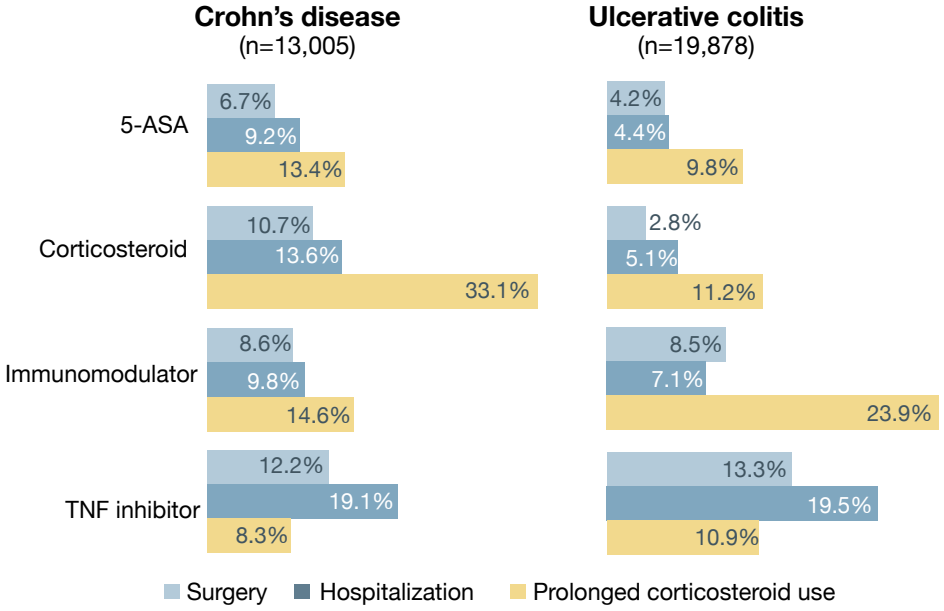


Figure 10. IBD-related surgery, hospitalization, and prolonged corticosteroid use among patients with Crohn's disease with suboptimal treatment.[51]
ASA, aminosalicylate; JAK, januse kinase; TNF, tumor necrosis factor.

Barriers to Translating Guidelines into Clinical Practice

With multiple guidelines in the US available to guide IBD management,[12,20,37,41,42,52] the growing volume of recommendations can become overwhelming for providers as well as payers. Indeed, IBD guidelines in the US at the time of writing collectively offer more than 180 recommendations. While many recommendations overlap and provide similar guidance, some are conflicting. Others may be complex and/or difficult to follow. Despite a high level of confidence in the quality of guidelines, gastroenterologists have identified time constraints and specific recommendations being difficult to remember as important barriers to adherence in clinical practice.[53,54]

Are guidelines generalizable?

Guideline recommendations are primarily based on evidence from randomized, controlled trials (RCTs) that are designed with strict inclusion criteria to create homogeneous study populations.[27] Although these criteria help ensure internal validity of the results, they cannot always be extrapolated to the general population encountered in real-world practice. For example, a retrospective cohort study found that nearly 70% of the 206 patients seen in an outpatient referral practice would not have qualified to participate in the pivotal RCTs of biologics at the time.[55] The most common reasons for not being eligible for trial participation were stricturing or penetrating Crohn's disease, high doses of steroids, comorbidities, and previous exposure to biologics.

Another gap between guidelines and clinical practice is the lack of recommendations regarding common off-label practices, such as dose escalation of biologics. Given the lack of industry support for studies outside of approved usage, evidence for off-label dose escalation of biologics is typically derived from post-hoc retrospective studies or small investigator-initiated studies. This type of low-grade evidence is insufficient support for guideline statements, leaving a void for clinicians regarding these practices.

