

Treatment Gaps, Surgical Burden, and Healthcare Resource Utilization Around the Time of Diagnosis in Fistulizing Crohn's Disease: A US Claims Analysis

Hsien-Yen Chang, PhD¹; Sumesh Kachroo, PhD²; Jennifer Seminerio-Diehl, MD³

¹Johnson & Johnson, Titusville, NJ, USA; ²Johnson & Johnson, Horsham, PA, USA; ³AdventHealth Orlando, Orlando, FL, USA

Introduction

- Fistulizing Crohn's disease (FCD) affects approximately 25% of patients with Crohn's disease (CD) and is associated with substantial clinical, humanistic, and economic burden^{1,2}
- Current guidelines recommend anti-TNF therapy for disease management;³ however evidence beyond this class remains limited
- Recently, the phase 3 FUZION study demonstrated significantly higher rates of combined fistula remission with guselkumab versus placebo at week 24 in adults with active perianal FCD⁴

Objective

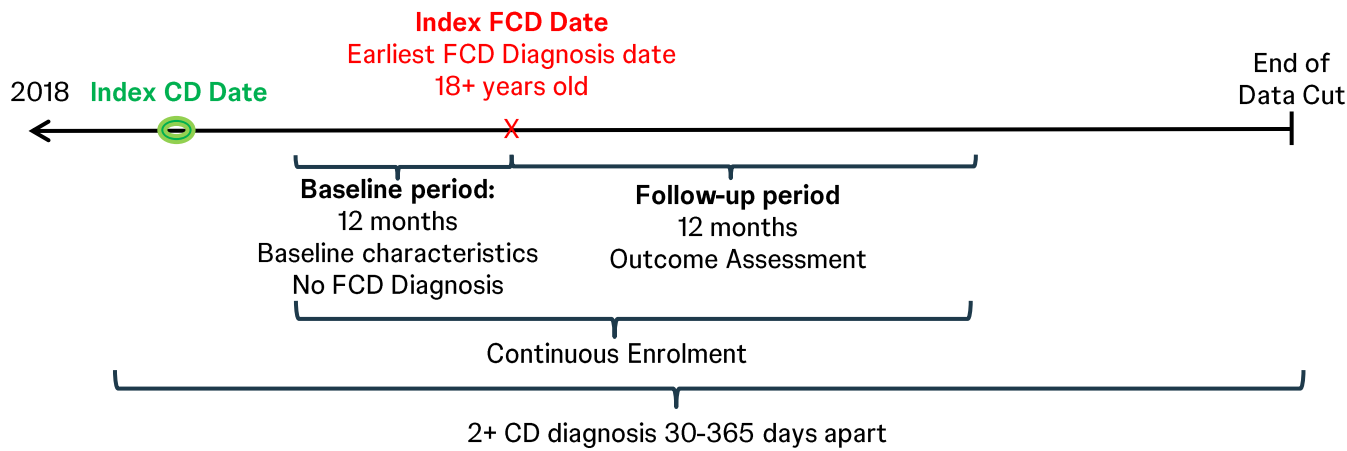
- This study describes annual FCD prevalence from 2018 to 2025, and evaluates unmet needs, evolving treatment patterns, and healthcare resource utilization (HCRU) among patients with newly diagnosed FCD, inclusive of patients who continued anti-TNF treatment pre and post FCD diagnosis.

Methods

Study design and data source

- This descriptive study used the HealthVerity taXonomy X claims data (2018–2026)
- A cross-sectional study design was used to estimate annual FCD prevalence
- A retrospective cohort study design was used to evaluate outcomes among patients with newly diagnosed FCD

Figure 1. Study design



Study population

- The newly diagnosed FCD cohort included adults (≥18 years) with CD and a new diagnosis of FCD. The index date was defined as the first FCD diagnosis
- Eligible patients had ≥12 months of continuous enrollment pre-index (baseline) and post-index (follow-up)
- Patients were excluded if they had a prior FCD diagnosis, ulcerative colitis, or FCD-related surgeries during baseline
- Anti-TNF continuing patients:** patients with the same closest ADT during the 90-day pre/post treatment change evaluation period, with the ADT as anti-TNF

