

Title: Overuse and Misuse in Inflammatory Bowel Disease: AGA Quality Indicators for Medical Management and Disease Monitoring of IBD

Short Title: Quality Indicators for IBD Medical Management

Authors: David I. Fudman¹, David P. Hudesman², Adam V. Weizman³, Jennifer K. Maratt^{4,5}, Joseph D. Feuerstein⁶, on behalf of the American Gastroenterological Association Quality Committee

Author affiliations:

1. Division of Digestive and Liver Diseases, University of Texas Southwestern Medical Center, Dallas, Texas
2. Division of Gastroenterology, NYU School of Medicine, New York, New York
3. Division of Gastroenterology, Mount Sinai Hospital, Department of Medicine, University of Toronto, Toronto, Ontario
4. Division of Gastroenterology and Hepatology, Indiana University School of Medicine, Indianapolis, Indiana
5. Richard L. Roudebush Veterans Affairs Medical Center, Indianapolis, Indiana
6. Division of Gastroenterology, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts

Funding: The AGA Institute provided funding for the creation of this document.

Disclosures: DF reports consulting/advisory board fees from Pfizer, Fresenius Kabi, Janssen and Eli Lilly. DH reports consulting/advisory board fees from Abbvie, Abivax, Avalo, Biocon, BMS, CorEvitas, Fresenius Kabi, Eli Lilly, Pfizer, Prometheus, Johnson and Johnson, Sanofi, Takeda. AW reports consulting/advisory board fees from Takeda, Abbvie, Ferring. JM and JF report no disclosures.

Address for correspondence:

American Gastroenterological Association
National Office, 4930 Del Ray Avenue
Bethesda, MD 20814
Email: dgodzina@gastro.org
Telephone: 301-941-2618

Acknowledgments: We would like to acknowledge the work of David Godzina and members of the AGA Quality Committee who participated in generating and evaluating these quality indicators.

Writing assistance: No writing assistance was used for this manuscript.

Author contributions: David I. Fudman: conceptualization, drafting, review/editing. David P. Hudesman: conceptualization, drafting, review/editing. Adam V. Weizman: conceptualization, drafting, review/editing. Jennifer K. Maratt: conceptualization, review/editing. Joseph D. Feuerstein: conceptualization, drafting, review/editing.

Keywords: quality indicators, inflammatory bowel disease, Crohn's, ulcerative colitis

Abstract

Despite increasing understanding of what constitutes high quality care for patients with inflammatory bowel disease (IBD), substantial variation in the quality of care delivered to patients with IBD persists, with gaps that include over-, under-, and misuse of therapies and disease monitoring. Here we report the development of quality indicators for medical management and monitoring of IBD, created according to the process established by the American Gastroenterological Association. In patients with either Crohn's or UC, these include: 1) corticosteroids should not be used for maintenance of remission for UC or CD; 2) patients with UC or CD that are treated with systemic corticosteroids should be transitioned to a steroid-sparing biologic, small molecule, or immunomodulator; 3) patients with moderate to severe UC or CD should be started on biologic/small molecule therapy based on disease severity and the practice of step-up therapy should not be used; and 4) routine care for all patients with asymptomatic UC or CD should include at least yearly objective monitoring for inflammation rather than monitoring of symptoms alone. In ulcerative colitis, 5) oral 5-aminosalicylic acid should not be continued in patients with moderate to severe ulcerative colitis who achieve remission with a biologic agent, immunomodulator, and/or small molecule. In Crohn's, 6) sulfasalazine and oral 5-ASA formulations should not be used to treat patients with moderate to severe CD, and 7) patients with active fistulizing CD should be treated with a biologic or small molecule.

Introduction

Inflammatory bowel disease (IBD), which includes Crohn's disease (CD) and ulcerative colitis (UC), is estimated to affect >0.7% of Americans and is expected to rise in prevalence with aging of the population.¹ Direct costs related to IBD are substantial, ranging \$9,000-12,000 per patient per year in the United States.² The natural history of IBD is at least partially modifiable, with evidence that early effective therapy prevents more disease complications than later initiation of therapy, particularly in CD.³⁻⁵ Despite increasing understanding of optimal chronic disease management for IBD, there is substantial variation in the quality of medical care delivered to patients with IBD, with gaps in care quality that include of over-, under-, and misuse of medical therapies and disease monitoring.⁶ For example, corticosteroid overuse remains prevalent despite an expanding toolbox of advanced therapies, while advanced therapies – and objective monitoring of inflammation after their initiation – remain underutilized.

Quality measures are formal, structured tools that allow for quantification of care quality, however quality measures regarding IBD care have been limited. The American Gastroenterological Association process for the creation of quality measures requires that development only be considered when a measure can be guided by guideline practice statements with strong recommendations based on at least moderate to high quality of evidence. Measures must also explicitly define inclusion and exclusion criteria, as well as definitions for the measurement of a numerator and denominator, in order to allow for their potential use in quality payment programs such as the Centers for Medicare and Medicaid Services Merit-Based Incentive Payment System (MIPS).⁷ This high threshold for measure consideration limits their potential scope, in large part because existing literature is often insufficient to support practice statements that are based on at least moderate quality evidence; moreover, guidelines do not address all aspects of clinical care..

