

Early Real-World Experience With Guselkumab Among Patients With Ulcerative Colitis and Crohn's Disease: Characteristics, Treatment Patterns, and Healthcare Resource Utilization

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Introduction

- Advanced therapies (ADTs) have improved outcomes in inflammatory bowel disease (IBD), yet unmet clinical needs and treatment burden persist¹
- Guselkumab (GUS) recently received US regulatory approval for the treatment of ulcerative colitis (UC) and Crohn's disease (CD)^{2,3} however, real-world evidence on its use in clinical practice remains limited

Objective

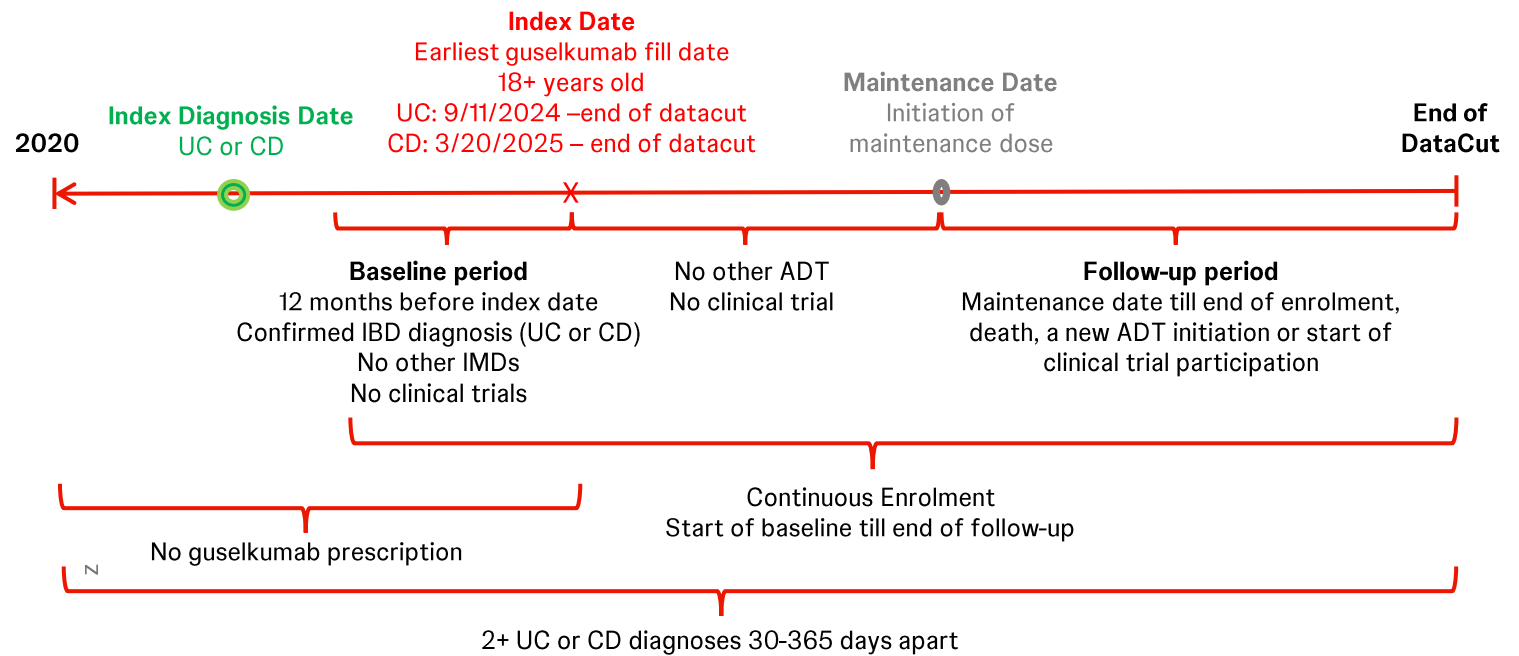
- This observational study describes patient characteristics, treatment patterns, healthcare resource utilization (HCRU), and early persistence with GUS among patients with UC or CD initiating GUS

