VANDERBILT HEALTH | Specialty Pharmacy

Dual Advanced Therapy in Inflammatory Bowel Disease: Time to Access and Patient Characteristics

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PURPOSE

Characterize the use of dual advanced therapy (DAT) in Inflammatory Bowel Disease (IBD) and the specialty pharmacist role in medication access.

METHODS

Study Design
Single-center, retrospective review

Study Setting
IBD outpatient clinic at VUMC with an integrated health-system specialty pharmacy

Study Sample
Inclusion: Patients with IBD newly referred for DAT from a Vanderbilt University Medical Center (VUMC) provider between April 2024 and April 2025
Exclusion: Patients who discontinued the first medication and continuing therapy under new insurance

Outcomes
Primary Outcome: Number of patients who started DAT and the type of treatment
- Drug classes used, reasons for non-initiation, alternative therapies started if DAT was not approved

Secondary Outcome: Time to DAT approval
- Number of days between prior authorization (PA) initiation and insurance approval or manufacturer assistance program (PAP) approval, number of patients approved through a PA or appeal, and the reasons for PA denial

Analysis
Descriptive statistics were used to summarize the data
Cox proportional hazard model assessed factors associated with time to DAT insurance approval
- Covariates: Medication type (intravenous [IV] or subcutaneous [SQ]), insurance type, age, number of previous therapies, history of dose escalation, and diagnosis were included in the model

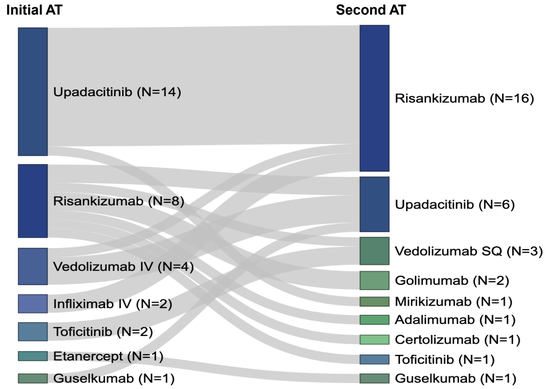
RESULTS

Table 1. Patient Characteristics (N=32)

Patient Characteristic	N=32 N (%)
Age at DAT decision date, Median (IQR)	42 (36, 53)
Gender	
Female	16 (50)
Male	16 (50)
Insurance	
Commercial	26 (82)
Medicare	6 (18)
Race	
White	28 (88)
Black or AA	2 (6)
Other	2 (6)
Diagnosis	
Crohn's disease (CD)	28 (88)
Ulcerative colitis (UC)	4 (12)

Abbreviations: Interquartile range (IQR); African American (AA), Hazard ration (HR), Confidence interval (CI)

Figure 1. Progression from Initial AT to DAT

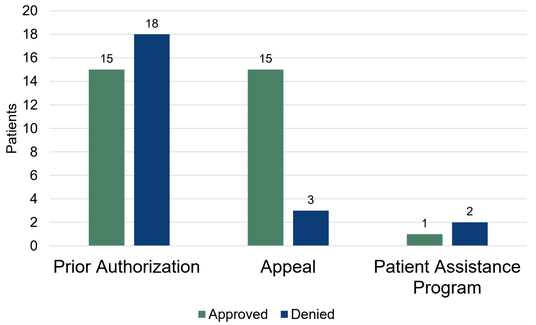


CONCLUSIONS

- Overall, median time to medication approval was **11 (IQR 1-24) days**
- **97%** of DAT treatment attempts required a PA
- Patients with **Medicare** (p=0.003) and **Ulcerative Colitis** (p = 0.046) were significantly more likely to receive approval for DAT sooner

RESULTS

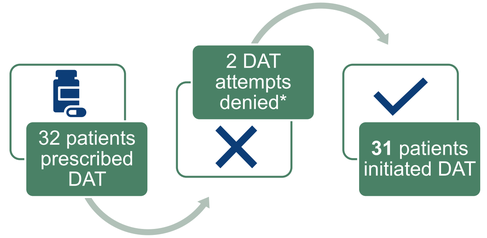
Figure 2. Patient Access Journey and Median Time to Approval



Prior Authorization: Median 1 day (IQR 0, 3)
Appeal: Median 24 days (IQR 16, 36)
Patient Assistance Program: Median 138 days (IQR 138, 138)

*1 patient did not require a PA, 1 patient did not start DAT , 1 patient did not start first DAT, then was approved for a second DAT regimen

Figure 3. DAT Initiation



97% of referred patients started DAT

One patients who was denied DAT, continued monotherapy
One patient who was denied DAT, started an alternative DAT, then initiated a second DAT regimen

Table 2. Reasons for PA Denial

Reason	N=18 N (%)
Combination Therapy	11 (61)
Did Not Meet Insurance Criteria	5 (28)
Off-Label Use	1 (6)
Required Formulary Alternative	1 (6)

Figure 4. Top 5 DAT Combinations

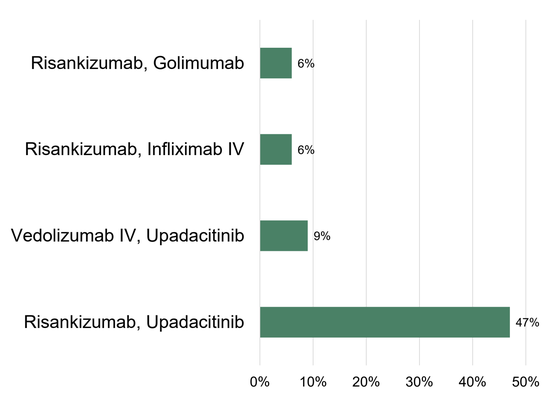
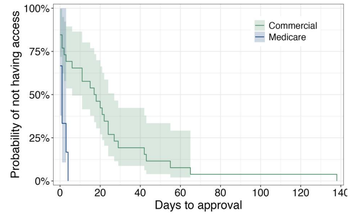


Table 3. Factors Associated with Time to DAT Insurance Approval

	HR	95% CI	p-value
IV to SQ	1.54	0.76-3.15	0.233
Medicare (Relative to commercial)	**5.02**	**1.71-14.77**	**0.003**
Age (per 10 years)	1.19	0.88-1.60	0.254
Number of previous therapies (per 1 additional therapy)	0.84	0.69-1.03	0.088
History of dose escalation	1.11	0.38-3.22	0.845
Ulcerative Colitis	**3.14**	**1.02-9.70**	**0.046**

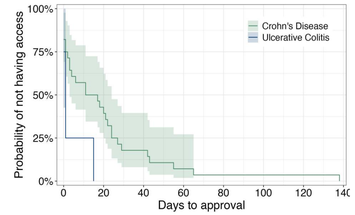
Figure 5. Time to Insurance Approval Model

Time to Approval by Insurance



Patients with **Medicare** were significantly **more likely** to receive DAT **approval sooner**

Time to Approval by Diagnosis



Patients with **Ulcerative Colitis** were significantly **more likely** to receive DAT **approval sooner**