Nonetheless, promoting and facilitating quality-related activities among practices and individual clinicians remains an important goal. In recognition of this and the limitations of formal quality measure development, the AGA in 2022 developed a pathway to create quality indicators that reflect evidence-based practice and expert consensus.⁸ Although they are not intended to describe all aspects of quality care for a particular condition, they can be deployed in quality improvement efforts to narrow care gaps and reduce care variation.

The processes by which quality measures and quality indicators are developed has been previously formalized and reported by the AGA Quality Committee.^{8,9} This has resulted in the recent development of quality indicators for irritable bowel syndrome and anti-obesity medication use (¹⁰, 10.1053/j.gastro.2025.08.006). Here we present the development of quality indicators for medical management and disease monitoring in IBD.

Development of Quality Indicators

We reviewed guidelines, clinical practice updates, and consensus statements related to medical management and disease monitoring of IBD from the American Gastroenterological Association, the American College of Gastroenterology, and the European Crohn's and Colitis Organization published between January 2020 and June 2025. Guideline and recommendation statements were reviewed for potential inclusion based on their generalizability, implementation potential, and quality of evidence. Their use of Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology was recorded at time of review (Table XX). Guideline or consensus statements from different sources that had discordant recommendations were not considered for indicator development. Following source document review, quality indicators related to medical management and monitoring of IBD were developed and refined until there was unanimous agreement among a 4-member panel from the AGA Quality Committee and were further revised with assistance of additional AGA Quality Committee members. After initial voting by the full Quality Committee membership, additional input was sought from a 30-day public comment period, and the indicators were refined prior to their final approval by the AGA Quality Committee, Quality Leadership Council, and Clinical Guidelines Committee. The indicators in this document reflect this formal review process and approval by voting members.

Quality Indicators

Crohn's Disease and Ulcerative Colitis

- **Corticosteroids should not be used for maintenance of remission for UC or CD**
- **All patients with UC or CD that are treated with systemic corticosteroids should be transitioned to a steroid-sparing biologic, small molecule, or immunomodulator**

When initiating systemic corticosteroids for UC or CD the goal should be to transition promptly to a steroid-sparing agent to maintain remission, given the well-established risks associated with corticosteroid use: increased risk of infection, osteopenia, hyperglycemia, psychiatric disturbances, cataracts, impaired wound healing, cardiovascular disease, thromboembolic events, and other systemic complications.¹¹ While many of these adverse effects are linked to long-term or cumulative use, data

suggest that once systemic corticosteroids are initiated in IBD, there is a high risk for future dependency. Supporting this, a population-based study from Olmsted County found that 51% of individuals with UC and 68% of those with CD required surgery or prolonged corticosteroid use within one year of initial corticosteroid use.¹² AGA guidelines specifically recommend against the use of corticosteroids for the maintenance of remission, but they remain one of the most commonly prescribed medications in IBD.¹³

Despite longstanding recognition that corticosteroids lack a role for maintenance of remission, continuous, prolonged or repeated corticosteroid courses are commonly overused in lieu of advanced therapy and/or immunomodulators, and durations of steroid treatment even when used appropriately as induction therapy are often excessively long. These patterns of misuse represent quality gaps and have been found across a variety of settings.

For example, a multicenter study in the UK found that 15% of patients had steroid excess or dependency in the prior year, with over half of excess steroid use deemed avoidable, and a quality improvement intervention led to both lower overall steroid use as well as fewer instances of excess steroid use, signaling that steroid use is modifiable and not merely a result of disease severity.¹⁴ A multicenter study of consecutive patients across multiple countries found rates of steroid overuse no lower than 12% and as high as 93% depending on phase of a patient's treatment.¹⁵

U.S. data also show that steroids are prescribed repeatedly in the absence of steroid-sparing therapy. In a U.S. Veterans Affairs cohort, 17% of patients with IBD who used steroids had prolonged exposure to steroids (<90 days between steroid courses), and three-quarters of these did not receive steroid-sparing therapy.¹⁶ Similarly, a U.S. claims-based study found that patients had 4-6 steroid courses on average prior to starting an advanced therapy.¹⁷ Adults over 65 years old are at particularly high risk of chronic steroid use despite their higher incidence of steroid-related adverse effects.¹⁸⁻²⁰ As such, a key quality indicator in IBD care is that systemic corticosteroids should not be used for maintenance therapy.

In Crohn's disease, neither conventional oral corticosteroid therapy nor oral budesonide reduce relapse risk among patients with clinically quiescent disease.^{21,22} Similarly, a study that employed budesonide as post-operative prophylaxis found no difference in endoscopic recurrence at 12 months.²³ In UC, since Trulove and Witts' landmark work with cortisone it has been reported that steroids do not maintain remission.^{24,25} In contrast to steroids, there is a wide armamentarium of steroid-sparing therapies that are effective for maintenance of remission, and these tools have considerably more favorable safety profiles.

For UC, the American College of Gastroenterology (ACG) published its updated clinical guideline in June 2025, which included a key recommendation regarding corticosteroids and maintenance therapy: the ACG recommends against the use of systemic corticosteroids, budesonide MMX, or topical corticosteroids for the maintenance of remission among patients with UC.²⁶ This is a strong recommendation supported by moderate-quality evidence. Analogously, the American Gastroenterological Association (AGA) Living Clinical Practice Guideline on the Pharmacological Management of Moderate-to-Severe Ulcerative Colitis recommends that patients with moderate-severe UC, defined in part by corticosteroid dependence or refractoriness, should be started early on an advanced therapy and/or immunomodulator.¹³ Accordingly, once a patient requires corticosteroids, a steroid-sparing advanced therapy should be initiated to prevent long-term morbidity and improve clinical outcomes for both individuals with UC and CD.

