Practical Strategies to Increase Patient Access to Biologic Therapy in IBD

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Activity Information

Activity Description and Educational Objectives
In this activity, an expert in the management of IBD narrates a guided tour of an infographic reviewing practical strategies to minimize the burden of prior authorization and improve the provider–payer relationship.

Upon completion of this activity, participants will be able to:
• Identify patients with IBD who would benefit from early intervention with biologic therapy
• Provide the appropriate information requested by individual insurers for prior authorization of IBD therapies
• Discuss the evolving role of technology to help gastroenterology practices reduce the burden of preauthorization protocols in IBD
• Effectively collaborate with payers, focusing on shared data, financial incentives, and care management, to improve health outcomes for patients with IBD

Target Audience
This activity has been designed to meet the educational needs of gastroenterologists, nurse practitioners, physician assistants, registered nurses, and other clinicians involved in the management of patients with IBD.

Requirements for Successful Completion
In order to receive credit, participants must view the activity and complete the post-test and evaluation form. There are no pre-requisites and there is no fee to participate in this activity or to receive CME/CNE credit. Statements of Credit are awarded upon successful completion of the post-test and evaluation form.

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Course Director
Stephen B. Hanauer, MD
Clifford Joseph Barborka Professor of Medicine
Northwestern Feinberg School of Medicine
Medical Director, Digestive Health Center
Chicago, Illinois

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CME Reviewer
Zach Weber, PharmD, BCPS, BCACP, CDE
Purdue College of Pharmacy
West Lafayette, Indiana

Zach Weber, PharmD, BCPS, BCACP, CDE, has no financial interests/relationships or affiliations in relation to this activity.

Nurse Reviewer
Becky Walters, MSN, RN, FNP-BC, CNE
Purdue University School of Nursing
West Lafayette, Indiana

Becky Walters, MSN, RN, FNP-BC, CNE, has no financial interests/relationships or affiliations in relation to this activity.

Medical Director
Kathryn B. Charalambous, PhD
PVI, PeerView Institute for Medical Education

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Identifying the Patient Who Would Benefit From Early Use of Biologic Therapy

Dr. Hanauer: Hello, this is Dr. Stephen Hanauer, Professor of Medicine and Medical Director of the Digestive Health Center at Northwestern Medicine and Northwestern University Feinberg School of Medicine in Chicago, Illinois. It’s my pleasure to welcome you to this unique educational activity, “Practical Strategies to Increase Patient Access to Biologic Therapy in IBD.”

This program is designed to offer healthcare professionals a graphic look at strategies to improve the provider–payer relationship to ensure that appropriate patients with inflammatory bowel disease, being ulcerative colitis and Crohn’s disease, receive preferred therapies in a timely manner.

Scroll down through the first infographic to begin this series of presentations, and tap the red “Get Certificate” button when you are ready to take the post-test and claim your credit.

Let’s begin by identifying the patient who would benefit from early use of biologic therapies. Inflammatory bowel disease, which includes Crohn’s disease and ulcerative colitis, is a chronic inflammatory disease of the gastrointestinal tract characterized by periods of relapses and remission. While the cause of inflammatory bowel disease is unknown, it is thought to be related to a combination of genetic predispositions, environmental triggers, and an impaired mucosal immune response. Inflammatory bowel disease affects people of any age, and diagnosis is most common in early adulthood.

Current treatment options for patients with IBD include medications, nutritional supplementations or diet therapy, surgery, and most often a combination of these options. Although surgery is indicated to treat refractory disease or specific complications, such as obstructions, fistula, or neoplasia, pharmacotherapy is the cornerstone of IBD management. Indeed, biologic therapies have revolutionized the treatment of both ulcerative colitis and Crohn’s disease.

The guiding principle of pharmacotherapy for patients with IBD is to induce and maintain clinical and mucosal remissions. We also want to achieve normal bowel function and modify the long-term disease outcomes, such as reducing the need for hospitalization and surgery, eliminating disability, minimizing exposure to corticosteroids, and doing all of these in a cost-effective manner.

Prevention of disease progression and prevention of complications are replacing symptomatic remission as a long-term goal of therapy. In other words, similar to rheumatoid arthritis, we would like to prevent the progression of both ulcerative colitis into neoplasia and Crohn’s disease into transmural complications, such as strictures and fistula that lead to hospitalization and the need for surgery.

