VANDERBILT UNIVERSITY MEDICAL CENTER

Ustekinumab Infusion to Subcutaneous Transition: Coordinating Care and Identifying Potential Gaps

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Purpose

Evaluate factors impacting the transition timing from clinic administered intravenous (IV) infusion to self-administered, subcutaneous (SubQ) injection ustekinumab for Crohn's disease (CD) and Ulcerative Colitis (UC) and potential delays or barriers in the patient journey

Study Design and Setting

Single-center, retrospective cohort analysis of data collected from electronic medication records and specialty pharmacy management system

Patients prescribed ustekinumab for CD or UC by a Vanderbilt University Medical Center (VUMC) provider

Study Methods

Inclusion and Exclusion Criteria

Inclusion: Patients prescribed ustekinumab for CD or UC by a VUMC provider between 11/1/21 – 3/31/22

Exclusion: Patients who never received an infusion or SubQ dose, received the SubQ dose at an infusion center, or lost to follow-up

Outcome Measures

Primary outcomes: 1) Time from decision to treat with ustekinumab to SubQ shipment date and 2) Number of patients with a SubQ ustekinumab shipments 4-8 weeks post-infusion

Secondary outcomes: Time between each step in the patient journey

Data Analysis

A logistic regression model was utilized to test for associations between shipment of SubQ within the appropriate window and age, insurance type (commercial vs not commercial) and whether the patient filled at VSP

VSP = Vanderbilt Specialty Pharmacy; PA = prior authorization

Figure 1. Study Attrition

Patients identified for inclusion (n=75)

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Screened for exclusion criteria

Patients excluded (n=5)

- Received SubQ ustekinumab dose at an infusion center (n=2)
- Lost to follow-up post infusion prior to receiving SubQ (n=1)
- Never received infusion (n=1)
- Never received SubQ dose (n=1)

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Included in analysis (n=70)

Conclusion

- Patients transitioning from ustekinumab IV infusion to SubQ maintenance dosing may experience delays due to PA requirements.
- SubQ prescriptions from the integrated health-system specialty pharmacy were more likely to ship in the appropriate timeframe window post-infusion.

Results

Table 1. Patient Demographics (n=70)

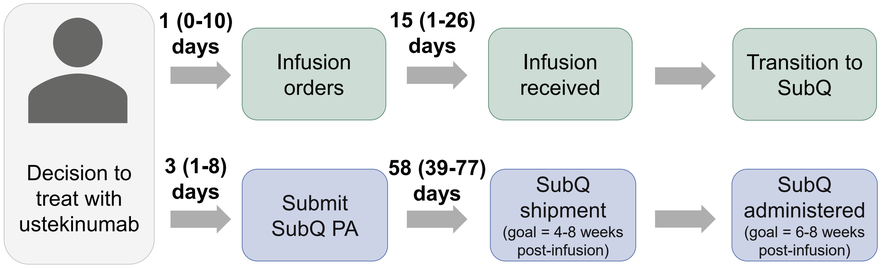
Characteristic	VSP n= 33 n (%)	Non-VSP n= 37 n (%)
Age (at time of SubQ), median (IQR)	44 (29 – 60)	32 (27 – 39)
Female	20 (61)	22 (60)
White	31 (94)	32 (87)
Diagnosis		
Crohn's Disease	24 (73)	22 (60)
Ulcerative Colitis	9 (27)	15 (41)
Commercial insurance	21 (64)	34 (92)
Infusion received at VUMC	9 (27)	16 (43)

Prior Authorization Approval Process

8 (11%) initial SubQ PAs were denied

- Formulary alternative required (n=6)
- Patient not meeting criteria (n=1)
- Infusion completion required prior to SubQ approval (n=1)

Figure 2. Patient Journey from Ustekinumab Infusion to SubQ



All values reported are listed as: median (IQR)

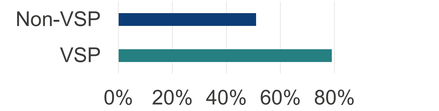
Figure 3. Primary Outcome Measures

Days from treatment decision to medication shipment, median (IRQ)

Non-VSP 55 (37-79) **vs.** **VSP** 71 (59-82)

Receiving a SubQ shipment prior to infusion **may lead to waste** if the patient does not tolerate the infusion.

Patients with goal SubQ shipment time (4-8 weeks post-infusion)



VSP patients had **2.5 times higher odds** of having medication shipped within 4 to 8 weeks from infusion (OR 2.5, 95% CI 0.8 - 7.8, p = 0.126)