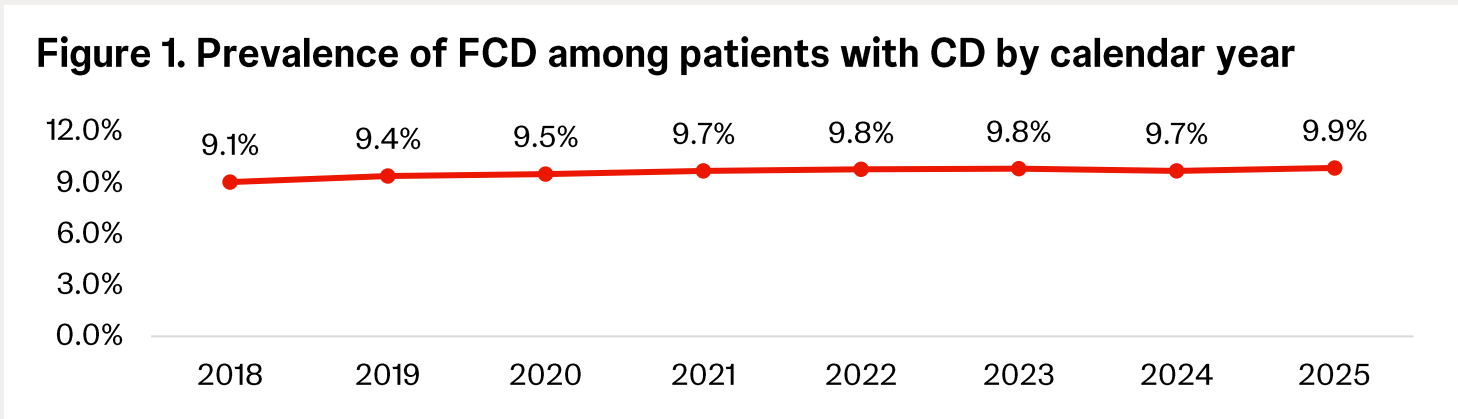
Data analysis

- Annual FCD prevalence was defined as the proportion of continuously enrolled patients with CD who had a diagnosis of FCD
- Treatment changes were assessed by comparing the closest advanced therapy (ADT) and all non-ADT (5-ASA, immunomodulators, antibiotics, or corticosteroids) within the 90-day pre- and post-index windows
- All analyses were descriptive

Results

Annual prevalence of FCD

- Annual prevalence of FCD among patients with CD increased over time, from 9.1% in 2018 to 9.9% in 2025 (Figure 1)



Characteristics of patients with FCD

- The newly diagnosed FCD cohort included 18,152 patients. Patient baseline characteristics are summarized in Table 1

Table 1. Table 1. Baseline characteristics of patients with newly diagnosed FCD

Baseline characteristic	N=18,152
Age at index date, mean (SD), years	43.5 (15.6)
Age category, n (%)	
18-39 years	8,070 (44.5)
40-64 years	8,386 (46.2)
≥65 years	1,696 (9.3)
Female, n (%)	9,379 (51.7)
Race, n (%)	
White	13,368 (73.6)
Black	2,069 (11.4)
Asian	248 (1.4)
Other/Unknown	2,467 (13.6)
Ethnicity, n (%)	
Hispanic	1,183 (6.5)
Non-Hispanic	13,959 (76.9)
Unknown	3,010 (16.6)
Primary payer type, n (%)	
Commercial	11,688 (64.4)
Medicaid	2,082 (11.5)
Medicare Advantage	4,382 (24.1)
QCCI, mean (SD)	0.7 (1.3)
Patients with QCCI ≤2, n (%)	16,616 (91.5)
Comorbidities and intestinal complications, n (%)	
Any general comorbid conditions	15,168 (83.6)
Any intestinal complications	4,758 (26.2)