To achieve these goals in individual patients, the approach is evolving to a treat-to-target strategy. This concept arose from the observation that therapeutic strategies have failed to alter progression of both ulcerative colitis and Crohn’s disease, and from the frequent discordance between symptoms and objective measures of disease activity.

The Selecting Therapeutic Targets in Inflammatory Bowel Disease, or STRIDE, program was initiated by the International Organization for the Study of Inflammatory Bowel Disease, the IOIBD. We examined potential treatment targets for IBD to be used for a treat-to-target clinical management strategy using an evidence-based expert consensus process. Selected targets included clinical targets, biomarkers, and endoscopy, and they are different for both Crohn’s disease and ulcerative colitis.

In Crohn’s disease, the clinical targets are resolution of abdominal pain and normalization of bowel habits. In ulcerative colitis, the targets are resolution of rectal bleeding, and again, normalization of bowel habits.

Biomarkers for Crohn’s disease include normalization of C-reactive protein, and in ulcerative colitis normalization of fecal calprotectin. And in both diseases, the endoscopic targets are absence of ulceration or normalization of the mucosa.

Although step-up therapy for Crohn’s disease and ulcerative colitis is the more conventional approach, emerging evidence suggests that top-down therapy, which makes use of biologics earlier in the course of moderate to severe disease, may be able to meet these treatment goals and targets more efficiently.

Recent data suggest that treatment during a specific window of opportunity—that is, before bowel damage occurs—is more likely to produce better outcomes. In general, a step-up approach is appropriate for patients considered to be at low risk for disease progression for both ulcerative colitis and Crohn’s disease. However, current recommendations from the American Gastroenterological Association Care Pathways include a more aggressive approach for moderate- or high-risk patients.
The key is identifying these patients who would derive benefit from the earlier use of aggressive therapy, including biologic agents. To provide some practical guidance on this, the AGA Clinical Care Pathways provide definitions of disease severity. In ulcerative colitis, patients are at low risk for colectomy if they have a limited anatomic extent and mild endoscopic disease. In contrast, patients at higher risk for colectomy include those with extensive ulcerative colitis, deep ulcerations, presentation at a younger age (that is, below the age of 40), elevated biomarkers such as C-reactive protein and sedimentation rate, the early need for corticosteroid management, as well as a history of hospitalization or coinfections with *Clostridium difficile* or cytomegalovirus.

In Crohn's disease, patients at low risk for rapid progression to transmural complications and the need for surgery include those with an initial diagnosis above the age of 30, those with limited anatomic involvement, the absence of perianal or severe rectal disease, the presence of superficial rather than deep ulcerations, no prior history of surgery, and no stricturing or penetrating, such as fistulization at presentation.

In contrast, patients with a moderate to high risk for rapid progression of Crohn's disease include those with an early diagnosis before the age of 30, those with an extensive anatomic involvement, the presence of perianal or severe rectal disease, the presence of deep ulcers, prior history of surgery, or patients with penetrating or fistulizing disease.

While there is obviously no perfect algorithm for every patient with ulcerative colitis and Crohn's disease, here is a figure developed by Jean-Frederic Colombel and colleagues highlighting management strategies and options for personalized treatment of ulcerative colitis and Crohn's disease. As you can see, it is important to assess disease severity and prognosis before selecting therapies, and there are recommendations for early combination therapy with immunomodulators and biologics in high-risk patients.

Now that we've discussed the why, how, and in whom regarding the early use of biologics in IBD, let's go through some of the obstacles we all encounter on a daily basis to make this happen. I'll also provide some guidance on navigating preauthorization protocols to increase patient access to biologic therapies.

Certolizumab pegol has been approved for Crohn's disease and golimumab for ulcerative colitis. Current anti-integrin therapies include natalizumab, which is approved for Crohn's disease not responding to anti-TNF agents, and vedolizumab, which is approved for both ulcerative colitis and Crohn's disease.

Most recently, ustekinumab has been approved for patients with Crohn's disease who have not responded to conventional agents or anti-TNF agents.
Navigating Preauthorization Protocols: How to Provide the Clinical Rationale for Biologic Therapy in IBD

Dr. Hanauer: Now we know that the impact of IBD on patients' quality of life is substantial due to early-onset, fluctuating disease course and the lack of a cure. There is also a large economic impact associated with Crohn's disease and ulcerative colitis. The annual financial burden of IBD in the United States is more than $31 billion. It's recently been recognized that 1% of the US population has inflammatory bowel disease according to the Centers for Disease Control, and the costs associated with ulcerative colitis and Crohn's disease have shifted from hospitalization and surgery to medical treatments, including biologic therapies.

