Treatment Discontinuation in Patients with Ulcerative Colitis or Crohn's Disease Receiving Biologic Therapies that Require Intravenous Infusions during Induction and Subcutaneous Injections during Maintenance

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Key Takeaways

- **Among patients with UC or CD treated with UST or RZB, approximately one in five discontinued treatment during the transition from IV induction to SC maintenance**
- **These findings reveal a high injectable biologic treatment discontinuation following the IV induction phase, emphasizing that changing the route of administration may be a key challenge in maintaining patients on injectable biologics**
- **Considerations regarding adherence should be given when deciding the route of administration of a drug, with a fully subcutaneous drug potentially offering advantages in treatment continuity**

Introduction

Adherence to biologic therapies that involve a transition from intravenous (IV) induction to subcutaneous (SC) maintenance can be challenging in patients with ulcerative colitis (UC) or Crohn's disease (CD)

Barriers exist with insurer-mandated prior authorization that can lead to delay in initiation and transition to maintenance therapy

Objectives

Describe the proportion of patients who discontinued biologic therapy within or at the end of the IV induction phase in CD or UC patients who required an IV to SC transition in the United States (i.e., UC: ustekinumab, risankizumab, and mirikizumab; CD: stekinumab and risankizumab)

Methods

Study design and cohort selection

- A retrospective cohort study used claims from the Optum's de-identified Clinformatics® Data Mart Database (1/1/2021–6/30/2024)
- **IBD overall cohort**
  1) Were ≥18 years old
  2) Had a diagnosis of UC or CD
  3) Had ≥1 claim indicating an IV infusion of ustekinumab, risankizumab, or mirikizumab on or after the respective FDA approval date
  4) Had continuous enrollment for 6 months prior to (baseline period) and 30 weeks post (follow-up period) the first biologic IV infusion (index biologic, of which the date defined as the index date)
- **Individual biologic sub-cohorts** were derived from the overall IBD cohort based on each patient's index biologic

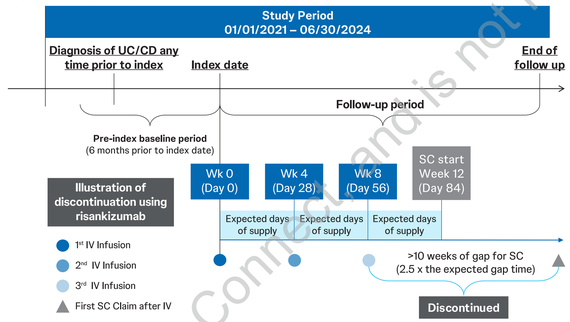
Study measures

- Treatment discontinuation was defined as a gap of ≥ 2.5 times the dosing interval between two consecutive IV infusions or between one IV infusion and one SC dose in the FDA label, i.e., 20 weeks for ustekinumab and 10 weeks for risankizumab/mirikizumab[2] (**Figure 1**)
  - The first observed IV infusion (index date) indicated the start of the induction phase, and the first observed SC pharmacy claim within the 30-week follow-up period indicated the beginning of a maintenance phase
- Proxy for discontinuation reasons potentially related to treatment effectiveness was defined as the use of a non-index advanced therapy, increased corticosteroid dose, or any IBD-related inpatient or emergency room visits between the index date and up to four weeks after discontinuation

Statistical analysis

- Discontinuation of the index biologic therapy during or by the end of the IV induction phase was summarized among the IBD overall cohort, sub-cohorts by index biologics, and among patients treated with the number of IV doses during induction per the FDA labels
- Study measures were summarized using means, standard deviations (SDs), medians, and interquartile ranges (IQRs) for continuous variables and counts and proportions for binary variables

Figure 1. Study design schema and illustration of treatment discontinuation



Results

A total of 3,261 eligible patients with UC or CD were included in the IBD overall cohort (Figure 2)

- ***Ustekinumab sub-cohort: 2,626 patients***
- ***Risankizumab sub-cohort: 635 patients***
- ***Mirikizumab sub-cohort: 0 patients[a]***

Among the overall cohort:

- ***72.1% of patients had CD and 27.9% of patients had UC***
- ***At baseline, 58.4% of patients had prior exposure to advanced therapies, with vedolizumab (17.0%) and adalimumab (16.0%) being the most common***

The distribution of baseline characteristics among the two sub-cohorts followed a similar pattern to that of the overall IBD cohort, except for IBD type

- ***Of the patients in the risankizumab sub-cohort who had three IV infusions, 24.2% discontinued during the transition from IV induction to SC maintenance therapy, with the majority (91.1%) not receiving any maintenance doses (Figures 3 & 4a)***
- ***Of the patients in the ustekinumab sub-cohort who had one IV infusion, 19.9% discontinued during the transition from IV induction to SC maintenance therapy, with the majority (96.0%) not receiving any maintenance doses (Figures 3 & 4b)***
- ***Among those who discontinued during the transition phase (N = 616), most patients (N = 586) did not receive a SC dose (Figure 4)***

Treatment discontinuation, overall and by key characteristics[a]

- ***During follow-up, 744 (22.8%) patients in the IBD overall cohort discontinued the index biologic therapy before receiving SC maintenance doses***
  - ***72 (9.7%) experienced at least one of the following events within four weeks of discontinuation: use of a non-index advanced therapy, an increased corticosteroid dose, or an IBD-related inpatient or emergency room visit, all of which suggest that treatment discontinuation may be associated with treatment effectiveness for some patients***
- ***The discontinuation rate was numerically higher among patients aged ≥65 years compared to those <65 years (49.1% vs. 15.0%), suggesting a greater treatment adherence burden in older populations, likely driven by multiple factors such as comorbidities***
- ***Discontinuation rates were similar across CD patient subgroups by CD location (ranging from 22.4% for ileocolonic location to 28.3% for ileal location)***
- ***Similarly, discontinuation rates were similar among patients with and without baseline disease-related hospitalization (23.5% and 22.7%, respectively)***

Note: [a] The numbers and percentages reported were out of the IBD overall cohort.