The problem of prior authorization

Despite the improved patient outcomes associated with the use of biologic agents in IBD, the high direct costs of these therapies have led to complex payer policies that require pre- or re-authorization of therapies.[56] Although designed to encourage cost-effective use of health care services, the prior authorization (PA) process has become a growing burden and important source of frustration for physicians, their staff, and their patients.[57–59] A survey of 1001 physician conducted in 2021 by the American Medical Association found that physicians and their staff complete an average of 45 PAs per week, requiring nearly 2 business days (14 hours) of their time.[57] Despite 35% of the respondents having staff who worked exclusively on PAs, 88% of physicians described the burden of PA as high or extremely high. In a smaller study focusing on 156 physician and advanced practice provider members of the ACG, 94% of the respondents reported the burden of PAs to be high or extremely high.[59]

In addition to administrative burden, the PA process may lead to delays in care that are inconsistent with evidence-based recommendations and may contribute to adverse patient outcomes.[57–61] In the AMA survey, 94% of physicians reported care delays due to PA, and 80% reported that the process can at least sometimes lead to treatment abandonment.[57] Further, 31% of the respondents reported that PA criteria are rarely or never evidence-based. In the ACG survey, more than half of the respondents reported choosing inferior treatments at least weekly due to the perceived PA burden of preferred agents, and a similar proportion had patients who experienced serious adverse events due to PA-related delays in care.[59]

Similar impact of the PA process on management has been described in IBD. In a review of 50 insurance policies in the United States, 98% of the policies were inconsistent with the AGA guidelines for managing IBD.[62] Only 2% of UC policies and 10% of Crohn's disease policies allowed for early initiation of biologic therapy to reduce the risk of complications. Over one-third of policies required the failure of 2 drugs before a biologic could be considered, potentially exposing patients to longer courses of

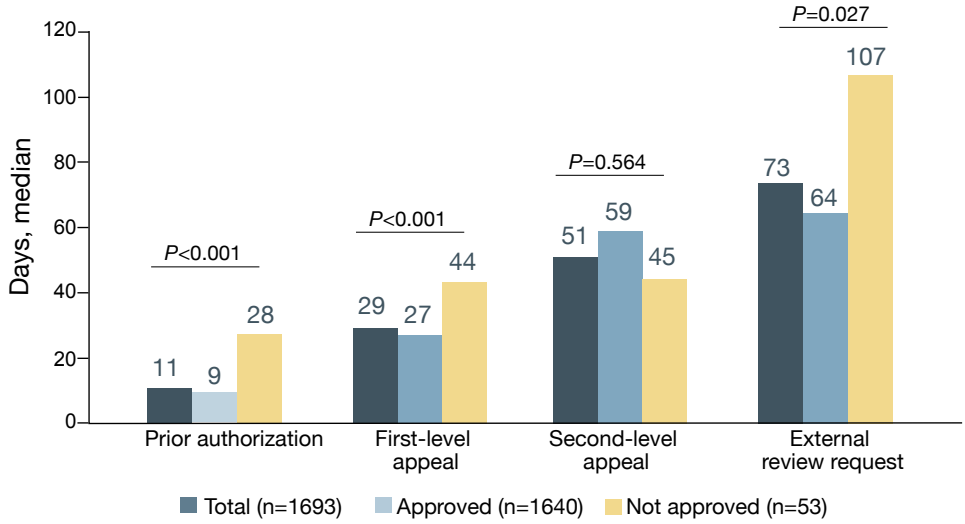


Figure 11. Days to determination by insurance.[58]
IQR, interquartile ratio.

corticosteroids and placing them at risk of developing complications from active ongoing inflammation.

More recently, the PA process has been found to lead to significant delays in care in both pediatric and adult patients with IBD.[60,63] A retrospective analysis of 1693 PAs submitted at the University of Chicago Medicine from October 2020 to October 2021 reported substantial delays in care, although 97% of PAs were eventually approved (Figure 11).[58] Interestingly, dose escalation requests had the lowest rate of approvals, and one-third of the denials were for continuation of therapy in stable patients. Similarly, a retrospective cohort study of 190 pediatric patients with IBD reported a 10.2-day and 24.6-day increase in biologic initiation time associated with PA and complicated PAs, respectively.[60] Further, PAs were associated with a 12.9% increased likelihood of IBD-related health care utilization within 180 days of biologic recommendation and a 14.1% increased likelihood of corticosteroid dependence by 90 days. These data translated to about 1 potentially avoidable health care utilization outcome for every 8 patients requiring PA.