Proposed general strategies for cost reduction in IBD include ensuring that all patients have access to treatment that is goal-oriented and effective and utilizes quality measures for overall effective care. It's also important to avoid high healthcare resource utilization by preventing complications and addressing comorbidities. We also need to optimize treatment regimens based on individual patients with the goal of long-term clinical and, when possible, mucosal remissions.

Assuring patient adherence and compliance to treatment recommendations is an important aspect of improving overall long-term patient care, whereas lack of coverage and high patient copayments are deterrents for individuals to remain on treatment.

Health insurers also have strategies to promote cost-effective utilization of healthcare services. The one we are most familiar with is prior authorization, and it's required by many payers to get access to biologics in IBD.

Securing approval for biologic therapies can be a complex and sometimes frustrating task for healthcare professionals, their clinical staff, as well as patients. An online survey of the members of the IBD Working Group was recently conducted, and results demonstrated that communication with US payers regarding IBD medications is a substantial burden on healthcare provider resources and results in compromised patient care.

As an example, gastroenterology practices described the need to communicate with payers more than five times daily regarding their inflammatory bowel disease patients, and 63% of US gastroenterologists state that more than 25% of their time is dedicated to payer communication.

So it seems that for many clinicians, specifically gastroenterologists, the prior authorization process disrupts their workflow and impedes their ability to provide quality care to patients. But unfortunately, failure to obtain prior authorization can result in a lack of or delay in treatment initiation, which leads to continuation of symptoms and suffering, progression of the disease, and ultimately increased direct and indirect costs.

Taking all of this together, delaying a patient's therapy due to a complicated prior authorization process actually highlights a lack of alignment between payer guidelines and treatment guidelines.

So what can we do as clinicians to minimize prior authorization delays? Well, first and foremost we need to ensure that all the payers' criteria are met. That means we need to check prior authorization requirements before sending prescriptions to the pharmacy.

It's important to note that criteria necessary for prior authorization are not uniform across insurers, and most private insurers and Medicare's authorization processes are specific in their criteria and clinical information requirements.

For example, according to Anthem, adalimumab is considered medically necessary for Crohn's disease when each of the following criteria are met: The individual is 6 years of age or older with moderate to severely active Crohn's disease, and the individual has failed to respond to infliximab, is intolerant of or has a medical contraindication to conventional therapies, such as 5-ASA products, sulfasalazine, systemic steroids, or immunosuppressives, or has lost response to or is intolerant to infliximab. And adalimumab is used for one of the following: to reduce the signs or symptoms, or induce or maintain clinical remission.

Another example is that vedolizumab is considered medically necessary for Crohn's disease when each of the following criteria are met: The individual is 6 years of age or older with moderate to severely active Crohn's disease and has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapies, such as a tumor necrosis factor antagonist or conventional drug therapy, such as aminosalicylates or 5-ASA products, such as mesalamine or sulfasalazine; an immunomodulator, such as azathioprine, 6-mercaptopurine, or methotrexate, or other immunosuppressive drugs; or the individual has failed to respond to, is intolerant of or has demonstrated dependence on systemic steroids, and vedolizumab is used for one of the following: to reduce the signs or symptoms of or induce or maintain clinical response or remission.

In contrast, looking at ulcerative colitis, Cigna believes that adalimumab is considered medically necessary for ulcerative colitis in an adult patient when the following criteria are met: failure or inadequate response, contraindication per FDA labeling, documented intolerance, or not a candidate for at least one conventional therapy, such as an aminosalicylate, steroid, or immunosuppressive.

Another example is that according to Cigna, vedolizumab is medically necessary for the treatment of ulcerative colitis in an adult older than the age of 18 when both of the following
criteria are met: failure or inadequate response, contraindication per FDA label, documented intolerance, or not a candidate for a corticosteroid or immunomodulator; or failure or inadequate response/contraindication per FDA label, documented intolerance, or not a candidate for adalimumab.

Again, as you can see, these are all very complicated, and each payer has different criteria for individual therapies.

