Impact of An Integrated Clinical and Specialty Pharmacy Service Model on Access to PCSK9 Inhibitor Therapy

Victoria W. Reynolds, PharmD[1]| Megan Peter, PhD[1] | Jacob A. Jolly, PharmD, CSP[2] | Melissa E. Chinn, PharmD[1] | Sam Nwosu, MS[3] | Leena Choi, PhD[3] | Autumn Zuckerman, PharmD, BCPS, AAHIVP, CSP[2]

[1]Vanderbilt Specialty Pharmacy, [2]Lipscomb University College of Pharmacy, [3]Vanderbilt University Medical Center Department of Biostatistics

VANDERBILT UNIVERSITY MEDICAL CENTER

Background

- Accessing PCSK9 inhibitors is difficult. Previous studies have reported:
  - Ultimate **approval rates** ranging from **43%- 47%.**[1,2]
  - Time to approval **up to 87 days.**[2]
  - Only **31%** of patients prescribed therapy **starting treatment**.[2]
- Vanderbilt Specialty Pharmacy integrated a pharmacist and technician to streamline and improve access to PCSK9 inhibitors.

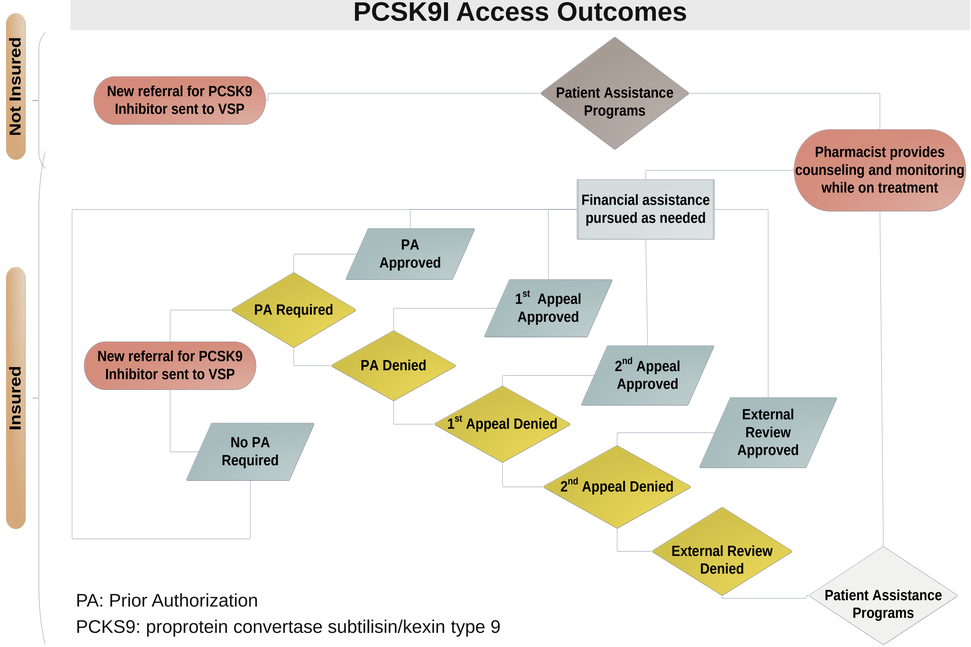
Methods

- Single-center, retrospective, cohort study of patients prescribed a PCSK9 inhibitor between 9/1/2015 to 12/1/2016.
- Variables included in multivariable linear regression: age, gender, ASCVD diagnosis, PCSK9 inhibitor, LDL-C, Ezetimibe use, number of statins tried, insurance type

Baseline Characteristics	Overall (n= 299)	Approved (n=287)	Denied (n=12)
Age (mean ±SD)	62 ± 10	62 ± 10	60 ± 11
Gender			
Female	138 (46%)	134 (47%)	4 (33%)
Statin use (%)	111 (37%)	104 (36%)	7 (58%)
Ezetimibe use (%)	71 (24%)	68 (24%)	3 (25%)
Insurance Type			
Commercial	169 (57%)	161 (56%)	8 (67%)
Government	126 (42%)	122 (43%)	4 (33%)
No Insurance	4 (1%)	4 (1%)	0 (0%)
No. of Statins Tried and Failed			
1	45 (15%)	42 (15%)	3 (25%)
2	43 (14%)	40 (14%)	3 (25%)
≥3	163 (55%)	161 (54%)	2 (17%)