Addressing the Barriers to Optimal Care in IBD in a Cost-Conscious Environment

Taken collectively, the evidence regarding the increasing cost of IBD care, the PA process for biologics, and the suboptimal quality of care in these patients highlights the need to educate clinicians regarding strategies for communicating with payers, navigating managed care requirements, and leveraging resources to improve patient outcomes. Given the considerable proportion of nursing and clerical time spent obtaining PAs, it is essential that nurses and other members of the care team in GI practices are educated regarding practical strategies and tools to minimize access barriers to biologic therapies and ultimately improve patient care.

Harmonizing clinical practice guidelines

The disconnect between treatment approaches in current IBD guidelines and payer policies[62] highlights the need to develop usable, guideline-informed tools that can help facilitate PA while discouraging policies from withholding effective therapies from patients.[64] Despite the availability of multiple IBD guidelines,[12,20,37,41] a harmonized guideline that represents standard-of-care treatment and is updated regularly does not exist. Such a document could serve as the basis for common standards of treatment and clinical algorithms that could improve

efficiency, help identify patients more likely to respond to a given therapy, and reduce discrepant decisions across payers.[64] Although a simple, harmonized guideline should be evidence-based, there is also a need for real-world evidence after drug approval to better inform optimal treatment strategies that reflect routine clinical practice rather than clinical trial settings.[27] Key aspects of therapy that need to be addressed include dose escalation of biologics for patients who require more intensive therapy and the appropriate sequencing of therapies.

Re-evaluating and streamlining the PA process

The AGA,[65] ACG,[66] and multiple IBD experts,[58–60] have called for the PA process to be re-evaluated and streamlined to reduce burden on clinical practices and prevent delays in patient care. Payers have been urged to realign the PA process with its initial objective of preventing misuse of high-cost medications in specific, medically inappropriate situations.[58–60] An important step in realigning this goal is for the basis of PA approvals to shift from FDA approval alone to evidence-based approaches for patients who may require more intensive therapy that may not be consistent with FDA-labeled indications or dosing.[58] Insurers are encouraged to avoid automatic denials that lead to unnecessary delays in care and to reconsider policies that deny continuation requests for patients who are well established on therapy.[58] Indeed, longer-term approvals for patients on maintenance therapy should be considered, particularly given the chronicity of IBD and the infrequent dosage schedules of many biologics (eg, every 8 weeks).

Several strategies for streamlining PA have been proposed (Table 1).[67] Audit-based strategies, or gold-carding, is a system where clinicians who have been deemed high-performing have PA requirements lifted for a specified time period. Electronic and automated processes should be used to reduce administrative burden, while proactive authorization can be used to flag patients with certain diagnoses or treatments for preapproval for downstream tests or therapies. Additionally, clinical decision support mechanisms can be leveraged to provide PA-related information when information regarding patient care is documented in the electronic health record, informing clinicians in real time if PA is warranted.

Providers are encouraged to advocate for changes to the medication approval process at both the national and state levels through collaboration with state boards and societies.[56] Collaborating with individual patients and patient advocacy groups to meet with insurance commissioners and state legislators may be a powerful strategy for advocating for change.[59] Additionally, developing a national committee with health care providers and stakeholders from both the pharmaceutical industry and the insurance sector could be an efficient mechanism for establishing acceptable clinical practices and facilitating timely, cost-effective care.