- **Patients with moderate to severe UC or CD should be started on biologic/small molecule therapy based on disease severity and the practice of step-up therapy should not be used**

Although step-up therapy has traditionally been used to manage moderate-to-severe inflammatory bowel disease (IBD), emerging data challenge this approach. In Crohn's disease (CD), early initiation of advanced therapy, within the first three years, and possibly even within the first 12 months, has been associated with reduced risks of disease progression, including hospitalization, surgery, dysplasia, and corticosteroid use, and improved rates of transmural healing.²⁷

The results of the PROFILE study underline the importance of early effective therapy. This open-label, randomized trial compared early combined infliximab and immunomodulator therapy initiated within two weeks of CD diagnosis to an accelerated step-up approach (starting with corticosteroids, followed by an immunomodulator, and then the addition of infliximab).²⁸ The primary endpoint, steroid- and surgery-free remission at week 48, was dramatically higher in the early combination group compared to the accelerated step-up group (79% vs 15%). In line with these findings, the ACG guidelines for the management of CD conditionally recommend against requiring failure of conventional therapy before initiating advanced therapy; this recommendation is based on low-certainty evidence.²⁹

Similarly, the American Gastroenterological Association (AGA) Living Clinical Practice Guideline on the Pharmacological Management of Moderate-to-Severe Ulcerative Colitis (UC), published in 2024, advises early use of advanced therapies, with or without immunomodulators, rather than a gradual step-up following failure of 5-ASA therapy.¹³ This was a conditional recommendation based on very low certainty of evidence, downgraded due to indirectness and an unclear magnitude of benefit. This is based on an analysis that found thiopurines are more effective than 5-ASA therapy in achieving clinical/endoscopic/corticosteroid-free clinical remission among individuals with corticosteroid-dependent UC (53% with azathioprine vs. 21% with 5-ASA; OR 4.78, 95% CI 1.57–14.5) [5]. Additionally, in the UC SUCCESS trial, infliximab demonstrated greater efficacy for endoscopic improvement compared to immunomodulator therapy among individuals with moderate-severe UC.³⁰ Taken together, this indirectly supports the use of advanced therapies, rather than a step-up approach, among individuals who meet criteria for their use based on disease severity.

While individualized risk-benefit discussions remain essential, it is critical to weigh the potential adverse effects of advanced therapy against the risks of under treatment, which include increased likelihood of hospitalization, surgery, corticosteroid exposure, reduced quality of life, and long-term dysplasia. Although additional research is needed to better tailor treatment decisions using clinical and biochemical markers, current evidence supports avoiding a step-up approach in patients whose disease activity warrants use of an advanced therapy.

- **Routine care for all patients with asymptomatic UC or CD should include at least yearly objective monitoring for inflammation rather than monitoring of symptoms alone. Objective monitoring can include any of the following: biomarkers (fecal calprotectin or C-reactive protein), imaging (CT or MR enterography, intestinal ultrasound), or endoscopy.**

Objective monitoring of inflammation through biochemical, endoscopic or imaging assessment is a cornerstone of the treat-to-target strategy in IBD.³¹ This recognizes that inflammation is often present in the absence of clinical symptoms, and that asymptomatic inflammation is a marker of risk for poorer disease outcomes, including clinical flare. In contrast, tight control of inflammation, including asymptomatic inflammation, is associated with improved disease outcomes. This cannot be achieved without the routine monitoring of objective measures of disease activity.

However, objective assessments of inflammation are greatly underutilized, even in the period following the initiation of a new therapy. For example, a 2019 study of administrative data found that half (51%) of patients had no disease monitoring (defined as FC, lower endoscopy or enterography) within 1 year of biologic initiation, and this gap narrowed only modestly (to 56-68%) at 2 years after starting a biologic; concerningly, there was significant geographic variation in performance of timely monitoring.³² Two other studies, one utilizing real-world data from academic centers and another using administrative data, both found that fewer than half of patients had a colonoscopy in the 3-15 months following the initiation of an advanced therapy.^{33,34}

Traditionally, objective monitoring of inflammation has been performed with endoscopy, or when inflammation affects endoscopically difficult-to-reach areas, cross-sectional imaging. While these modalities have distinct advantages, they are difficult to repeat serially due to cost, resource utilization and access considerations, patient acceptability, and in the case of endoscopy, invasiveness. Therefore, biomarkers play an important role in the routine monitoring of IBD, particularly fecal calprotectin (FC), which has a higher sensitivity to detect endoscopic inflammation than CRP, and ACG, AGA and ECCO guidance support their use for this purpose.³⁵⁻⁴⁰

Biomarker elevation in the absence of symptoms is common and prognostic in both UC and CD. Considering elevations in fecal calprotectin (FC), a review performed for AGA guideline development of 17 cohort studies with 1286 patients with UC in symptomatic remission found that about a third (36%) of patients had an elevated fecal calprotectin (>150 µg/g in most studies), and that these patients at median follow up of 1 year were 4.4 times as likely to have disease relapse compared to those with normal calprotectin. This correlated to an estimated annual relapse risk of 64% among patients with clinically quiescent UC and an elevated FC.³⁵ Similarly, a AGA review of 12 cohort studies with 982 patients with CD in symptomatic remission found that about a third (38%) of patients had an elevated FCP (variably defined as >200-300 µg/g).³⁶ Their risk of disease relapse at a median follow up of 1 year was similar to those with asymptomatic UC and an elevated FC, 4.8 times higher than those with a normal calprotectin, correlating to a 53% risk of relapse over a year.

