South Carolina
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To:
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Dear Decision Makers,

The South Carolina Gastroenterology Association leadership recently reviewed your updated (5/30/22) policy on biologic therapies in patients with inflammatory bowel disease. We specifically focused on the step-therapy algorithm (CAM 104), a specific BCBS of SC template applied to use of vedolizumab, but generalized to other biologics in your policy white papers. FDA-approved for use in moderate to severe ulcerative colitis and Crohn's since 2014, vedolizumab is a humanized monoclonal antibody that specifically targets integrin receptors in the gut.

Vedolizumab is emblematic of the kind of breakthrough therapeutics that treat IBD by targeting specific elements of the immune system, without weakening other protective immune mechanisms. Such target-specific strategy combines successful clinical outcome with significantly fewer side effects compared to older therapies.

As recounted in their recent editorial in the July issue of the American Journal of Gastroenterology, Dr. Kim Isaacs (UNC Chapel Hill) and Dr. Sunanda Kane (Mayo Clinic Rochester) discussed the current state of choosing therapeutics in IBD care:

> *When the only biologics were antitumor necrosis factor agents, it was not hard to treat our sick Crohn's patients. Now with multiple mechanisms of action, the therapeutic landscape is more broad but can be confusing. When deciding what agent is "best" for any specific patient, multiple factors have to be taken into consideration.*
> [Am J Gastroenterol 2022;117:1041–1043]

As clinicians on the front line of IBD care, gastroenterologists strive to heal patients afflicted with this challenging disease, while cleaving to the Hippocratic tenet of "First, do no harm." This means choosing the drug most likely to help, and least likely to harm.

We believe that drug-treatment guidelines—in this case, the use of biologics—should not ignore the patient's perspective. For those of us with Crohn's or ulcerative colitis patients, it is an ever-present reality, and a growing concern on social media. Here is Eitan's story:

I was 21 years old, healthy, active, and pursuing a degree when I was diagnosed with ulcerative colitis. My doctor started me on steroids and other oral drugs right away, but they didn't help. I felt hopeful when he recommended a stronger, targeted biologic therapy, but my insurance company said I'd have to try and fail on other less costly medications before they would pay for the new one.

I dedicated six months of my life to trying and failing on the medications my insurer preferred, a protocol they call step therapy. That was half a year of continued symptoms—urgency, bleeding, weight loss, inflammation, and ulceration. By the time my insurer approved the medication my doctor originally prescribed, my colon was in bad shape. I spent 15 weeks on the treatment but saw no improvement—the damage done was irreversible. That summer, my colon was surgically removed, and I began life with an ostomy bag. I have to deal with the effects of long-term steroid use, including cataracts & weakened bones. I often wonder whether I could have avoided pain, hospitalizations, surgeries, and emotional struggles if I had been allowed to follow my doctor's earliest medical direction. I don't want other IBD patients to go through the struggles I did. [https://www.crohnscolitisfoundation.org/stories]

We know that getting a patient on the right treatment as soon as possible can significantly change disease trajectory; even a small course correction early on can sidestep complications and bring the patient to a much better place. For this to work, it has to happen before that window of opportunity closes, especially for the biologically-naive patient. Each step in the current IBD policy algorithm takes time, time that can easily add up to a 6 month delay, a time when even the "right drug" cannot undo the damage.

Step therapy, while not ideal, does provide a structured approach for navigating the growing expanse of therapeutic choices. We believe that a collaborative approach can identify specific modifications to improve traditional step therapy, such that all stakeholders benefit. That is why we are closely coordinating with our member gastroenterologists around the state, IBD specialists at the Medical University of SC, and, at the national level, the Crohn's and Colitis Foundation, and the American College of Gastroenterology.

While many states have passed step therapy legislation, we feel that a collegial approach is preferable and highly achievable. It seems eminently reasonable to optimize patient treatment using the more efficacious and safer biologics now available. These agents target specific cytokines and receptors involved in the inflammatory pathway. Selecting the one most appropriate for the individual patient, while avoiding delays in treatment, seems the smartest way to approach this.

We are all in this together—patients, physicians, insurers, and drug manufacturers—and it doesn't have to be a zero sum game. We believe we can find a way forward together, and communication is the first step in this process. That is why we are reaching out to you now, in order to start a dialogue, acknowledge each other's concerns and goals, and recognize that when patients win, we all win.

We also believe that businesses—insurance companies, pharmaceutical enterprises, and medical practices alike—must maintain good fiscal stewardship, not just to survive, but to excel at the critical role each plays in the continuum of IBD care. Costs are a reality we all share, but it's sometimes helpful to remind ourselves that the most expensive therapy is the one that doesn't work.

We look forward to your reply. Hopefully we can find a time to meet—virtually or in person—and start working together on these issues.

Sincerely,

John K. Corless MD AGAF
Chairman, IBD Healthcare Advocacy Committee
South Carolina Gastroenterology Association

cc:
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