Methods

Study design and data source

- This retrospective cohort study used HealthVerity taXonomy X claims data to identify adults (≥18 years) with UC or CD who initiated GUS between 1/1/2020 and 2/28/2026
- The index date was defined as the date of the first claim for GUS on or after the corresponding FDA approval for UC (9/11/2024) or CD (3/20/2025)
- Follow-up began at the start of GUS maintenance treatment and ended at disenrollment, data cutoff, clinical trial participation, or death

Figure 1. Study design



Study population

- Patients were eligible if they had ≥12 months of continuous enrollment before index, ≥1 post-index GUS algorithm-defined maintenance dose, and continuous enrollment between the index date and maintenance
- Patients were excluded if they had prior GUS use, baseline clinical trial participation or other immune-mediated conditions, or non-GUS ADT use or clinical trial participation between the index date and maintenance

Data analysis

- Descriptive statistics summarized characteristics, treatment patterns, HCRU (per 1000 patient months), and treatment persistence (Kaplan-Meier curve)
- Treatment changes were assessed from 90 days before the index date to 90 days after maintenance initiation among patients with ≥90 days of follow-up

Results

Patient characteristics

- A total of 525 patients with UC and 447 patients with CD who had ≥1 GUS maintenance dose were identified. Patient characteristics are summarized in Table 1

Table 1. Patient characteristics

Baseline characteristic	Patients with UC (n=525)	Patients with CD (n=447)
Age at index date, mean (SD), years	42.5 (15.9)	43.8 (15.5)
Age category, n (%)		
18-39 years	279 (53.1)	200 (44.7)
40-64 years	182 (34.7)	196 (43.8)
≥65 years	64 (12.2)	51 (11.4)
Female, n (%)	252 (48.0)	248 (55.5)
Race, n (%)		
White	374 (71.2)	327 (73.2)
Black	42 (8.0)	44 (9.8)
Asian	13 (2.5)	3 (0.7)
Other/Unknown	96 (18.3)	73 (16.3)
Ethnicity, n (%)		
Hispanic	63 (12.0)	35 (7.8)
Non-Hispanic	359 (68.4)	329 (73.6)
Unknown	103 (19.6)	83 (18.6)
Primary payer type, n (%)		
Commercial	388 (73.9)	296 (66.2)
Medicaid	67 (12.8)	85 (19.0)
Medicare Advantage	70 (13.3)	66 (14.8)
QCCI, mean (SD)	0.7 (1.3)	0.7 (1.3)
Patients with QCCI ≤2, n (%)	489 (93.1)	405 (90.6)
Patients with ≥1 FCD diagnosis, n (%)	NA	61 (13.6)
Comorbidities and intestinal complications, n (%)		
Any general comorbid conditions	474 (90.3)	403 (90.2)
Any intestinal complications	172 (32.8)	152 (34.0)
Mean follow-up (SD), days	235 (99)	178 (62)

Abbreviations: CD, Crohn's disease; FCD, fistulizing Crohn's disease; QCCI, Quan-Charlson Comorbidity Index; SD, standard deviation; UC, ulcerative colitis.