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

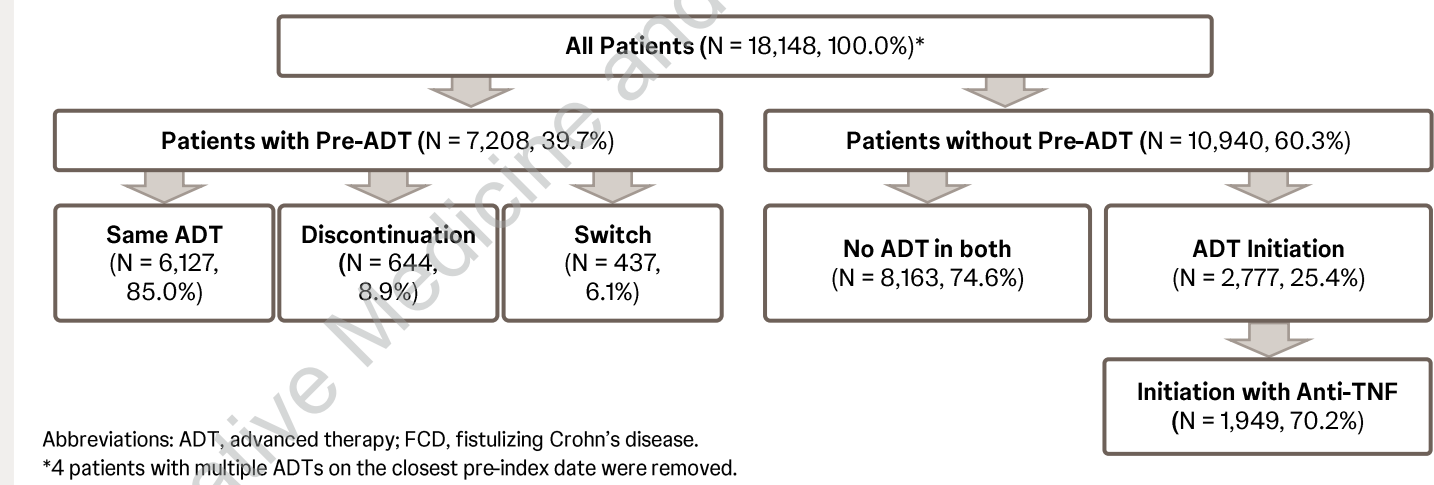
Treatment patterns

- From baseline to follow-up, biologic use increased from 44.6% to 62.5%, with anti-TNF therapies remaining predominant among biologic users (70.6% at baseline; 66.6% during follow-up)
- Despite increased biologic use, 23.5% underwent FCD-related surgery during follow-up, occurring a mean of 66.7 days post-diagnosis

Changes in ADT exposure status

- Changes in ADT and non-ADT use were observed within the 90 days pre- and 90 days post-index windows (Figure 2)

Figure 2. Changes in ADT exposure status around the time of FCD diagnosis (90 days pre- and post-index)

