Exploring Rates of PCSK9 Inhibitor Persistence and Reasons for Treatment Non-Persistence in an Integrated Specialty Pharmacy Model

Nicole Hall, PharmD Candidate, Fatima Rizvi, PharmD Candidate, Josh DeClercq, MS, Victoria W. Reynolds, PharmD, BCACP, Dustin R. Donald, PharmD, CSP, Leena Choi, PhD

Quick Facts

Evaluated

477

Patients on PCSK9i therapy through Vanderbilt Specialty Pharmacy

86% of patients ASCVD

41% of patients with familial hypercholesterolemia (HeFH)

3% of patients with primary hyperlipidemia

Results

At 12 months:

- 80% persistent to initial PCSK9i

At 24 months:

- 68% persistent to initial PCSK9i
- Top reasons for non-persistence at 24 months:
  - Side-effects: 30% (17/57)
  - Lost to follow-up: 21% (12/57)
  - Insurance mandate: 16% (9/57)

59%

Median LDL decrease after 24 month PCSK9i use **(157mg/dL to 65 mg/dL)**

Percentage of patients who achieved LDL goal at 24 months

78% HeFH

59% ASCVD

At an integrated pharmacy, patients are able to maintain PCSK9i therapy and can achieve LDL goal

VANDERBILT HEALTH

Exploring Rates of PCSK9 Inhibitor Persistence

Dustin R. Donald, PharmD, CSP[1], Victoria W. Reynolds, PharmD, BCACP[1], Nicole Hall, PharmD[2], Fatima Rizvi, PharmD[3], Josh DeClercq, MS[4], Leena Choi, PhD[4]

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Background

Proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9i), evolocumab and alirocumab, are injectable 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

Persistence to PCSK9i remains low or unreported, despite a favorable safety profile and positive clinical utility.

Previous studies show nearly 40% of patients are non-persistent to PCSK9i after 6 months.[3] Limited work has assessed persistence to PCSK9i in an integrated specialty pharmacy model.

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
- The pharmacist oversees the insurance approval process and obtains financial assistance as needed
- At therapy start, the pharmacist educates the patient on potential side effects and medication administration
- The pharmacist reviews monthly refill calls to the patient to monitor for side effects and continued adherence
- 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, 2015and 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	46% (218)
Commercial	54% (259)
Indication	
ASCVD	86% (409)
Familial Hypercholesterolemia	41% (196)
Primary hyperlipidemia	3% (14)
Historical lipid management	
Ezetimibe	49% (235)
Statin	98% (467)
None	2% (9)
Baseline LDL, mg/dL	157 [131-190]
Initial PCSK9i	
Alirocumab	45% (216)
Evolocumab	55% (261)

Results

Figure 2: Persistence from Baseline to 24 Months

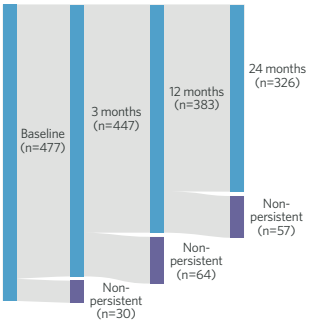
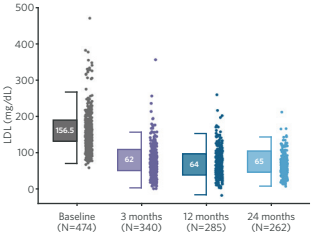


Figure 3: Change in LDL from Baseline to 24 Months*



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

Results

Table 2: Reasons for Non-Persistence

Discontinuation Reason	3 months (n=30)	12 months (n=64)	24 months (n=57)	Combined (n=151)
Side effects	83% (25)	63% (40)	30% (17)	54% (82)
Lost to follow-up	13% (4)	16% (10)	21% (12)	17% (26)
Insurance mandate	0% (0)	5% (3)	16% (9)	8% (12)
Deceased	0% (0)	8% (5)	11% (6)	7% (11)
Cost	0% (0)	5% (3)	7% (4)	5% (7)
Patient decision	0% (0)	5% (3)	5% (3)	4% (6)
Other*	0% (0)	0% (0)	7% (4)	3% (4)
No/suboptimal response	3% (1)	0% (0)	4% (2)	2% (3)

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

Conclusions

Sixty-eight percent of patients were persistent on their prescribed PCSK9i at 24 months

Among patients who were persistent at 24 months with LDL levels available, median LDL decreased 59% from baseline

- Higher rates of persistence to PCSK9i were seen in patients receiving care within an integrated specialty pharmacy model than in previous studies.
- Results highlight the benefit of an integrated specialty pharmacist on mitigating many of the common reasons for PCSK9i non-persistence.
- Further studies are needed to assess persistence outside of an integrated model.

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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.

[1]Vanderbilt Specialty Pharmacy, Vanderbilt University Medical Center, [2]University of Louisville Health-Jewish Hospital, [3]University of Tennessee Health Science Center College of Pharmacy, [4]Department of Biostatistics, Vanderbilt University Medical Center

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