So what can we do to secure approval for biologic therapies for our patients with IBD? Well, we have to provide payers with the clinical rationale for biologic therapy, and this can be done with a letter of medical necessity, the key components of which include the patient’s history and current diagnosis, including diagnosis codes where appropriate, clinical findings that led to the diagnosis, and emphasis on the parameters for aggressive disease, leading to the recommendation for biologic therapy. The letter of medical necessity should also include laboratory results, prior therapies, including the duration and outcome, and a clear rationale for the currently recommended therapy and dosing.

Keep in mind that diligent documentation, including a complete medication history to meet step therapy requirements, speeds the approval process and minimizes the amount of time you and your staff need in the prior authorization process. Remember, if you can document that treatment with a biologic agent is medically necessary or that contraindications to traditional therapies with corticosteroids or immunosuppressives exist, requests for appeals to use biologics as first-line agents are often successful.

Additionally, some insurance plans include coverage for biologics as first-line agents in specific circumstances with no need for appeal, such as fistulizing Crohn’s disease. Thus, it’s important to become familiar with policies of individual large insurance companies and Medicare to ease the burden of prior authorization.
Additional Strategies to Reduce the Prior Authorization Burden

Dr. Hanauer: So let’s discuss some additional strategies to reduce the prior authorization burden. With several choices available, it’s important for you and your practice to select the prior authorization method that will be most efficient, given your particular situation and options. These include standard electronic transactions, a payer portal, multi-payer portals, faxes, telephone calls, and secure email. Having a designated staff or staff members who understand the details of biologic approval can be both time-effective and cost-effective.

Using interconnectivity, electronic prior authorization provides real-time information to all participants in the prior authorization decision-making process. While there is growing interest in activity in the healthcare industry to adopt prior authorization standard electronic transactions, these automated solutions are not yet widely available.

Why do we need such an automated process? Well, nearly 40% of prior authorization requests are abandoned due to complex procedures and policies, and nearly 70% of patients encountering paper-based prior authorization requests do not receive the original prescription.

What are some of the benefits of electronic prior authorization? Well, this leverages eligibility and formulary data to notify providers of medications and prior authorization requirements before e-prescribing, and instead of forms, specific prior authorization questions are sent to the electronic health record system based on patient, health plan, and medication.

Pre-population of required patient information adds efficiency and accuracy to administrative tasks, and real-time communication with pharmacy benefits managers to complete prior authorization review before sending e-prescriptions can be adding to your efficiency.

These preapproved e-prescriptions that are routed to pharmacies won’t be subject to prior authorization blockade. So again, this isn’t widely available yet, but it is critical that the healthcare industry adopt a solution that creates cost and administrative efficiencies and ensures patients are not lost in the prior authorization process.

In conclusion, how can we address the ethical dilemmas in payer coverage? Insurance companies have special obligations and unique power. Tensions exist between providing care, emerging evidence, and the insurance bottom line for their fiduciary responsibilities.

Insurance companies do have an ethical obligation to patients as well as providers to understand the emerging medical research, to provide transparency in potential conflicts of interests, and to fund clinical research and education where there may be gaps.

Providers and payers can establish a relationship of trust to succeed in accountable inflammatory bowel disease care. They can share and learn from each other’s data and expertise. With mutual accountability and common goals for patient outcomes, providers and payers can get one step closer to the three-part aim of improved care quality, lower costs, and a better patient experience.
References

**Biologic Indication**

CD UC

Anti-TNF agents

- Infliximab
- Adalimumab
- Certolizumab pegol
- Golimumab

IL-12/-23 antagonist

- Ustekinumab

Anti-integrin agents

- Natalizumab
- Vedolizumab

**Therapeutic Target**

"Step-Up" for Low-Risk Patients

"Top-Down" for Moderate/High-Risk Patients

Recent data suggest that the early initiation of biologic therapy can modify disease progression.