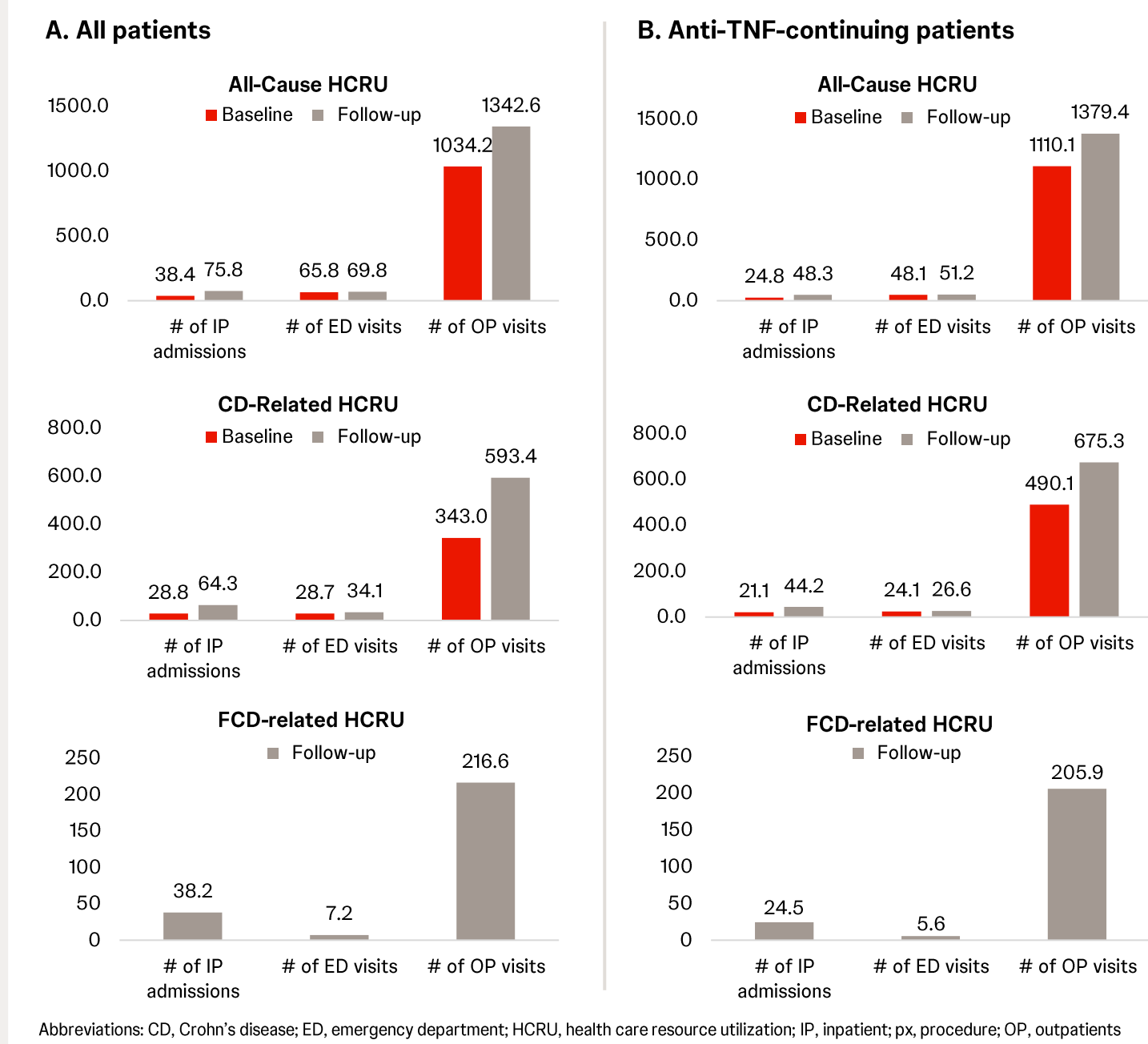


Abbreviations: ADT, advanced therapy; FCD, fistulizing Crohn's disease.
*4 patients with multiple ADTs on the closest pre-index date were removed.

HCRU

- Both all-cause and CD-related HCRU across all measured categories increased from baseline to follow-up after FCD diagnosis (Figure 3A)

Figure 3. All-cause, CD- and FCD-related HCRU (per 1000 patient months)



Subgroup analysis

- Among 4,660 patients receiving anti-TNF as their latest ADT within 90 days pre index, 4,050 patients (86.9%) continued their anti-TNF treatment into the follow-up period
- The mean duration of anti-TNF treatment was 596.1 days overall (285.1 days prior to FCD and 311.0 days following FCD diagnosis); 488 patients (12.0%) received ≥1 non-anti-TNF advanced therapy during follow-up
- Anti-TNF containing patients had all-cause HCRU increased from baseline to follow-up, particularly outpatient visits (1,110.1 to 1,379.4 per 1000 patient months) (Figure 3B)

Key Takeaways

- Annual FCD prevalence among patients with CD increased from 9.1% in 2018 to 9.9% in 2025
- Biologic use increased around the time of FCD diagnosis, yet 23.5% of patients underwent FCD-related surgery
- Most patients maintained their pre-diagnosis ADT exposure status after FCD diagnosis, with many patients continuing the same ADT or not initiating an ADT
- Both all-cause and CD-related HCRU increased after FCD diagnosis, including among the subgroup of patients continuing anti-TNF treatment

Conclusions

- Rising prevalence, substantial surgical burden, frequent absence of ADT use or modification around the time of diagnosis, and increased HCRU highlight persistent unmet needs and suboptimal disease control in FCD within a treatment landscape that remains largely anchored in anti-TNF therapies
- Collectively, these findings suggest that currently available treatment approaches may be insufficient for many patients with FCD and provide real-world context for the recent FUZION data in perianal FCD
- These findings underscore the need for more effective, mechanism-diverse, and durable treatment strategies

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