CRP is less sensitive and specific than other modalities, notably including calprotectin, for the detection of endoscopic inflammation, risking false reassurance or alarm. However, it is more convenient to collect compared to FC.^{35,36}

ECCO guidelines recommend FC monitoring every 3 months based in part on data that FC levels may rise about 3 months prior to clinical manifestations of disease relapse. This may be difficult in practice, and AGA guidelines suggest that biomarker monitoring may be performed every 6 to 12 months.^{26,29,35–37}

Intestinal ultrasound is an emerging modality in the United States for objective monitoring of disease activity in both CD and UC.^{26,29,41} In a systematic review and meta-analysis that compared IUS to endoscopic and biomarker monitoring, IUS had high pooled sensitivity and specificity.⁴² IUS can be used alone or in combination with biomarker assessment for routine disease monitoring, keeping in mind that it may not be well suited to all clinical situations (for example, mild colitis or rectal disease).

To avoid overuse of high-resource or invasive monitoring, biomarkers and/or IUS should be the most frequently formed monitoring modalities for the great majority of patients. In asymptomatic patients with normal biomarkers, other forms of cross-sectional imaging or colonoscopy should be reserved for more periodic monitoring or, in the case of colonoscopy, according to recommended intervals for colorectal cancer surveillance.⁴³

Ulcerative Colitis

- **Oral 5-aminosalicylic acid should not be continued in patients with moderate to severe ulcerative colitis who achieve remission with a biologic agent, immunomodulator, and/or small molecule**

Treatment with 5-aminosalicylic acid (5-ASA) is the most commonly prescribed medication for ulcerative colitis (UC).⁴⁴ While it is considered first line therapy for patients with mild UC, a subset of patients with mild disease do not respond to 5-ASA therapy or progress to moderate/severe disease despite treatment.^{45–47} Therefore, a significant proportion of patients starting immunomodulators or advanced therapies are on 5-ASA therapy. There is significant variation in practice as to whether the 5-ASA therapy is continued among these patients. As such, a quality indicator addressing this practice can lead to clarity on best practice and potentially simplify care.

Both the 2025 ACG and 2024 AGA guidelines on the medical management of ulcerative colitis address this topic.^{13,26} The ACG guideline suggests against using 5-ASA for added efficacy among patients with UC who have failed 5-ASA therapy and are utilizing an advanced therapy for induction of remission (conditional recommendation, very low quality of evidence). This is based on post-hoc analyses of clinical trial data, a study of population-based cohorts, and a cost effectiveness analysis; these, in sum, suggest that patients on advanced therapies do not achieve better outcomes with concurrent 5-ASA therapy, while incurring greater costs.

The AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis published in 2024 recommended that 5-ASA therapy be discontinued in adult outpatients with moderate-to-severe UC who have failed 5-ASAs and have escalated to therapy with immunomodulators or advanced therapies.¹³ This was a conditional recommendation of low certainty of evidence. Evidence was rated down due to imprecision and indirectness. This recommendation was based on a pooled analysis performed by the guideline authors of individual patient-level data of RCTs of advanced therapies in patients with moderate-to-severe UC. The analysis included 10 RCTs with 6044

patients. Among these, 4134 patients received concomitant 5-ASA at baseline upon escalating therapy and maintained stable dose throughout the induction period. The authors found the ratio of relative risk (RR) for achieving clinical remission on the new therapy in those that remained on 5-ASA vs no 5-ASA was 1.04 (95% CI, 0.78–1.39), suggesting no benefit of continuing 5-ASA. There is more direct evidence supporting 5-ASA discontinuation among patients in remission on immunomodulators, with the AGA's prior guideline in 2020 suggesting against continue 5-ASA agents in patients who achieved remission on an immunomodulator or advanced therapy.⁴⁸ These recommendations were in keeping with a prior and ACG guideline.⁴⁵

The 2024 AGA guideline also defined two implementation considerations. One relates to patients who have significant but not complete response with advanced therapies or immunomodulators that may benefit from ongoing 5-ASAs to achieve remission, particularly patients with residual proctitis who may benefit from adding rectal 5-ASA. The other consideration is related to the benefit of long-term 5-ASAs in preventing colorectal cancer in patients with IBD, however contemporary literature suggests that the chemoprotective effect of 5-ASAs owes to resolution of inflammation via any therapy rather than an effect inherent to 5-ASAs.⁴¹

Crohn's Disease

- **Sulfasalazine and oral 5-ASA formulations should not be used to treat patients with moderate to severe CD**

The use of 5-aminosalicylates (5-ASA) in patients with Crohn's disease remains common.^{49,50} This may be due to the relative safety of these therapies and the fact that they are not immunosuppressive.⁵¹ Despite only limited data suggesting benefit for 5-ASA therapies in Crohn's disease, these remain among the most commonly prescribed medications for Crohn's disease and patients often remain on them for an extended period of time, even after the initiation of more advanced therapies.^{51,52} This can contribute to gaps in quality of care as trialing 5-ASA therapy for a prolonged period could lead to delays in starting a more effective therapy. Moreover, continuing ineffective therapy leads to unnecessary cost and while 5-ASA is generally a safe therapy, there are still associated adverse effects.

