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Sent via email to brian.wheeler@carefirst.com and stephanie.spence@carefirst.com

Dear Mr. Wheeler and Dr. Spence:

On behalf of the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA), American Society of Gastrointestinal Endoscopy (ASGE), Crohn's and Colitis Foundation, Improve Care Now (ICN) and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), we write regarding changes CareFirst Blue Cross Blue Shield (CareFirst) made to its preferencing strategy for select medications effective Jan. 1, 2025.

Remicade and Renflexis have non-preferred status under CareFirst's updated policy, which leaves Avsola and Inflectra as the only preferred infliximab products. The updated policy requires that preferred medications must be tried first before a non-preferred medication can be covered. This is problematic because Avsola and Inflectra are now widely considered as "underwater" — a situation that arises when reimbursement for a biosimilar is generally lower than practice acquisition costs. This policy will have a detrimental impact on timely patient access to care and will lead to higher out-of-pocket costs for CareFirst beneficiaries who rely on biologic products to treat their inflammatory bowel disease (IBD) — Crohn's disease and ulcerative colitis. **We urge CareFirst to ensure provider reimbursement for biologic products with preferred status under its policy at least match provider acquisition cost.**

Across the country, gastroenterology practices have stopped providing infusions for patients who are forced by their insurance company onto Inflectra or Avsola because they cannot provide infusions for those biologics due to the significant financial loss to the practice. As a result, patients may need to seek infusion care in the hospital which may have greater negotiating leverage to acquire biologics at a lower cost; yet, the cost of care provided in the hospital is higher for the patient and to the health care system.

CareFirst's policy states that its "Medical Preferred Drug Strategy supports utilization of preferred medications which are equally safe and clinically effective as non-preferred medications and leverages lower drug costs associated with biosimilar therapies to manage cost." While it may be true in some cases that a preferred medication is "equally safe and clinically effective as a non-preferred medication," there is significant risk, particularly among pediatric patients, with switching patients from one biologic

therapy to another. When CareFirst moves a biologic from preferred to non-preferred status it oftentimes forces a patient to switch therapies. Year-to-year formulary changes, and sometimes more frequently than that, means that many patients may be forced to switch therapies not once, but multiple times and against the recommendation of the treating physician.

IBD patients are vulnerable to potential immunogenicity from multiple non-medical therapy switches throughout their lifetimes. This risk in pediatric patients is clearly established in well-documented, large epidemiologic studies that show children with IBD have more severe disease phenotype than adult-onset IBD[1] which further impacts how the pediatric patient will respond to biologic agents. Children have the unfortunate unique situation with a longer lifetime burden of disease, more severe disease, and increased risk for progression to certain types of intestinal cancer if inflammation is not kept under appropriate control. Without restrictions of non-medical switching, children and adults are at risk of being repeatedly forced to switch on and off biologic therapies.

Changes to preferred drugs are occurring with increasing frequency, putting IBD patients, and particularly pediatric patients, at risk for adverse outcomes. **We therefore request that CareFirst's policy not mandate a switch to a preferred biologic of a patient who is stable on existing therapy.**

The new CareFirst policy also moved Skyrizi (risankizumab) and Entyvio (vedolizumab) from preferred to non-preferred status. **We strongly oppose this change.**

In addition to anti-TNF therapies, we would like to draw attention to several other biologics used to treat IBD. **Specifically, we highlight the medical evidence for why Skyrizi and Entyvio should be moved back to preferred status:**

1) In the SEQUENCE trial,[1] Skyrizi (risankizumab) was non inferior to Stelara (ustekinumab) with regard to clinical remission at week 24 in adults with moderate-to-severe Crohn's disease. Most notably, Skyrizi was superior to Stelara with regard to endoscopic remission at week 48 (31.8% vs. 16.2%; $p<0.001$). Skyrizi also demonstrated superior efficacy to Stelara across all secondary endpoints including the incidence of hospitalization related to Crohn's disease., This trial also found similar adverse events between the two medications. Based on this head to head clinical trial Skyrizi is preferred over Stelara for adults with Crohn's disease because of significant improvement of endoscopic remission compared to Stelara. Requiring patients with Crohn's disease to fail on Stelara prior to initiating Skyrizi will ultimately increase cost of care for patients, increase hospitalization, increase Crohn's disease related complications, and effect patients' quality of life.

2) Entyvio (vedolizumab) has been shown to be effective for Crohn's Disease, as well as for ulcerative colitis with minimal side effects including very low rates of infections due to its gastrointestinal

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[1] Peyrin-Biroulet L, Chapman JC, Colombel JF, Caprioli F, D'Haens G, Ferrante M, Schreiber S, Atreya R, Danese S, Lindsay JO, Bossuyt P, Siegmund B, Irving PM, Panaccione R, Cao Q, Neimark E, Wallace K, Anschutz T, Kligys K, Duan WR, Pivorunas V, Huang X, Berg S, Shu L, Dubinsky M; SEQUENCE Study Group. Risankizumab versus Ustekinumab for Moderate-to-Severe Crohn's Disease. N Engl J Med. 2024 Jul 18;391(3):213-223. doi: 10.1056/NEJMoa2314585. PMID: 39018531.

selective mechanism of action. In the VARSITY trial, patients with moderate-to-severe ulcerative colitis were randomized to adalimumab or Entyvio (vedolizumab). This study found a higher rate of patients in clinical remission at week 52 in patients on Entyvio (vedolizumab) vs adalimumab (31% vs. 22.5%; $p<0.0006$) In addition, the American Gastroenterological Association guidelines for treating adults with ulcerative colitis who have not responded corticosteroids and mesalamines recommends Entyvio (vedolizumab), infliximab, or Skyrizi (risankizumab) over Stelara (ustekinumab) and adalimumab.[2] In adults, in cases of non-severe ulcerative colitis, Entyvio is the preferred option because of its efficacy and safety profile.

In updating its preferencing strategy for select medications, CareFirst states in its policy, "When medically appropriate, the preferred medications… will need to be tried first before a non-preferred medication can be covered." We want to make it very clear that due to their specific mechanisms of action (MOA), it is not medically appropriate to switch someone on Skyrizi or Entyvio to any of the listed preferred drugs as none share the same MOAs. **By moving Skyrizi and Entyvio to non-preferred status, CareFirst would be forcing patients who were being effectively treated by these drugs to switch to another agent and MOA.**

In summary, we respectfully ask you to make the following changes:

- **Ensure provider reimbursement for biologic products with preferred status matches provider acquisition costs.**

- **Not mandate a switch for a preferred biologic for a patient who is stable on an existing therapy.**

- **Move Skyrizi and Entyvio back to preferred status.**

Our societies welcome a virtual meeting opportunity to expand upon these concerns and answer questions you may have. To arrange a meeting, please contact Camille Bonta, ASGE and NASPGHAN policy advisor at cbonta@summithealthconsulting.com or (202) 320-3658.

Sincerely,

American College of Gastroenterology
American Gastroenterological Association
American Society for Gastrointestinal Endoscopy
Crohn's and Colitis Foundation
Improve Care Now
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

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[2] Singh S, Loftus EV Jr, Limketkai BN, Haydek JP, Agrawal M, Scott FI, Ananthakrishnan AN; AGA Clinical Guidelines Committee. Electronic address: clinicalpractice@gastro.org. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. Gastroenterology. 2024 Dec;167(7):1307-1343. doi: 10.1053/j.gastro.2024.10.001. PMID: 39572132.