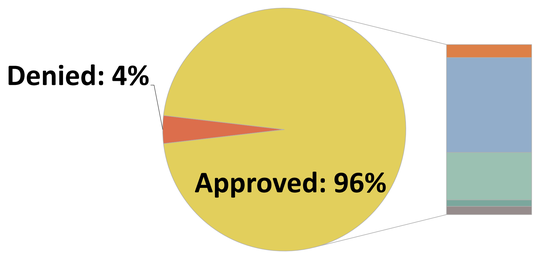
Results

PCSK9I Access Outcomes



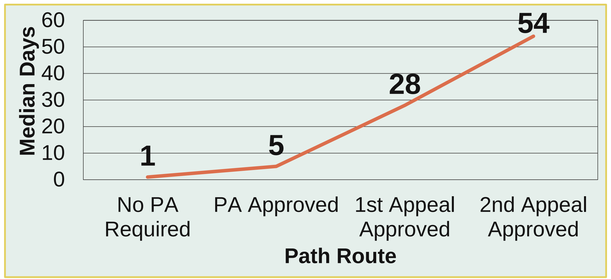
PA: Prior Authorization

PCKS9: proprotein convertase subtilisin/kexin type 9



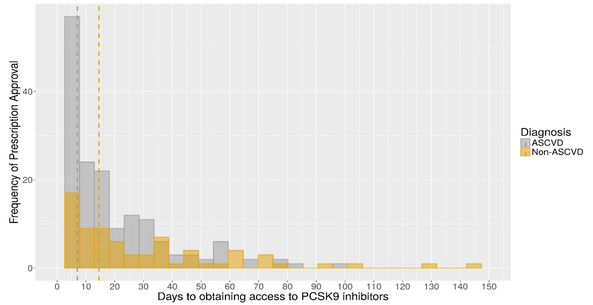
- **Approved with no PA or appeal: 8%**
- **Approved with PA: 58%**
- **Approved with 1st level appeal: 29%**
- **Approved with 2nd level appeal: 4%**
- **Patient Assistance Programs: 5%**

Time to Approval



Overall median (IQR) days to approval: **8** (3-25)

Factors Impacting Time to Approval



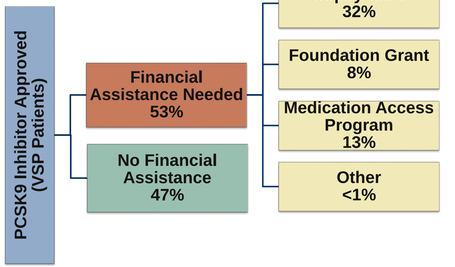
Univariate linear regression:

- Presence of **ASCVD diagnosis** (ref= no ASCVD; p=0.022)

Multivariable linear regression:

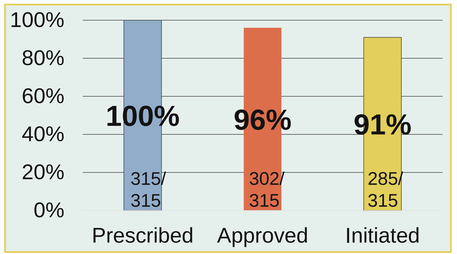
- **ASCVD diagnosis** (ref= no ASCVD; p=0.022)
- Government insurance (ref= commercial; p=0.048)

Financial Assistance



Median (range) of out of pocket cost per month for VSP patients: **$0** (0-571.70)

Patient Journey



Conclusion

- An integrated specialty pharmacy improves access and initiation rates, and reduces time to PCSK9 inhibitor approval,.

References:

1. Hess G, Natarajan P, Faridi K, Fievitz A, Valsdottir L, Yeh R. Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitor Therapy: Payer Approvals and Rejections, and Patient Characteristics for Successful Prescribing. Circulation. 2017;CIRCULATIONAHA.117.028430. doi: 10.1161/circulationaha.117.028430.
2. Navar AM, Taylor B, Mulder H, et al. Association of Prior Authorization and Out-of-pocket Costs With Patient Access to PCSK9 Inhibitor Therapy. JAMA Cardiol. 2017.