As such, the 2021 AGA Guideline on the medical management of moderate to severe luminal and fistulizing Crohn's disease recommended against the use of 5-ASA over no treatment for the induction or maintenance of remission).⁵³ This was considered a strong recommendation with moderate certainty evidence. This recommendation was based on two randomized controlled trials comparing 5-ASA to placebo for induction or remission that did not reach the minimal clinically important difference of 10% over placebo (RR, 0.90; 95% CI, 0.81–1.00). Similarly, 11 RCTs that included 2014 patients did not find 5-ASA to be more effective than placebo for maintenance (RR, 1.02; 95% CI, 0.92–1.16). A recent large nationwide study from Israel of 19,264 further supports this recommendation.⁵⁴ The study demonstrated 5-ASA to be not superior to no 5-ASA for maintenance and was in fact associated with higher rates of adverse events such as kidney injury. This recommendation is in keeping with the 2025 ACG guideline as well as the 2024 ECCO Guidelines on Therapeutics in Crohn's Disease, which recommends against the use of 5-ASA both for induction and maintenance in any patient with Crohn's disease (strong recommendation with moderate quality evidence).^{29,40}

Data on the use of sulfasalazine in CD is more conflicting. In its 2021 guideline, the AGA recommended against the use of sulfasalazine over no treatment for the induction or maintenance of remission and Crohn's disease.⁵³ This recommendation was based on 3 RCTs evaluating sulfasalazine compared to placebo and while sulfasalazine demonstrated superiority for induction of remission, the certainty of evidence for sulfasalazine was considered very low and the severity of patients in the studies was unclear. Potential adverse events and lack of efficacy were the rationale for this statement. Moreover, 4 RCTs evaluating maintenance with sulfasalazine did not show any difference when compared to placebo. This recommendation contrasts with the ACG guideline on the management of Crohn's disease in adults, which recommends sulfasalazine only be considered in symptomatic mild colonic CD.²⁹

- **Patients with active fistulizing CD should be treated with a biologic or small molecule**

Fistulizing CD is an aggressive CD phenotype and challenging to treat. Whether a primary phenotype or a perianal disease complication, fistulae usually require a combined approach including medical management with biologics or small molecules and surgical management.^{55,56} Untreated, fistulizing CD is associated with increased morbidity and poor quality of life including higher rates of hospitalizations, surgeries, and fecal incontinence.⁵⁷ There are very few randomized control trials focused on the treatment of fistulizing CD or on perianal CD, which limits the data available to determine the most effective therapy. The largest RCT focused on the use of infliximab for induction of remission and maintenance of remission for fistulizing CD.⁵⁸ Fistula response was achieved in 62% of patients and 46% achieved fistula remission with higher rates of sustained remission in those who were on infliximab. Other anti-tumor necrosis factor agents have shown similar success in treatment of perianal fistula.^{29,53,59} The AGA provides a strong recommendation for the use of infliximab in induction and maintenance of fistula remission.⁵³ For other biologic therapies, the data supporting use stems from subgroup post-hoc analyses from phase 2 and phase 3 trials. Small molecules have shown success in fistula management as well. Upadacitinib in a post hoc analysis and filgotinib in the RCT DIVERGENCE 2 both showed efficacy in achieving fistula remission.⁵⁸

Given that most patients with perianal fistula will require surgery at some point, early initiation of biologic or small molecule agents is advisable. Both the AGA and ACG provide a strong recommendation for the use of infliximab for fistulizing CD.^{29,53} Other advanced therapies are all given conditional recommendations in both guidelines given the more limited data supporting their use. Vuyyuru SK et al performed a meta-analysis of 38 RCTs showing most of the biologics and small molecules are effective for managing fistulizing disease except for vedolizumab, but the certainty of evidence was very low to moderate.⁵⁹ While the data supporting the use of biologics and small molecules for management of fistulizing CD is limited, non-use of the therapies is likely to lead to deleterious outcomes and worsening fistulizing disease. Further studies specifically targeting fistula management are needed to improve to overall quality of evidence surrounding the management of fistulizing CD.

Summary

In summary, this document defines 7 quality indicators for the management and monitoring of patients with inflammatory bowel disease. In line with the AGA's process for indicator development, these were chosen for their generalizability, implementation potential and quality of evidence; moreover, the

indicators defined here represent domains of IBD care subject to tremendous practice variation. Identification of these quality indicators provides a framework for clinicians and groups to execute quality improvement efforts to bridge gaps in care delivery for patients with IBD.

