

Reviewing the Current Structure: Documentation, Denials, Prior Authorizations, and Costs

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Disclosure

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The Dilemma of Genomics, Biotechnology, and "Personalized Medicine"

- Unprecedented speed to identify drug targets with genetic data in humans and to develop novel therapies with biotechnology and show efficacy in humans
- However, much greater cost of goods to develop biologicals and consequently increased costs for clinical development and cost of new therapies to consumer/payers



Principles of a Sound Drug Formulary System

- "Overall goals of formulary management are to improve patient outcomes and decrease costs by providing safe and appropriate drug therapy"

Happe LE et al. *J Manag Care Spec Pharm* 2014;20:677-84. | Academy of Managed Care Pharmacy. Principles of a sound drug formulary system. October 2000. Available at: www.amcp.org/WorkArea/DownloadAsset.aspx?id=9280.



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Commonly Used Formulary Restrictions

- Cost sharing (copayments, coinsurance, deductibles)
- Prior authorization
- Step therapy
- Preferred drug lists



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Do Formulary Restrictions Reduce Pharmacy Costs and Utilization?

YES !

For every 10% increase in cost sharing, a 2–6% decrease in drug use or expenditures



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Prior Authorization: Appropriate Use of Newer Expensive drugs

- FDA-approved indications
- Clinical criteria established by specific insurance plans which are designed to target therapy to patients with greatest potential benefit, i.e., best value



FDA-Approved PCSK9 Inhibitors

Alirocumab is indicated as an adjunct to diet and:

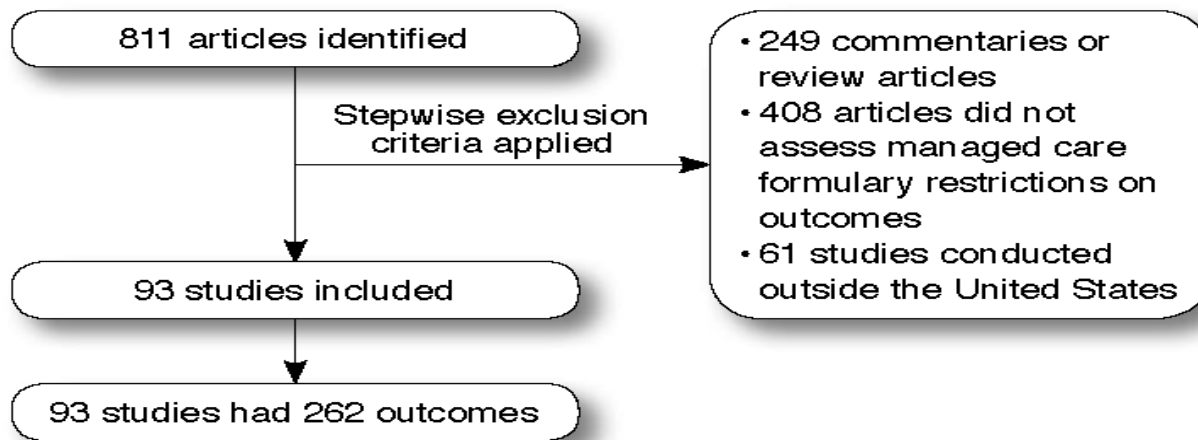
1. Maximally tolerated statin therapy for treatment of adults with
 - a) Heterozygous familial hypercholesterolemia (HeFH) or
 - b) Clinical atherosclerotic cardiovascular disease (CVD),
who require additional lowering of LDL-C.

Evolocumab is indicated as an adjunct to diet and:

1. Maximally tolerated statin therapy for treatment of adults with
 - a) Heterozygous familial hypercholesterolemia (HeFH) or
 - b) Clinical atherosclerotic cardiovascular disease (CVD),
who require additional lowering of LDL-C.
2. Other LDL-lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.



Managed Care Formulary Restrictions: What is the Evidence?

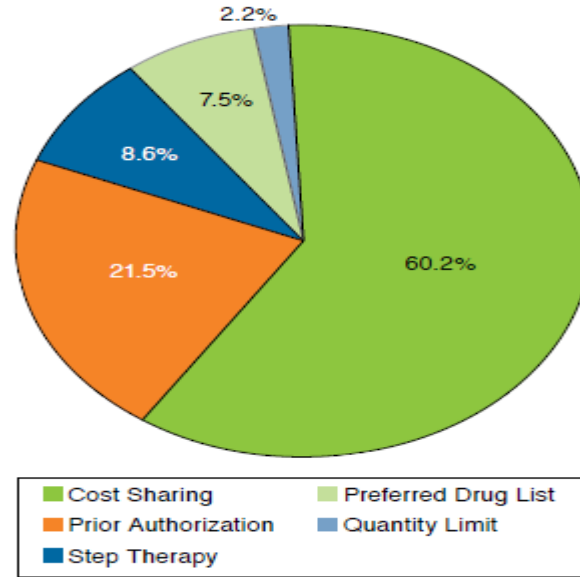


Happe LE et al. *J Manag Care Spec Pharm* 2014;20:677-84.



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Distribution of Formulary Restriction Studies



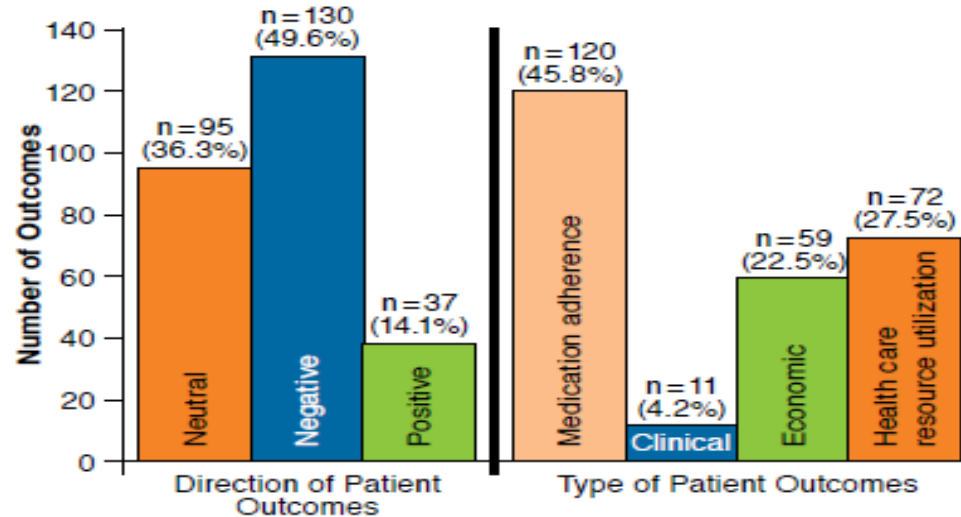
N=93 studies

Happe LE et al. *J Manag Care Spec Pharm* 2014;20:677-84.



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Direction and Type of Patient Outcomes



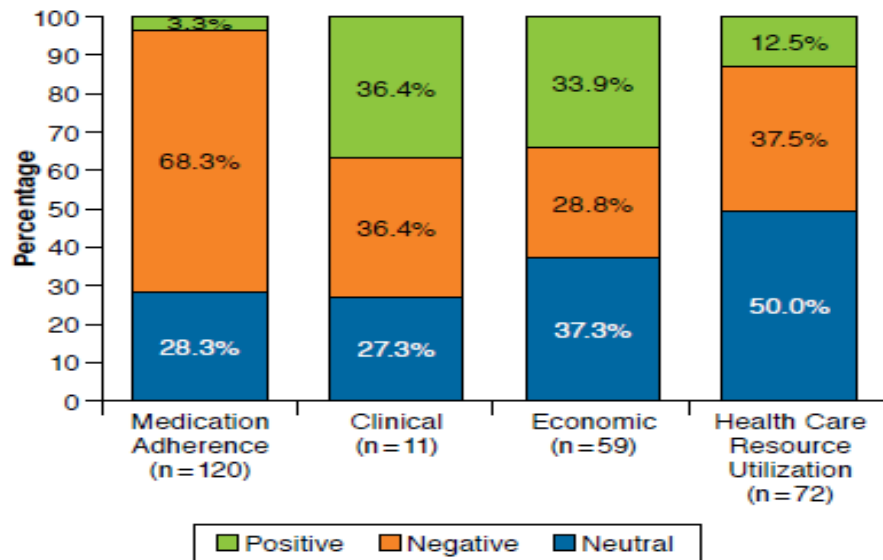
N=262 outcomes

Happe LE et al. *J Manag Care Spec Pharm* 2014;20:677-84.



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Direction of Patient Outcomes Stratified by Type of Outcomes



N=262 outcomes

Happe LE et al. *J Manag Care Spec Pharm* 2014;20:677-84.



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Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical Outcomes, Economic Outcomes, and Health Care Resource Utilization

- Formulary restrictions are associated with reduced medication adherence (including discontinuation and persistency) in the existing literature base
- Despite the evidence that formulary restrictions reduce expenditures of the restricted drug, there is no distinct trend in the direction of association between formulary restrictions and broader economic measures, including total costs, medical costs, and total pharmacy costs

Happe LE et al. *J Manag Care Spec Pharm* 2014;20:677-84.



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Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical Outcomes, Economic Outcomes, and Health Care Resource Utilization

- Health care resource utilization has no significant association with formulary restrictions in half of the outcomes assessed in the literature
- There is a paucity of evidence assessing the relationship between formulary restrictions and clinical patient outcomes. Future research should focus on the impact of formulary restrictions on patient health outcomes

Happe LE et al. *J Manag Care Spec Pharm* 2014;20:677-84.



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Denial Shock



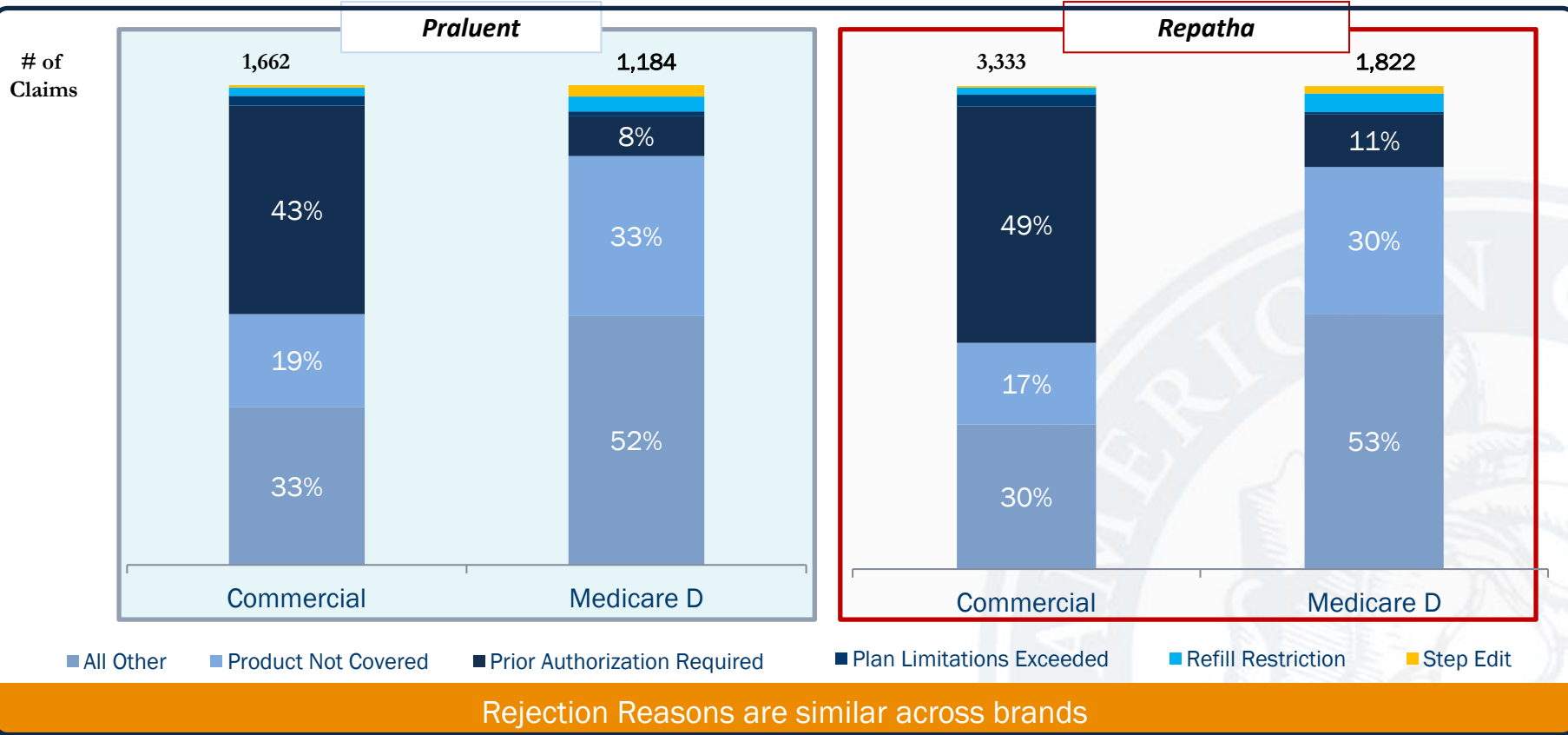
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Denial Response



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Reasons for a Rejected Claim



Data Available – Week Ending 5/6

Data source: FIA Weekly
Includes final and stand alone claims



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PCSK9 Inhibitors: Payer Dynamics

- During the first 6 months post-launch, patients who were new for a PCSK9 and made an initial attempt to fill the drug were approved 11.7% in Commercial Pay Type, and were rejected at a rate of 88.3%. In Medicare, the initial approval rate was 24.6% with an initial rejection rate of 75.4%
- Using the PDE4 as an example, the denial rate for claims was 77% for the initial prior authorization attempt during the first 12 months post-launch. Of the rejected claims, 23% were eventually overturned and ultimately were approved as a final claim status



PCSK9 Inhibitors: Payer Dynamics

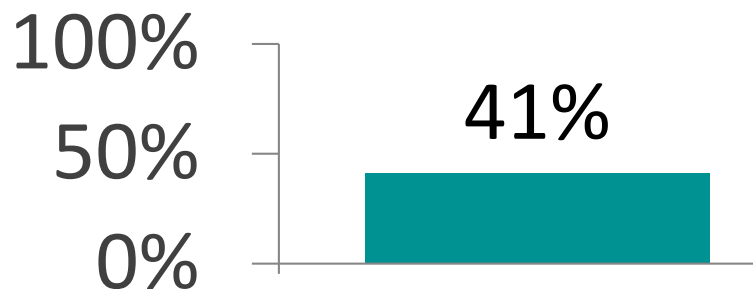
- The final approval and rejection rates with a 14 day look forward for Commercial Pay Types is 25% Approval with a final rejection rate of 75% (based on all new prescriptions irrespective of new or existing patients)
- The final approval and rejection rates with a 14 day look forward for Medicare Pay Type is 50% Approval with a final rejection rate of 50%



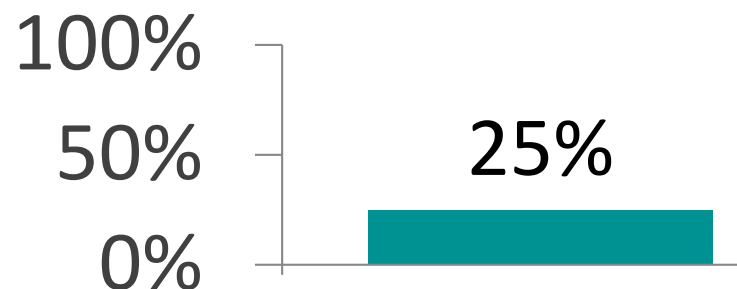
LDL-C goal attainment

Data from the CASCADE FH™ Registry

Reduction in LDL-C ≥ 50%



Treated LDL-C < 100 mg/dl



N = 1295

CHD, overall cohort

36%

Age at onset, years

51

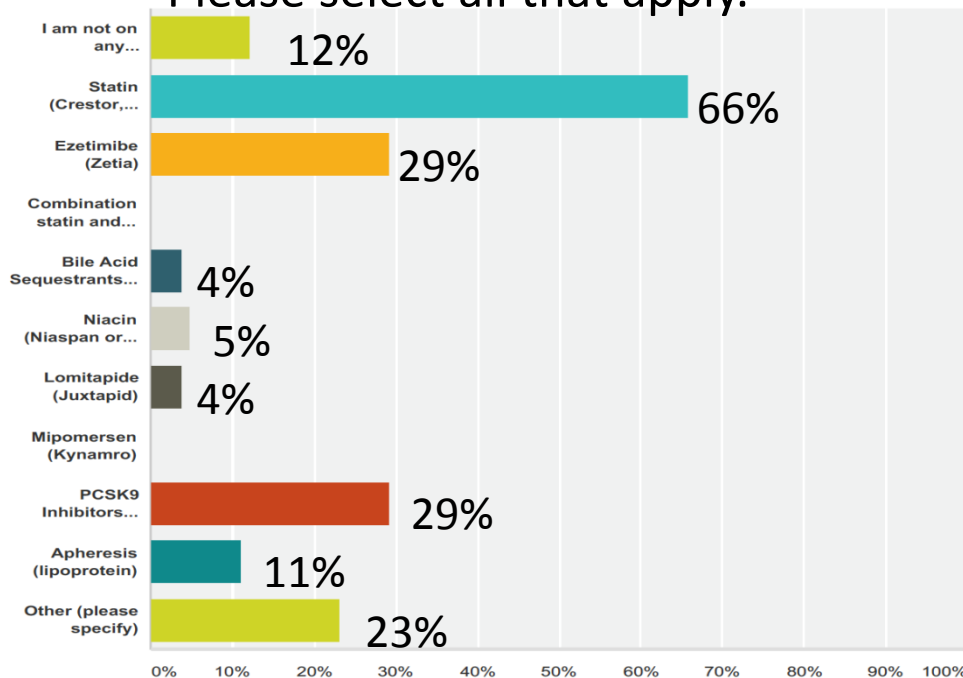
FH Optimal Care in the U.S.

(FOCUS) Survey



Which FH treatment(s) are you currently on?

Please select all that apply.



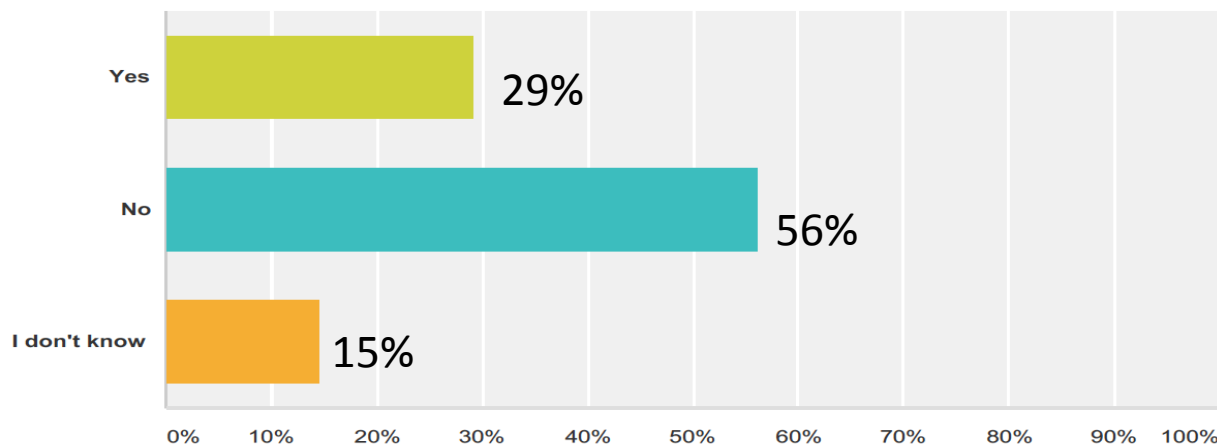
Answered: 82/116

FH Optimal Care in the U.S.

(FOCUS) Survey

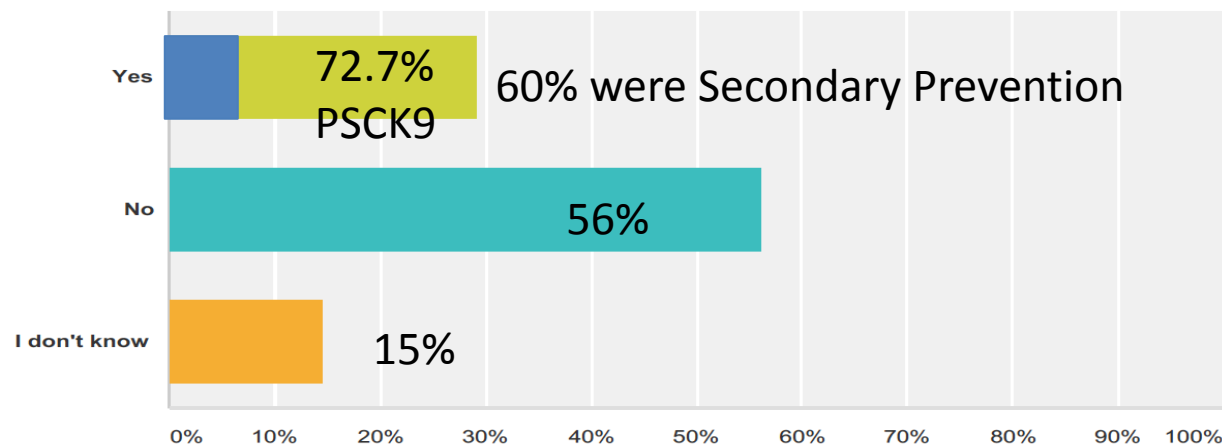


In the last 12 months, has your insurance company denied coverage for any of your FH treatment(s)?



Answered: 82/116

In the last 12 months, has your insurance company denied coverage for any of your FH treatment(s)?



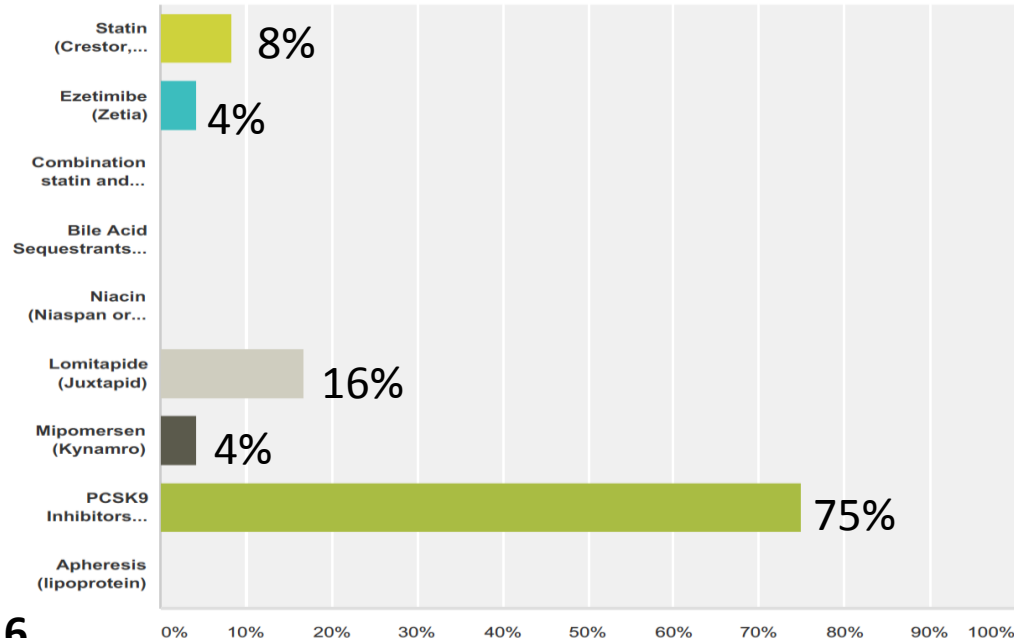
Answered: 82/116

FH Optimal Care in the U.S. (FOCUS) Survey



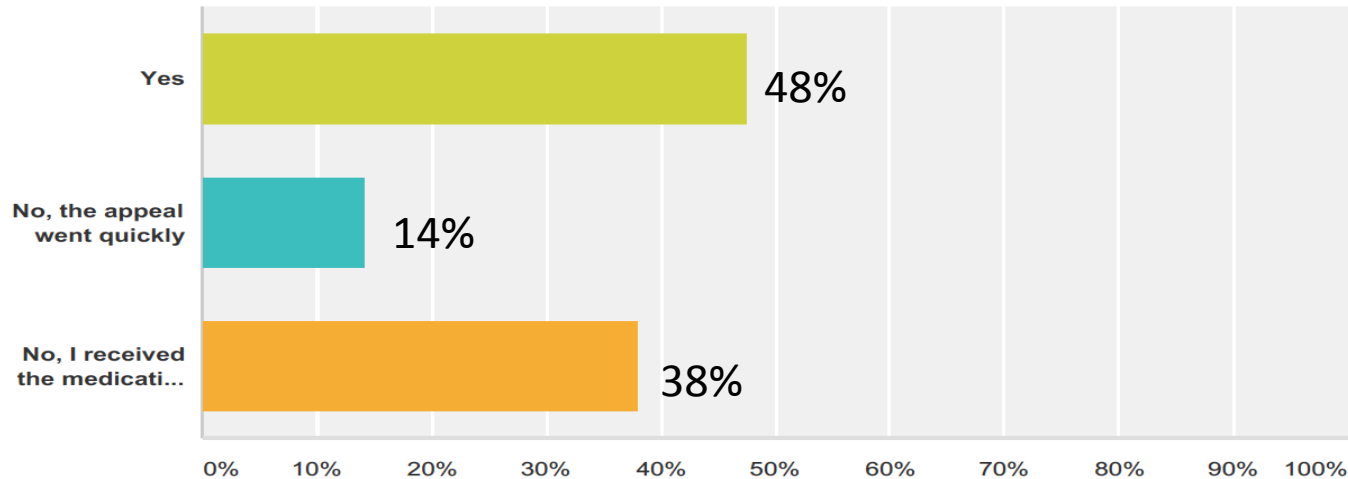
Which treatment option(s) were denied coverage by your insurance?

Please select all that apply.



Answered: 24/116

Did you miss any treatment(s) due to the insurance company's denial:



Answered: 21/116

Summary

- Formulary restrictions reduce formulary costs
- Evidence as to which methods are most effective in improving patient and overall health care costs are unclear and additional studies are warranted
- Although overall rates of approvals for new therapies such as PCSK9 inhibitors are low, there is considerable site variability related to patients selection, documentation, and the approach to the process. At the current time, even patients with the greatest potential benefit (FH with ASCVD) are frequently denied



Can we develop “Google maps” to help health care providers and patients to navigate the maze of the approval process?

- More consistent criteria by payers and checklists, algorithms, apps, sharing of best practices which improve
 - Patient selection
 - Help to assure that required documentation is submitted
 - Reduce wasted time and avoid frustration by health care providers and patients in the approval/ denial process