**Crohn’s Disease**

**Ulcerative Colitis**

**Clinical**

- Resolution of abdominal pain
- Normalization of bowel habits
- Resolution of rectal bleeding
- Normalization of bowel habits

**Biomarkers**

- Normalization of CRP
- Normalization of fecal calprotectin

**Endoscopic**

- Absence of ulceration

**Definitions of Disease Severity in UC and CD**

**AGA Clinical Care Pathways**

**Algorithm for the Optimal Management of IBD**

**Current IBD Treatment Approaches**

**Top Down** for Low Risk Patients

**Step Up** for Moderate/Moderate-High Risk Patients

**Low Risk for Rapid Progression**

- Age at initial diagnosis >30 years
- Limited anatomic involvement
- No perianal and/or severe rectal disease
- Superficial ulcers
- No prior surgical resection
- No stricturing and/or penetrating pattern

**Moderate/Moderate-High Risk for Rapid Progression**

- Age at initial diagnosis ≤30 years
- Extensive anatomic involvement
- Perianal and/or severe rectal disease
- Deep ulcers
- Prior surgical resection
- Stricturing and/or penetrating pattern

**High Risk for Rapid Progression**

- Extensive colitis
- Deep ulcers
- Age <40 years
- High CRP and ESR
- Corticosteroid dependent
- History of hospitalization
- C. difficile infection
- CMV infection

**Predicting response to therapy:**
Determining who needs early surgery

**Selection of therapy**

**Current IBD Treatment Approaches**

**Top Down** for Low Risk Patients

**Step Up** for Moderate/Moderate-High Risk Patients

**Low Risk for Rapid Progression**

- Age at initial diagnosis >30 years
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- No perianal and/or severe rectal disease
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**Moderate/Moderate-High Risk for Rapid Progression**

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**High Risk for Rapid Progression**

- Extensive colitis
- Deep ulcers
- Age <40 years
- High CRP and ESR
- Corticosteroid dependent
- History of hospitalization
- C. difficile infection
- CMV infection

**Predicting response to therapy:**
Determining who needs early surgery

**Selection of therapy**

**Defining the Patient Who Would Benefit From Early Use of Biologic Therapy**

Ulcerative colitis (UC) and Crohn’s disease (CD) are lifelong inflammatory bowel diseases (IBDs) with a progressive course characterized by exacerbations and remissions.
To promote cost-effective healthcare, strategies are needed that minimize the amount of resources required for prior authorization. The UnitedHealthcare Criteria for prior authorization are not uniform across insurers, and most private insurers’ payer guidelines and step therapy protocols can be complex. Efforts to standardize payer guidelines and step therapy protocols can improve treatment adherence and compliance, resulting in overall effective care and reduced healthcare costs.

**The Prior Authorization Burden**

- Communication with 34 payers regarding IBD treatment guidelines and 25 payer step therapy protocols can be a substantial burden.
- The Big 5: Aetna, Cigna, Humana, UnitedHealthcare, and Anthem are the largest payers in the United States, and their criteria are met:
  - Ulcerative colitis (UC) in an adult individual has failed to respond to, is intolerant of, or has a medical contraindication to either of the following:
    - Conventional drug therapy, such as aminosalicylates/5-ASA (eg, sulfasalazine, mesalamine), corticosteroids, or immunosuppressants (eg, azathioprine, mercaptopurine)
    - A tumor necrosis factor (TNF) antagonist drug; adalimumab is used for one of the following:
      - Failure or inadequate response, contraindication per FDA label, or immunosuppressants (eg, azathioprine, mercaptopurine)
      - Individual has failed to respond to, is intolerant of, or immunomodulator (eg, azathioprine, mercaptopurine)
    - Vedolizumab is used for one of the following:
      - Failure or inadequate response, contraindication per FDA label, or immunomodulator (eg, azathioprine, mercaptopurine)
  - Crohn’s disease (CD) has a medical contraindication to either of the following:
    - Conventional drug therapy, such as aminosalicylates/5-ASA (eg, sulfasalazine, mesalamine), corticosteroids, or immunosuppressants (eg, azathioprine, mercaptopurine)
    - A tumor necrosis factor (TNF) antagonist drug; adalimumab is used for one of the following:
      - Failure or inadequate response, contraindication per FDA label, or immunomodulator (eg, azathioprine, mercaptopurine)
      - Individual has failed to respond to, is intolerant of, or immunomodulator (eg, azathioprine, mercaptopurine)
    - Vedolizumab is used for one of the following:
      - Failure or inadequate response, contraindication per FDA label, or immunomodulator (eg, azathioprine, mercaptopurine)
  - Medications are considered medically necessary in Crohn’s disease and ulcerative colitis when BOTH of the following criteria are met:
    - To induce or maintain clinical response or remission
    - To reduce signs or symptoms