Draft

Table 1. Quality indicators for medical management and monitoring of IBD with corresponding guideline and consensus statements

Quality indicator	Strong recommendation	Conditional	Consensus
Ulcerative colitis and Crohn's disease			
Corticosteroids should not be used for maintenance of remission for UC or CD	ACG ^{29,26} ECCO ⁴⁰ AGA ⁵³		AGA ⁶⁰ ECCO ³⁸ ECCO ³⁹
Patients with UC or CD that are treated with systemic corticosteroids should be transitioned to a steroid-sparing biologic, small molecule, or immunomodulator		ACG ²⁶ AGA ¹³	ECCO ^{38,40} ACG ²⁹
Patients with moderate to severe UC or CD should be started on biologic/small molecule therapy based on disease severity and the practice of step-up therapy should not be used		ACG ²⁹ AGA ^{13,53}	ACG ²⁶
Routine care for all patients with asymptomatic UC or CD should include at least yearly objective monitoring for inflammation rather than monitoring of symptoms alone. Objective monitoring can include any of the following: biomarkers (fecal calprotectin or C-reactive protein), imaging (CT or MR enterography, intestinal ultrasound), or endoscopy.	ACG ²⁶	AGA ^{35,36}	ECCO ^{38,40} AGA ⁴¹ ACG ²⁹
Ulcerative colitis			
Oral 5-aminosalicylic acid should not be continued in patients with moderate to severe ulcerative colitis who achieve remission with a biologic agent, immunomodulator, and/or small molecule		ACG ²⁶ AGA ^{13,48}	
Crohn's disease			
Sulfasalazine and oral 5-ASA formulations should not be used to treat patients with moderate to severe CD	AGA ⁵³ ACG ²⁹ ECCO ⁴⁰		

Patients with active fistulizing CD should be treated with a biologic or small molecule	AGA ⁵³ ACG ²⁹		ECCO ⁴⁰
---	--	--	--------------------

Draft

Supplementary Table 1. Guidelines and consensus statements included in development of quality indicators for medical management and monitoring of IBD

Title	Year	GRADE methodology used
AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis ⁴⁸	2020	Yes
AGA Clinical Practice Update on Management of Inflammatory Bowel Disease in Elderly Patients ⁶⁰	2020	No
Quality of Care Standards in Inflammatory Bowel Diseases: A European Crohn's and Colitis Organisation [ECCO] Position Paper ³⁸	2020	No
AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease ⁵³	2021	Yes
ECCO Guidelines on Therapeutics in Ulcerative Colitis: Medical Treatment ⁶¹	2022	Yes
AGA Clinical Practice Guideline on the Role of Biomarkers for the Management of Crohn's Disease ³⁶	2023	Yes
AGA Clinical Practice Guideline on the Role of Biomarkers for the Management of Ulcerative Colitis ³⁵	2023	Yes
Results of the Eighth Scientific Workshop of ECCO: Prevention and Treatment of Postoperative Recurrence in Patients with Crohn's Disease Undergoing an Ileocolonic Resection with Ileocolonic Anastomosis ³⁹	2023	No
AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis ¹³	2024	Yes
AGA Clinical Practice Update on the Role of Intestinal Ultrasound in Inflammatory Bowel Disease ⁴¹	2024	No
ECCO Guidelines on Therapeutics in Crohn's Disease: Medical Treatment ⁴⁰	2024	Yes
ACG Clinical Guideline Update: Ulcerative Colitis in Adults ²⁶	2025	Yes
ACG Clinical Guideline: Management of Crohn's Disease in Adults ²⁹	2025	Yes

References

1. 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.
2. 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.
3. Law CCY, Tkachuk B, Lieto S, et al. Early Biologic Treatment Decreases Risk of Surgery in Crohn’s Disease but not in Ulcerative Colitis: Systematic Review and Meta-Analysis. *Inflamm Bowel Dis* 2024;30:1080–1086.
4. Rodríguez-Lago I, Del Hoyo J, Pérez-Girbés A, et al. Early treatment with anti-tumor necrosis factor agents improves long-term effectiveness in symptomatic stricturing Crohn’s disease. *United Eur Gastroenterol J* 2020;8:1056–1066.
5. Safroneeva E, Vavricka SR, Fournier N, et al. Impact of the early use of immunomodulators or TNF antagonists on bowel damage and surgery in Crohn’s disease. *Aliment Pharmacol Ther* 2015;42:977–989.
6. Singh S, Velayos FS, Rubin DT. Common Instances of Low-value Care in Inflammatory Bowel Diseases. *Clin Gastroenterol Hepatol* 2024;22:923–932.
7. Adams MA, Allen JI, Saini SD. Translating Best Practices To Meaningful Quality Measures: From Measure Conceptualization to Implementation. *Clin Gastroenterol Hepatol* 2019;17:805–808.
8. Sheth SG, Maratt JK, Newberry C, et al. AGA Institute Quality Indicator Development and Uses. *Clin Gastroenterol Hepatol* 2023;21:1399–1402.
9. Adams MA, Allen JI, Saini SD. Translating Best Practices To Meaningful Quality Measures: From Measure Conceptualization to Implementation. *Clin Gastroenterol Hepatol* 2019;17:805–808.
10. Hung KW, Leiman DA, Kaza A, et al. AGA Institute Quality Indicator Development for Irritable Bowel Syndrome. *Gastroenterology* 2025;168:612-622.e4.
11. Feuerstein JD, Rubin DT, Aberra FN, et al. Appropriate Use and Complications of Corticosteroids in Inflammatory Bowel Disease: A Comprehensive Review. *Clin Gastroenterol Hepatol* 2025:S154235652500535X.
12. Faubion WA, Loftus EV, Harmsen WS, et al. The natural history of corticosteroid therapy for inflammatory bowel disease: A population-based study. *Gastroenterology* 2001;121:255–260.
13. Singh S, Loftus EV, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology* 2024;167:1307–1343.