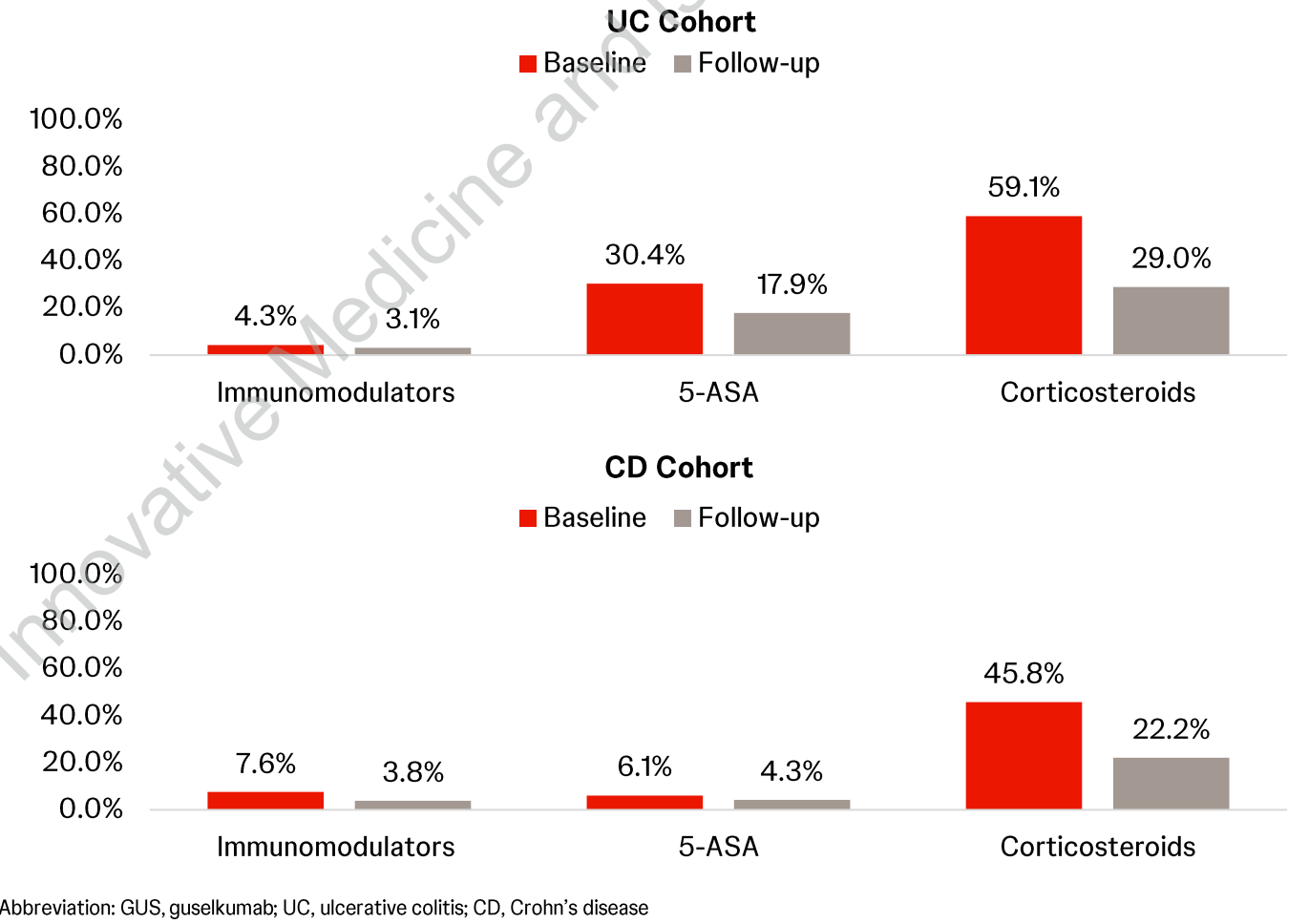
Treatment patterns among patients with UC

- Among patients with UC who initiated GUS, 41.0% were ADT-naïve at baseline, while 49.1% had received 1 ADT during baseline
- Most patients (87.8%) started GUS maintenance treatment with 200 mg q4w dosing
- From baseline to follow-up, the use of immunomodulators, 5-ASA, and corticosteroids decreased (Figure 1)

Treatment patterns among patients with CD

- Among patients with CD who initiated GUS (N=447), 35.8% were ADT-naïve at baseline and 56.2% had received 1 ADT during baseline
- Most patients (92.4%) started GUS maintenance with 200 mg q4w dosing
- Use of 200 mg maintenance dose was more common among biologic-naïve patients (95.9%) than among patients with prior biologic use (90.2%)
- From baseline to follow-up, the use of immunomodulators, 5-ASA, and corticosteroids decreased (Figure 1)

