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## Background

- Praluent (alirocumab) and Repatha (evolocumab) are PCSK9 inhibitors (PCSK9i) approved by the FDA in 2015 as add-on therapy for high-risk patients with inadequate LDL-C lowering.<sup>1,2</sup>
- Early uptake of PCSK9i was limited by high list prices, restrictive coverage, and Medicare Part D cost sharing, contributing to low patient adherence and persistence.
- In 2018, both manufacturers implemented major list price reductions (~60%).<sup>3,4</sup>
- It is unclear whether these reductions translated into improved patient affordability, and in turn better adherence and persistence.

## Objective

To evaluate national trends in PCSK9 inhibitor costs, adherence, and persistence among Medicare beneficiaries following the 2018 reductions in list price.

## Methods

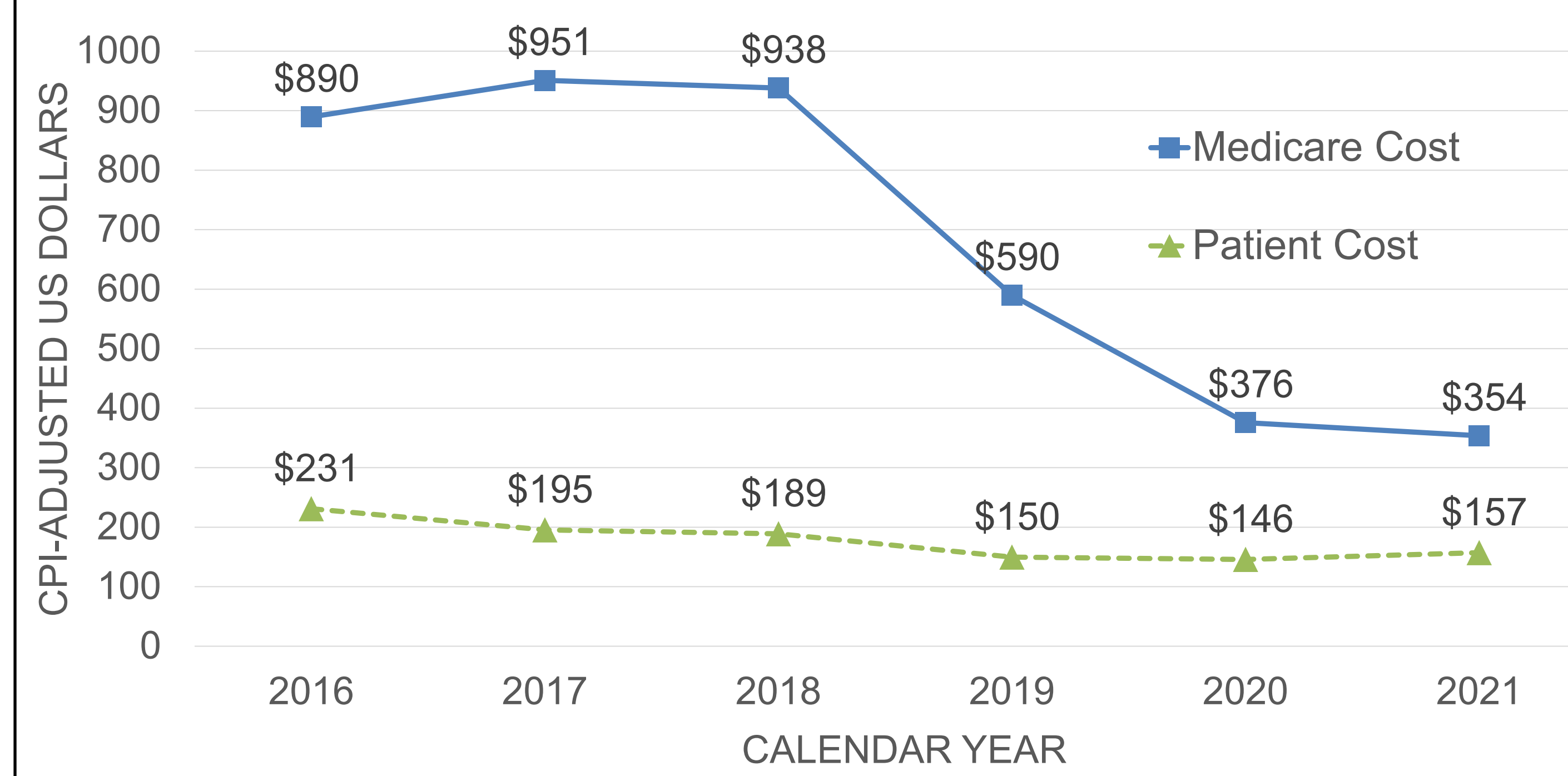
- Study design: Retrospective cohort study using Medicare Fee-for-Service Part D claims from 2016 to 2021.
- Population: Adults aged ≥65 years with ≥1 PCSK9i fill and ≥12 months of continuous enrolment.
- Cost: Patient out-of-pocket (OOP) costs and Medicare drug spending were inflation-adjusted to 2021 US dollars and standardized to a 30-day supply equivalent.
- Adherence: Defined as proportion of days covered (PDC) ≥80% over one year.
- Persistence: Defined as no gap in fill exceeding 60 days.
- Statistical analysis: Cost outcomes, adherence, and persistence were descriptively analyzed, with patients assigned to calendar year based on treatment initiation date. Multivariable logistic regression was conducted to assess the association between patient copay and adherence while adjusting for age, race, sex, baseline comorbidities, and statin use.