14. Selinger CP, Parkes GC, Bassi A, et al. Assessment of steroid use as a key performance indicator in inflammatory bowel disease—analysis of data from 2385 UK patients. *Aliment Pharmacol Ther* 2019;50:1009–1018.
15. D'Amico F, Gomollón F, Bamias G, et al. Proportion of inflammatory bowel diseases patients with suboptimal disease control in daily clinical practice—Real-world evidence from the inflammatory bowel diseases-podcast study. *United Eur Gastroenterol J* 2024;12:705–716.
16. Waljee AK, Wiitala WL, Govani S, et al. Correction: Corticosteroid Use and Complications in a US Inflammatory Bowel Disease Cohort. *PLOS ONE* 2018;13:e0197341.
17. Siegel CA, Sharma D, Griffith J, et al. Treatment Pathways in Patients With Crohn's Disease and Ulcerative Colitis: Understanding the Road to Advanced Therapy. *Crohns Colitis* 2024;6:otae040.
18. Juneja M, Baidoo L, Schwartz MB, et al. Geriatric Inflammatory Bowel Disease: Phenotypic Presentation, Treatment Patterns, Nutritional Status, Outcomes, and Comorbidity. *Dig Dis Sci* 2012;57:2408–2415.
19. Parian A, Ha CY. Older Age and Steroid Use Are Associated with Increasing Polypharmacy and Potential Medication Interactions Among Patients with Inflammatory Bowel Disease: *Inflamm Bowel Dis* 2015:1.
20. Geisz M, Ha C, Kappelman MD, et al. Medication Utilization and the Impact of Continued Corticosteroid Use on Patient-reported Outcomes in Older Patients with Inflammatory Bowel Disease: *Inflamm Bowel Dis* 2016;22:1435–1441.
21. Kuenzig ME, Rezaie A, Seow CH, et al. Budesonide for maintenance of remission in Crohn's disease Cochrane IBD Group, ed. *Cochrane Database Syst Rev* 2014;2020. Available at: <http://doi.wiley.com/10.1002/14651858.CD002913.pub3> [Accessed August 18, 2025].
22. Steinhart AH, Ewe K, Griffiths AM, et al. Corticosteroids for maintenance of remission in Crohn's disease Cochrane IBD Group, ed. *Cochrane Database Syst Rev* 2003. Available at: <https://doi.wiley.com/10.1002/14651858.CD000301> [Accessed August 18, 2025].
23. Hellers G, Cortot A, Jewell D, et al. Oral budesonide for prevention of postsurgical recurrence in Crohn's disease. *Gastroenterology* 1999;116:294–300.
24. Truelove SC, Witts LJ. Cortisone and Corticotrophin in Ulcerative Colitis. *BMJ* 1959;1:387–394.
25. Lennard-Jones JE, Misiewicz JJ, Connell AM, et al. PREDNISONE AS MAINTENANCE TREATMENT FOR ULCERATIVE COLITIS IN REMISSION. *The Lancet* 1965;285:188–189.
26. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J Gastroenterol* 2025;120:1187–1224.
27. Burisch J, Kiudelis G, Kupcinskas L, et al. Natural disease course of Crohn's disease during the first 5 years after diagnosis in a European population-based inception cohort: an Epi-IBD study. *Gut* 2019;68:423–433.

28. Noor NM, Lee JC, Bond S, et al. 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.
29. Lichtenstein GR, Loftus EV, Afzali A, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol* 2025;120:1225–1264.
30. Panaccione R, Ghosh S, Middleton S, et al. Combination Therapy With Infliximab and Azathioprine Is Superior to Monotherapy With Either Agent in Ulcerative Colitis. *Gastroenterology* 2014;146:392-400.e3.
31. Turner D, Ricciuto A, Lewis A, 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* 2021;160:1570–1583.
32. Limketkai BN, Singh S, Jairath V, et al. US Practice Patterns and Impact of Monitoring for Mucosal Inflammation After Biologic Initiation in Inflammatory Bowel Disease. *Inflamm Bowel Dis* 2019;25:1828–1837.
33. Yang JY, Lund JL, Funk MJ, et al. Utilization of Treat-to-Target Monitoring Colonoscopy After Treatment Initiation in the US-Based Study of a Prospective Adult Research Cohort With Inflammatory Bowel Disease. *Am J Gastroenterol* 2023;118:1638–1647.
34. Yang JY, Lund JL, Pate V, et al. Utilization of Colonoscopy Following Treatment Initiation in U.S. Commercially Insured Patients With Inflammatory Bowel Disease, 2013-2019. *Inflamm Bowel Dis* 2023;29:735–743.
35. Singh S, Ananthakrishnan AN, Nguyen NH, et al. AGA Clinical Practice Guideline on the Role of Biomarkers for the Management of Ulcerative Colitis. *Gastroenterology* 2023;164:344–372.
36. Ananthakrishnan AN, Adler J, Chachu KA, et al. AGA Clinical Practice Guideline on the Role of Biomarkers for the Management of Crohn's Disease. *Gastroenterology* 2023;165:1367–1399.
37. Sturm A, Maaser C, Calabrese E, et al. ECCO-ESGAR Guideline for Diagnostic Assessment in IBD Part 2: IBD scores and general principles and technical aspects. *J Crohns Colitis* 2019;13:273–284.
38. Fiorino G, Lytras T, Younge L, et al. Quality of Care Standards in Inflammatory Bowel Diseases: a European Crohn's and Colitis Organisation [ECCO] Position Paper. *J Crohns Colitis* 2020;14:1037–1048.
39. Ferrante M, Pouillon L, Mañosa M, et al. Results of the Eighth Scientific Workshop of ECCO: Prevention and Treatment of Postoperative Recurrence in Patients With Crohn's Disease Undergoing an Ileocolonic Resection With Ileocolonic Anastomosis. *J Crohns Colitis* 2023;17:1707–1722.
40. Gordon H, Minozzi S, Kopylov U, et al. ECCO Guidelines on Therapeutics in Crohn's Disease: Medical Treatment. *J Crohns Colitis* 2024;18:1531–1555.