**The Letter of Medical Necessity**

- A letter of medical necessity is required to document the rationale for the currently recommended therapy:
  - Patient’s history and current diagnosis
  - Previous therapy, duration, and outcomes
  - Clinical findings that led to diagnosis
  - Emphasis on parameters for aggressive disease (eg, hospitalizations, procedures, ED visits, etc)
  - Diagnosis codes where appropriate
  - Laboratory results
  - Clear rationale for the currently recommended therapy
  - Why patient is a good candidate for biologic therapy
  - Patient’s willingness to comply with therapy
  - Patient’s financial commitment to therapy
  - Provider’s willingness to continue therapy once initiated
  - Signatures of healthcare professionals, clinic staff, and patients

**Strategies for Cost Reduction**

- Improve treatment adherence and compliance
- Optimize treatment regimens based on individual patients, including a complete medication history to prevent medication nonadherence
- Ensure all of the payer’s criteria are met
- Provide the clinical rationale for biologic therapy in IBD

**Economic Burden of Disease**

- The annual financial burden of IBD in the United States is >$31 billion!
- Costs associated with IBD affect patients and their families, from hospitalization for surgical-related complications, to substantial burden for employers, and to loss of productivity for patients.

**Providing the Clinical Rationale for Biologic Therapy in IBD**

- To induce or maintain clinical response or remission
- To reduce signs or symptoms

**Failure to Obtain Prior Authorization Can Result in a Lack of or Delay in Treatment Initiation**

- Delaying a patient’s therapy can lead to a lack of alignment between payer guidelines and treatment guidelines, resulting in a lack of or delay in treatment initiation.
- Preventing medication nonadherence, including a complete medication history to prevent medication nonadherence, improves compliance, quality of life, and outcomes for the patient, and saves healthcare dollars needed to reach the pharmacy.
Additional Strategies to Reduce the Prior Authorization Burden

Having a designated staff member(s) to handle the logistical details of biologic approval can be both time-effective and cost-effective.

While there is growing interest and activity in the healthcare industry to adopt PA standard electronic transactions, these automated solutions are not yet widely available.

Using interconnectivity, provides real-time information to all participants in the PA decision-making process.

Electronic Prior Authorization

5 Benefits of New Electronic Prior Authorization Standards11
1. Leverages eligibility and formulary data to notify providers of medication PA requirements before e-prescribing
2. Instead of forms, specific PA questions are sent to the electronic health record system, based on patient, health plan, and medication
3. Pre-population of required patient information adds efficiency and accuracy to administrative tasks
4. Real-time communication with pharmacy benefits managers to complete PA review before sending e-prescription
5. Pre-approved e-prescriptions routed to pharmacy and won’t be subject to PA block

Nearly 40% of PA requests are abandoned due to complex procedures and policies10
Nearly 70% of patients encountering paper-based PA requests do not receive the original prescription10

Regularly Follow Up to Ensure Timely Prior Authorization Approval9

- Whether therapy is delayed, changed to a suboptimal choice, or abandoned altogether because of the lengthy appeal process, the patient’s health will be negatively affected
- Despite these challenges and negative impacts on patient care, physicians should exercise their PA appeal rights when they believe that the denied medical service or prescription is medically necessary
- Insurance companies have special obligations and unique power
- Tensions exist between providing care, emerging evidence, and the insurance “bottom line” (fuduciary responsibility)
- Insurance companies have an ethical obligation to patients (and providers):
  - To understand the emerging medical research
  - To provide transparency in potential conflicts of interest
  - To fund clinical research and education where there are gaps (maybe)

When a PA is inappropriately denied, submit an organized, concisely articulated appeal with supporting clinical information

5 Benefits of New Electronic Prior Authorization Standards11

- Pharmaceutical manufacturers
  - PA and appeals support
  - Patient assistance programs
- Specialty pharmacy dispensing the biologic
  - Reimbursement hubs
- Crohn’s & Colitis Foundation of America12
- AMA Prior Authorization Toolkit13
- AGA Roadmap to the Future of GI Toolbox14

Additional Resources and Tools to Facilitate Approval and Optimal Clinical Use of Biologics in IBD

For full references, accreditation, and disclosure information, please refer to the online activity.
Practical Strategies to Increase Patient Access to Biologic Therapy in IBD

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