VANDERBILT HEALTH | Specialty Pharmacy

Evaluating the Access Process for Patients Transitioning from Intravenous to Subcutaneous Biologic Administration for Inflammatory Bowel Disease

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Background

Vedolizumab and infliximab were approved for subcutaneous (SC) administration in 2023 for inflammatory bowel diseases (IBD), including moderate to severe Crohn's disease (CD) and ulcerative colitis (UC).

Purpose

Evaluate the vedolizumab and infliximab SC access process, factors that delay time to access, and factors that impact whether a patient starts SC vedolizumab or infliximab after insurance approval.

Methods

Study Design

Single center, ambispective cohort study at Vanderbilt Health System IBD Clinic with an integrated health system specialty pharmacy (HSSP)

Population

Patients with CD or UC referred to start or transition to SC vedolizumab or infliximab between September 1, 2023 to December 31, 2023

Outcomes

Primary: time to medication access
Secondary: ability to access SC therapy, method of access, initiation rate, reasons for not starting SC

Figure 1. Study Attrition

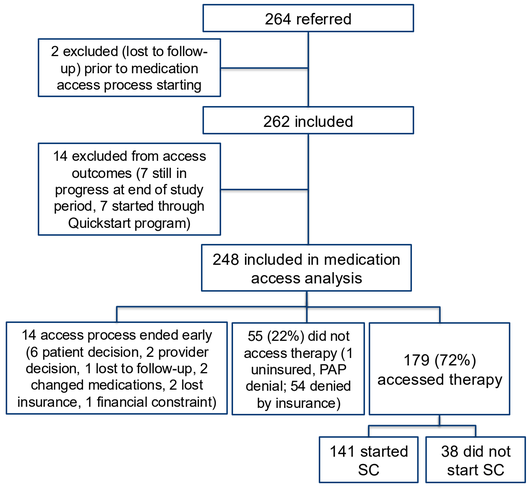
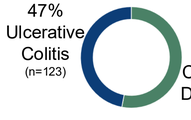


Table 1. Patient Characteristics (N=262)

Age (median)	Gender	Race
44 years Interquartile range (IQR) 34-56	55% Female (n=145) 45% Male (n=117)	89% White (n=234) 11% Other (n=28)

Diagnosis



Median disease duration: 14 years (IQR 7-23)

Prescription Insurance

84% Commercial (n=221)
12% Medicare (n=31)
5% Other (n=10)

SC Medication

81% Vedolizumab (n=212) 19% Infliximab (n=50)	81% Established on IV maintenance (n=211) 19% New start therapy (n=51)	92%% Standard dose (n=241) 8% Escalated dose (n=21)

CONCLUSION

- Patients referred to transition from IV to SC vedolizumab or infliximab often experience delays in access
- Many patients prescribed SC vedolizumab or infliximab do not start due to payer restrictions or patient preference
- Patients with commercial insurance may be less likely to access SC therapy

Results

Figure 2. Time to Access

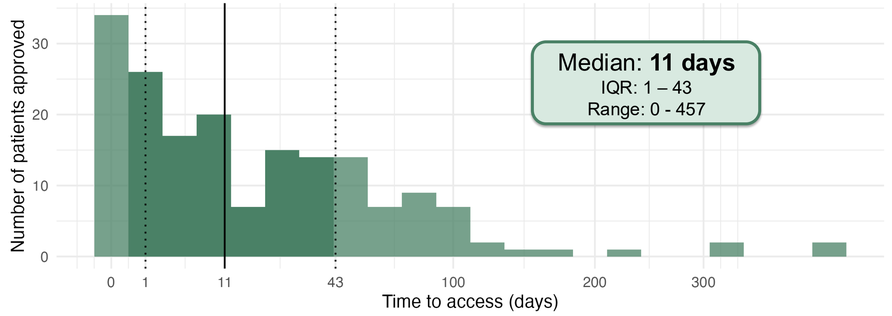
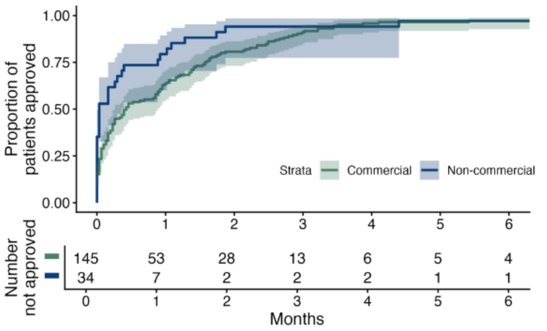
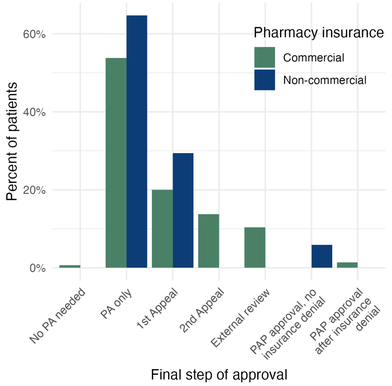


Figure 3. Probability of SC Approval



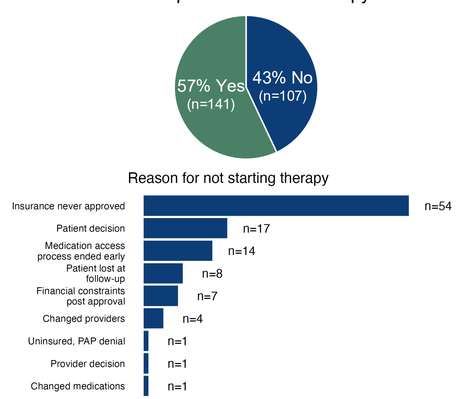
Patients with commercial insurance were **3x more likely** to have a **longer time** to medication access compared to those with non-commercial insurance (OR: 3.40 95% CI 1.5 - 6.1, p =0.003).

Figure 4. Method of SC Approval



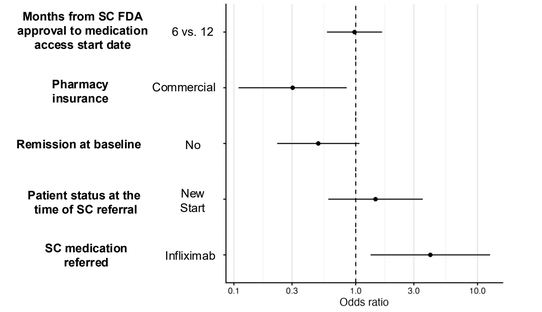
In patients able to access SC treatment, **56%** was through a **PA approval** (n=100) and **22%** was through a **first level appeal** (n=39).

Figure 5. SC Abandonment



43% of patients who started the SC access process did not start SC therapy, frequently due to **insurance denial** (22%, n=54). Of patients approved for SC, 21% (n=38) did not start, largely due to **patient decision** (45%, n=17).

Figure 6. Access Rate Multiple Regression Analysis



Patients referred to start **infliximab** SC were **4x more likely** to achieve access compared to vedolizumab SC (OR: 4.1, 95% CI 1.3 - 12.7, p=0.014). Patients with **commercial insurance** were **70% less likely** to access SC therapy (OR: 0.3, 95% CI 0.1 - 0.8, p=0.022).