41. Chavannes M, Dolinger MT, Cohen-Mekelburg S, et al. AGA Clinical Practice Update on the Role of Intestinal Ultrasound in Inflammatory Bowel Disease: Commentary. *Clin Gastroenterol Hepatol* 2024;22:1790-1795.e1.
42. Huynh D, Rubtsov D, Basu D, et al. The Diagnostic Utility of Biochemical Markers and Intestinal Ultrasound Compared with Endoscopy in Patients with Crohn's Disease and Ulcerative Colitis: A Systemic Review and Meta-Analysis. *J Clin Med* 2024;13:3030.
43. Murthy SK, Feuerstein JD, Nguyen GC, et al. AGA Clinical Practice Update on Endoscopic Surveillance and Management of Colorectal Dysplasia in Inflammatory Bowel Diseases: Expert Review v. *Gastroenterology* 2021;161:1043-1051.e4.
44. Fumery M, Singh S, Dulai PS, et al. Natural History of Adult Ulcerative Colitis in Population-based Cohorts: A Systematic Review. *Clin Gastroenterol Hepatol* 2018;16:343-356.e3.
45. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol* 2019;114:384-413.
46. Wang Y, Parker CE, Bhanji T, et al. Oral 5-aminosalicylic acid for induction of remission in ulcerative colitis Cochrane IBD Group, ed. *Cochrane Database Syst Rev* 2016. Available at: <https://doi.wiley.com/10.1002/14651858.CD000543.pub4> [Accessed August 18, 2025].
47. Ko CW, Singh S, Feuerstein JD, et al. AGA Clinical Practice Guidelines on the Management of Mild-to-Moderate Ulcerative Colitis. *Gastroenterology* 2019;156:748-764.
48. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology* 2020;158:1450-1461.
49. Hart A. The use of 5-aminosalicylates in Crohn's disease: a retrospective study using the UK Clinical Practice Research Datalink. *Ann Gastroenterol* 2020. Available at: http://www.annalsgastro.gr/files/journals/1/earlyview/2020/ev-07-2020-21-AG_5138-0521.pdf [Accessed August 18, 2025].
50. Siegel CA, Yang F, Eslava S, et al. Treatment Pathways Leading to Biologic Therapies for Ulcerative Colitis and Crohn's Disease in the United States. *Clin Transl Gastroenterol* 2020;11:e00128.
51. Noureldin M, Cohen-Mekelburg S, Mahmood A, et al. Trends of 5-Aminosalicylate Medication Use in Patients With Crohn Disease. *Inflamm Bowel Dis* 2021;27:516-521.
52. Ungaro RC, Kadali H, Zhang W, et al. Impact of Concomitant 5-Aminosalicylic Acid Therapy on Vedolizumab Efficacy and Safety in Inflammatory Bowel Disease: *Post Hoc* Analyses of Clinical Trial Data. *J Crohns Colitis* 2023;17:1949-1961.
53. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology* 2021;160:2496-2508.

54. Atia O, Goren I, Fischler TS, et al. 5-aminosalicylate maintenance is not superior to no maintenance in patients with newly diagnosed Crohn's disease—A nationwide cohort study. *Aliment Pharmacol Ther* 2023;57:1004–1013.
55. Parian AM, Obi M, Fleshner P, et al. Management of Perianal Crohn's Disease. *Am J Gastroenterol* 2023;118:1323–1331.
56. Schwartz DA, Lightner AL, Aswani-Omprakash T, et al. Better Together: Implementing a Multidisciplinary Approach to Optimizing Diagnosis and Management of Crohn's Perianal Fistulas. *Gastroenterology* 2025;168:640-644.e1.
57. Atia O, Asayag N, Focht G, et al. Perianal Crohn's Disease Is Associated With Poor Disease Outcome: A Nationwide Study From the epiIIRN Cohort. *Clin Gastroenterol Hepatol* 2022;20:e484–e495.
58. Present DH, Rutgeerts P, Targan S, et al. Infliximab for the Treatment of Fistulas in Patients with Crohn's Disease. *N Engl J Med* 1999;340:1398–1405.
59. Vuyyuru SK, Solitano V, Narula N, et al. Pharmacological Therapies for the Management of Fistulizing Crohn's Disease: A Systematic Review and Meta-Analysis. *J Crohns Colitis* 2024;18:589–603.
60. Ananthakrishnan AN, Nguyen GC, Bernstein CN. AGA Clinical Practice Update on Management of Inflammatory Bowel Disease in Elderly Patients: Expert Review. *Gastroenterology* 2021;160:445–451.
61. Raine T, Bonovas S, Burisch J, et al. ECCO Guidelines on Therapeutics in Ulcerative Colitis: Medical Treatment. *J Crohns Colitis* 2022;16:2–17.