Table 1. Strategies to streamline PA.[67]

Concept	Strategy	Description
Rewarding PA success	**Gold Card programs**	Recognize clinicians who are regularly approved for PA by lifting requirements for them over a time period.
	Sunset programs	Eliminate PA or drugs and services that are regularly approved.
Reducing the manual burden of PA	**Electronic PA**	PA forms filled out electronically online can reduce personnel and resource burden.
	Automated PA	Use an algorithm (potentially informed by machine learning) to screen the PA request and match it to the payer's utilization policies. Rejected requests would be reviewed manually.
Addressing PA early in the process	**Increased information at point of care**	Clinical decision support and real-time pharmacy benefit checks can be used to inform clinicians at the point of care whether PA is warranted.
	Proactive authorization	Patients with certain diagnoses or medical treatments are preapproved to have downstream tests or therapies that are typically requested for their conditions.

PA, prior authorization.

Leveraging resources to facilitate PA

Although the PA process can be burdensome, following certain steps and leveraging available resources can help facilitate the process (Tables 2 and 3).[56] Prior authorization submissions should be constructed to mirror and address the exact requirements and language of the specific payer, since even one missing element can delay the process. Key tips for successful PAs include obtaining a single point of contact for the payer, submitting detailed supporting materials with the initial request, and implementing a tracking system to document progress.[56] Customizable requests and appeal letters available through the Crohn's & Colitis Foundation[68] can be used for various steps of the process. Given the time required to navigate PAs, assigning a dedicated individual or team to manage the process is critical. Models that utilize on-site specialty pharmacies and their staff to oversee the entire PA process have been successful for academic and large community-based practices.[56]

Integrating cost-saving measures into practice

In addition to measures related to the PA process, cost-saving measures can be implemented in the care of IBD, where appropriate. For example, the costs of biologics can be mitigated by prescribing biosimilars where appropriate and by de-escalating therapy when deep remission has been achieved.[27] Empowering staff through multidisciplinary teams or protocols for specific segments of care, such as incorporating IBD nurses to coordinate care and provide support, has been found to be cost-effective.[27,69,70] Other interventions that have been found to reduce the direct costs of IBD (hospitalization, ER utilization) include changing the structure of care delivery (eg, IBD medical home), incorporating digital technologies, and utilizing electronic medical record (EMR)-driven care aids.[27,69]

Table 2. Tips for successful PAs.[56]

1. Identify top payers in your practice to know which insurance companies to focus on and better understand their formularies and PA processes
2. Obtain a copy of payer formularies online or via fax
3. Obtain information for a single point of reliable contact
4. Keep a list of preferred products by most common payers to avoid selecting a nonpreferred product when a preferred product may be acceptable
5. Before initiating the PA process, (a) complete an eligibility check to identify the patient's current insurance plan; and (b) select the appropriate PA form (pharmacy vs medical)
6. Before submitting the PA form, consider (a) providing complete medication history, including past failed treatments; (b) attaching a letter of medical necessity; and (c) referring to guidelines and/or other reputable sources. These steps can help speed up the PA review and increase the chances of PA approval

Table 3. Tips for navigating the appeal process and peer-to-peer review.[56]

1. Emphasize the aggressiveness of the patient's disease and consequences of ineffective therapy
2. Stress the high cost of hospitalization should the disease progress
3. Review contraindications to the payer's formulary alternatives to emphasize why the selected treatment plan for the patient is the most patient-centered
4. If applicable to the patient, mention needle phobia, which can lead to medication nonadherence
5. Provide progress notes, labs, endoscopic reports, imaging results, and past/current therapies
6. Refer to society guidelines
7. Implement and maintain a tracking system to document every step of all PAs submitted

Conclusions

Despite significant advances in medical treatments for IBD and updated clinical practice guidelines informing their use, the quality of care for these chronic and costly diseases continues to be suboptimal. Although designed to contain costs and avoid improper use of medication, the PA process is burdensome and often leads to delays in care that are inconsistent with evidence-based recommendations and contribute to adverse patient outcomes. Accordingly, providers and payers are encouraged to work together to harmonize clinical guidelines, reimagine and streamline the PA process, and utilize available resources to improve the care of patients with chronic and disabling diseases.

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