Study limitations include potential misclassification of treatment discontinuation due to the lack of information on free trial offers for biologics and the infeasibility to determine reasons for discontinuation from claims data. Future studies are needed to validate these findings and examine the reasons for such discontinuations

Figure 2: Sample selection flow chart of the IBD overall cohort

Step 1
Patients with ≥1 medical claim indicative of IV infusion of ustekinumab, risankizumab, or mirikizumab during the study period (1/1/2021 - 6/30/2024)

N = 7,421

Step 2
Patients with ≥1 diagnosis for UC or CD during the study period prior to or on the index date

N = 7,405 (99.8%)

Step 3
Patients with index date on or after the FDA approval date of the index biologic therapy

N = 7,349 (99.2%)

Step 4
Patients were at least 18 years old as of index date

N = 7,145 (97.2%)

Step 5
Patients with continuous enrollment for at least 26 weeks (6 months) prior to the index date and at least 30 weeks after the index date

N = 3,261 (45.6%)

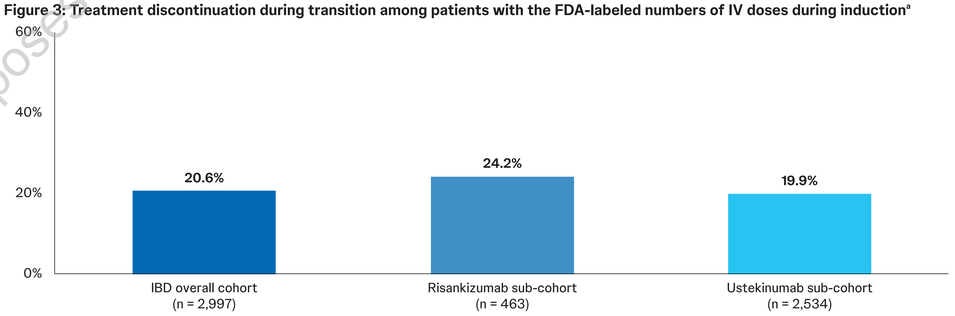
*Note: [a] Due to mirikizumab's FDA approval for UC on October 26, 2023, the data cutoff of June 30, 2024, and the required 30-week follow-up, no patients treated with mirikizumab were identified. Abbreviations: **CD**=Crohn's disease; **FDA**=Food and Drug Administration; **IBD**=inflammatory bowel disease; **IV**=intravenous; **UC**=ulcerative colitis*

Table 1: Baseline characteristics among the IBD overall cohort and by index biologics

	IBD overall cohort (N = 3,261)	Risankizumab sub-cohort (N = 635)	Ustekinumab sub-cohort (N = 2,626)
Demographics as of the index date			
Age at index, mean ± SD	48.8 ± 17.6	48.8 ± 17.1	48.8 ± 17.7
Female, n (%)	1,728 (53.0%)	356 (56.1%)	1,372 (52.2%)
Education, n (%)			
Less than bachelor degree	2,273 (69.7%)	445 (70.1%)	1,828 (69.6%)
Bachelor degree and above	770 (23.6%)	143 (22.5%)	627 (23.9%)
Unknown	218 (6.7%)	47 (7.4%)	171 (6.5%)
Clinical characteristics at baseline			
IBD type, n (%)			
CD	2,350 (72.1%)	635 (100.0%)	1,715 (65.3%)
UC	911 (27.9%)	0 (0.0%)	911 (34.7%)
History of advanced therapies at baseline, n (%)			
Any prior use of advanced therapies	1,904 (58.4%)	393 (61.9%)	1,511 (57.5%)
Vedolizumab[a]	554 (17.0%)	100 (15.7%)	454 (17.3%)
Adalimumab[a]	522 (16.0%)	83 (13.1%)	439 (16.7%)
Infliximab[a]	445 (13.6%)	94 (14.8%)	351 (13.4%)
CCI, mean ± SD	0.7 ± 1.3	0.8 ± 1.4	0.7 ± 1.3

*Note: [a] Three most frequently used advanced therapies are presented. Abbreviations: **CCI**=Charlson Comorbidity Index; **CD**=Crohn's disease; **IBD**=inflammatory bowel disease; **SD**=standard deviation; **UC**=ulcerative colitis*

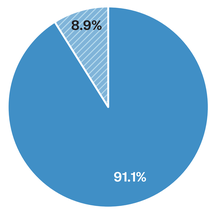
Figure 3: Treatment discontinuation during transition among patients with the FDA-labeled numbers of IV doses during induction[a]



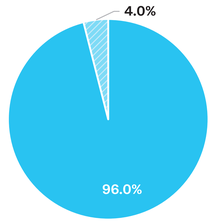
*Note: [a] Patients received the required number of IV doses during induction per FDA label, regardless of discontinuation during the induction phase. Abbreviations: **FDA**=Food and Drug Administration; **IBD**=inflammatory bowel disease; **IV**=intravenous*

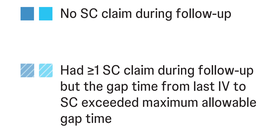
Figure 4: Discontinuation type during transition from IV induction to SC maintenance phase by index biologics

(a) Risankizumab sub-cohort who discontinued after the last IV (n = 112)



(b) Ustekinumab sub-cohort who discontinued after the last IV (n = 504)





*Abbreviations: **IV**=intravenous; **SC**=subcutaneous*

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