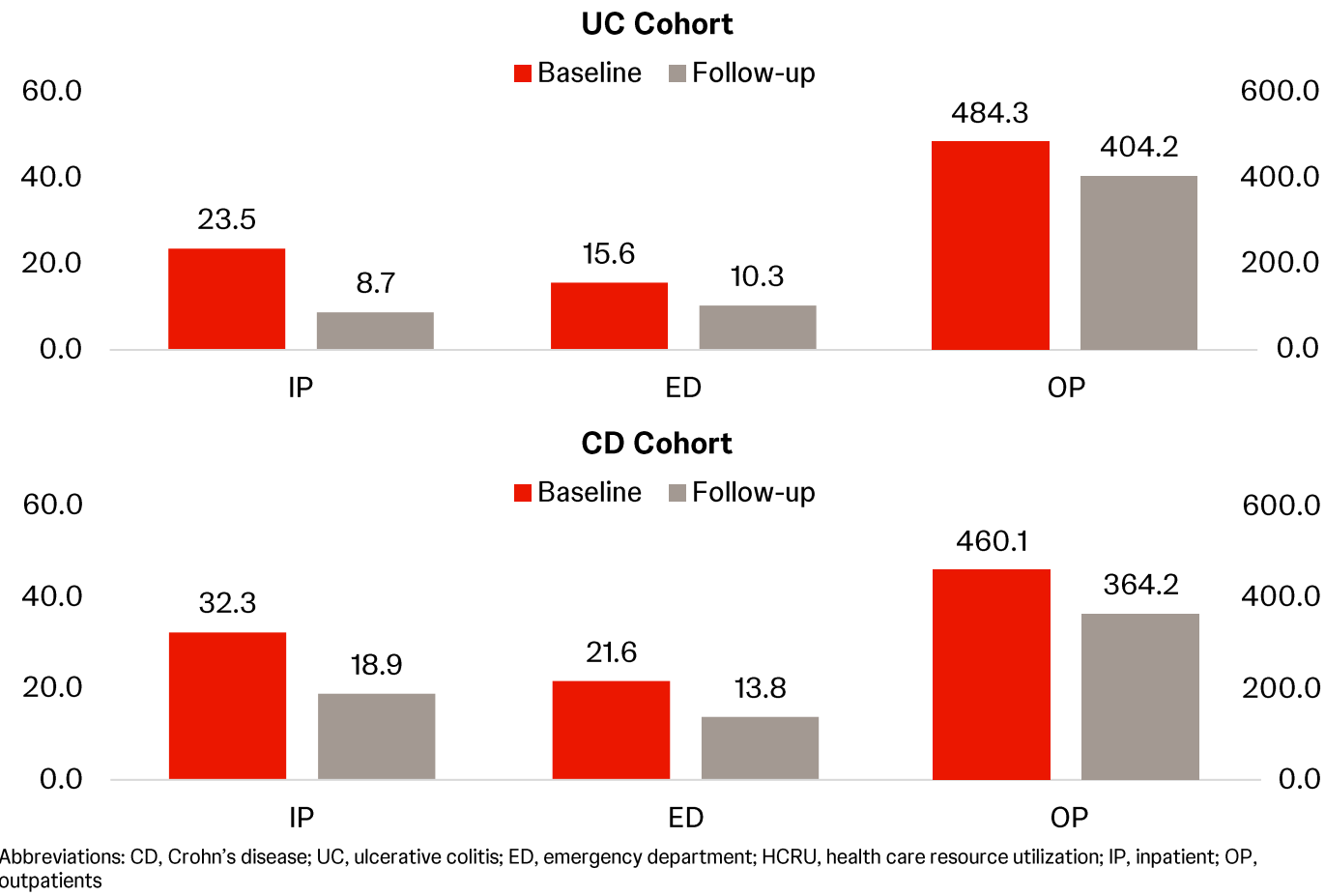
Figure 1. Changes in therapy class use from baseline to follow-up



HCRU among patients with UC and CD

- IBD-related HCRU decreased from baseline to follow-up in both patients with UC and patients with CD (Figure 2)

Figure 2. IBD-related HCRU among patients with UC or CD (per 1000 patient months)



Treatment persistence

- Among patients with UC who initiated GUS, 90-day persistence after maintenance initiation was 83.8% (95% CI: 79.9%, 87.0%)
- Among patients with CD who initiated GUS, 90-day persistence after maintenance initiation was 76.3% (95% CI: 70.8%, 81.0%)

Key Takeaways

- Approximately 36%–41% of patients with UC or CD who initiated GUS were ADT-naïve before GUS initiation
- Use of non-ADT therapies, including corticosteroids, and IBD-related HCRU decreased during follow-up among patients with UC or CD

Conclusions

- In this real-world cohort of early GUS initiators, GUS was used across diverse patients with UC or CD, including many ADT-naïve patients
- Declines in the use of corticosteroids and other non-ADT therapies, together with lower IBD-related HCRU during follow-up, suggest favorable early treatment and utilization patterns
- Longer follow-up is needed to evaluate real-world effectiveness, long-term persistence and outcomes, and dose optimization among patients initiating GUS

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