



January 19, 2021

Ashley Bieck
UnitedHealthcare
Vice President, National Provider Advocacy
9800 Health Care Lane
Minnetonka, MN 55343

Dear Ms. Bieck,

The American College of Gastroenterology (ACG), American Gastroenterological Association (AGA), American Society for Gastrointestinal Endoscopy (ASGE) and North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) collectively represent all practicing gastroenterologists in the United States. We are writing to ask United to ***delay implementation of its policy change on Remicade coverage announced in the [December 2020 Medical benefit specialty drug update bulletin](#)***.

We are concerned the timing of the announcement over the winter holidays and during a surge in the COVID-19 pandemic caused the change to go unnoticed by providers. In our outreach to members of our societies' coverage policy workgroups, we have found no one who was aware of the change. This is particularly concerning given its impact to their patients.

Our coverage policy experts who treat patients with Crohn's disease, ulcerative colitis and other gastrointestinal diseases are concerned the policy change does not provide the option of remaining on originator infliximab when deemed clinically necessary. First, this policy does not allow for appropriate shared decision making between clinician and patient. Additionally, the policy change requires switching in all clinical scenarios, which could include a one-time switch to a biosimilar for patients on stable dosing in clinical remission, but also for those are not on a stable dose, not in clinical remission, and/or who have already switched previously, resulting in "multiple switches" for these patients. This can result in mandating switching agents in clinical scenarios for which there is no data regarding safety and efficacy, resulting in potential loss of response and disease flare.

This policy, while designed to decrease costs, could ultimately create a more expensive situation that can involve emergency department (ED) visits, hospital admission, and surgery, as well as lost work and school days. Additionally, any policy that requires switching to a specific agent must specify that United will not require additional switches in the future, based on contracting changes and availability of newer biosimilar options.

Pediatric gastroenterologists have additional concerns, and it is imperative more pediatric data on the use of biosimilars (e.g., dosing parameters, efficacy and outcome data, and short- and long-term safety information) are obtained before implementing the policy change for children, as there is very little data

in pediatric patients with any of the biosimilars, particularly as first-line therapy and almost no data on switching to biosimilars from the originator agent. It is not appropriate to force pediatric patients to change therapies. Doing so increases distress in the children and their families and takes away from the ability for families to have informed discussions utilizing shared decision making with their pediatric gastroenterologist.

We urge United to postpone the planned February 1, 2021 implementation date and work with us on a solution. We understand United must watch the bottom line for its clients, and we are not asking United to consider implementing a full grandfather for all patients currently on Remicade. We would like to work with United to provide clinical information, studies and other data that support creating a pathway that will allow patients currently stable on Remicade to stay on the product if they and their gastroenterologist agree that doing so is best for the patient. **We also request a call between United policy experts and our staff and physician policy experts to better understand what United wishes to accomplish with this policy change and to provide clinical expertise to inform future policy changes so they do not adversely affect our United patient population. -**

Please contact Brad Conway, ACG, at 301-263-9000 or bconway@gi.org; Leslie Narramore, AGA, at 410-349-7455 or Lnarramore@gastro.org; Lakitia Mayo, ASGE, at 630-570-5641 or lmayo@asge.org; and Camille Bonta, NASPGHAN, at 202-320-3658 or cbonta@summithealthconsulting.com and we will be happy to begin the discussion with United. We look forward to hearing from you.

Sincerely,

American College of Gastroenterology
American Gastroenterological Association
American Society for Gastrointestinal Endoscopy
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition