EXPLORING RATES OF PCSK9 INHIBITOR PERSISTENCE AND REASONS FOR TREATMENT NON-PERSISTENCE IN AN INTEGRATED SPECIALTY PHARMACY MODEL

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BACKGROUND

Proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9is), evolocumab and alirocumab, are injectable specialty medications indicated to[1,2]:

- Reduce low-density lipoprotein cholesterol (LDL-C) in patients with primary hyperlipidemia (including heterozygous familial hypercholesterolemia)
- Reduce risk of cardiovascular events in patients with established cardiovascular disease

PCSK9is are high-cost specialty medications that typically require insurance approval.

Previously reported persistence rates of PCSK9is are low, and reasons for non-persistence to therapy is generally not reported.[3] Furthermore, persistence data beyond 6 months is limited.

Vanderbilt Specialty Pharmacy (VSP) is an integrated health system specialty pharmacy with pharmacists embedded within outpatient clinics.

Figure 1. Pharmacist Role Within the Lipid Clinic

A patient is prescribed a PCSK9i and referred to VSP

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The pharmacist oversees insurance approval process, completing prior authorizations and/or appeals as needed

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At therapy start, the pharmacist educates the patient on potential side effects and medication administration

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The pharmacist reviews monthly refill calls to the patient to monitor for side effects and continued adherence

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The pharmacist conducts annual reassessments for continued beneficial response and appropriateness of therapy

OBJECTIVES

- Quantify rates of persistence for patients on PCSK9i therapy receiving care through an integrated specialty pharmacy model
- Describe reasons for non-persistence to PCSK9i therapy
- Evaluate LDL values while on PCSK9i therapy

METHODS

Study Design	• Retrospective cohort • Conducted at Vanderbilt University Medical Center (VUMC)
Outcomes	• Persistence at 3, 12, and 24 months • Reasons for non-persistence • Change in LDL from baseline to 24 months
Inclusion Criteria	• Patients initiating a PCSK9i by a VUMC provider between September 1, 2015 and August 31, 2018
Exclusion Criteria	• Patients who received medication through a manufacturer patient assistance program (PAP) • Patients who never received insurance approval or started therapy

RESULTS

Table 1. Characteristics of the Sample (n=477)

Characteristic	% (n) or Median [IQR]
Age, years	63 [56-70]
Race, White	91% (436)
Gender, male	53% (253)
Pharmacy insurance type	
Government funded	45% (217)
Commercial	55% (260)
Indication	
ASCVD	86% (408)
Familial hypercholesterolemia	41% (196)
Primary hyperlipidemia	3% (15)
Historical lipid management	
Ezetimibe	49% (235)
Statin	98% (467)
None	2% (9)
Baseline LDL, mg/dL	156.5 [130-190]
Initial PCSK9i	
Alirocumab	45% (215)
Evolocumab	55% (262)

RESULTS

Figure 2. Persistence from Baseline to 24 Months

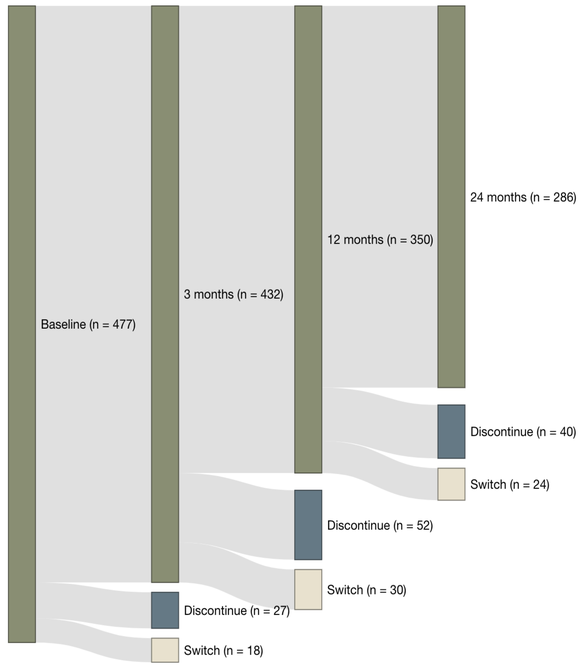
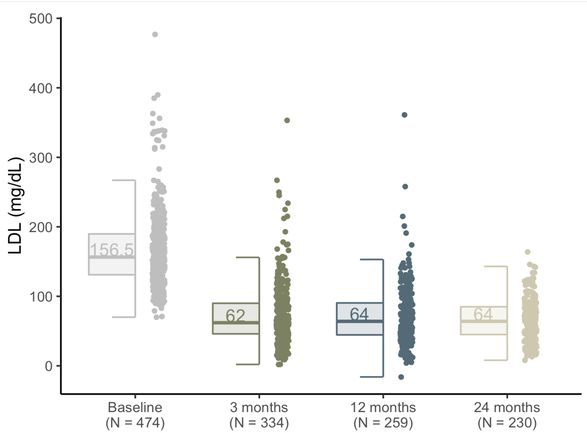


Figure 3. Change in LDL from Baseline to 24 Months*



*Values reflect LDL levels for patients with available LDL data at the specified time points

Table 2. Reasons for Non-Persistence

Reason	Discontinue (n=119)	Switch (n=72)	Combined (n=191)
Side effects	52% (62)	49% (35)	51% (97)
Cost	4% (5)	4% (3)	4% (8)
No/suboptimal response	2% (2)	6% (4)	3% (6)
Patient decision	5% (6)	0% (0)	3% (6)
Lost to follow-up	22% (26)	0% (0)	14% (26)
Insurance mandate	3% (3)	42% (30)	17% (33)
Deceased	9% (11)	0% (0)	6% (11)
Other*	3% (4)	0% (0)	2% (4)

*Other reasons for discontinuation were leukemia diagnosis (1), chemotherapy (1), planned pregnancy (1), and insurance loss (1)

CONCLUSIONS

- Sixty percent of patients were persistent on their initially prescribed PCSK9i at 24 months
- Among patients who were persistent at 24 months with LDL levels available, median LDL decreased 59% from baseline

- These results highlight the benefit of an integrated specialty pharmacy model on maintaining persistence for patients on PCSK9i therapy. Further studies are needed to assess persistence outside of an integrated model.
- Side effects, high cost, insurance mandate, and loss to follow-up were the most common reasons for non-persistence.
- Future efforts are needed to further mitigate non-persistence due to side effects and loss to follow-up.

References:

1. Praluent [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC/Tarrytown, NJ: Regeneron Pharmaceuticals, Inc.; 2020.
2. Repatha [package insert]. Thousand Oaks, CA: Amgen Inc.; 2019.
3. Hines DM, Rane P, Patel J, Harrison DJ, Wade RL. Treatment patterns and patient characteristics among early initiators of PCSK9 inhibitors. *Vasc Health Risk Manag.* 2018;14:409-418.