## Results

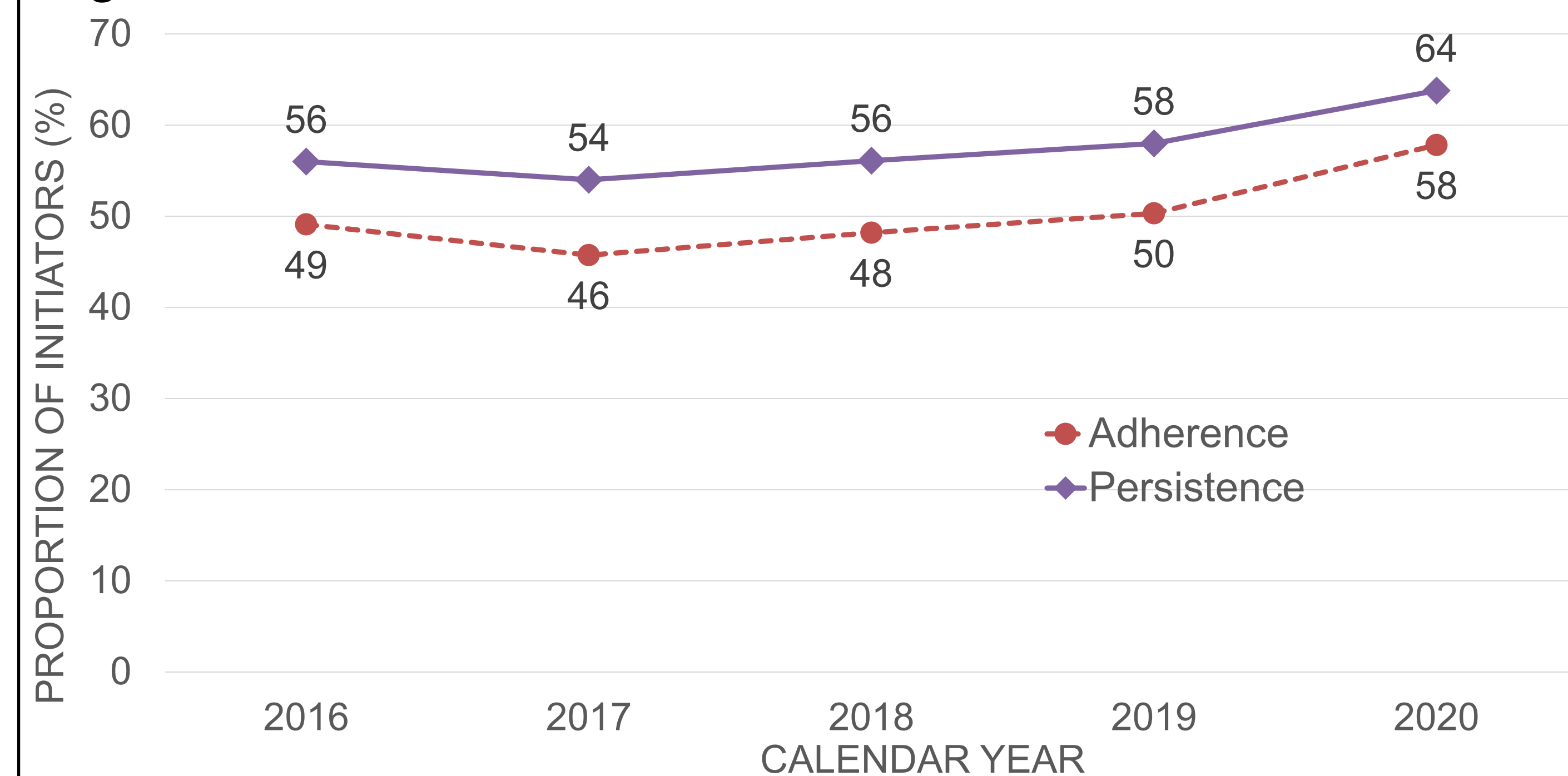
**Table 1:** Characteristics of patients initiated any PCSK9i between 2016-2021 (n=63,961)

Demographic Characteristics	
Age	75 (13.1)
Female	34,497 (53.9)
White	55,072 (86.1)
Black	2,519 (3.9)
Hispanic	2,299 (3.6)
Other race or ethnicity	4,071 (6.4)
Calendar Year	
2016	5,948 (9.3)
2017	5,541 (8.7)
2018	7,007 (11.0)
2019	11,306 (17.7)
2020	15,918 (24.9)
2021	18,241 (28.5)
Comorbid Conditions	
Atrial Fibrillation	13,017 (20.4)
Stable Angina	15,723 (24.6)
Unstable Angina	7,785 (12.2)
ASCVD	49,487 (77.4)
Cardiac Conditions	8,161 (12.8)
Cardiomyopathy	4,381 (6.8)
Congestive Heart Failure	1,095 (1.7)
Type 2 Diabetes	27,201 (42.5)
Deep Vein Thrombosis	1,836 (2.9)
Heart Failure	12,797 (20.0)
Hypertension	57,816 (90.4)
Hyperlipidemia	63,030 (98.5)
Myocardial Infarction	5,456 (8.5)
Stroke	19,155 (29.9)
Statin Use	
Low Intensity Statin	2,185 (3.4)
Medium Intensity Statin	10,421 (16.3)
High Intensity Statin	11,479 (17.9)

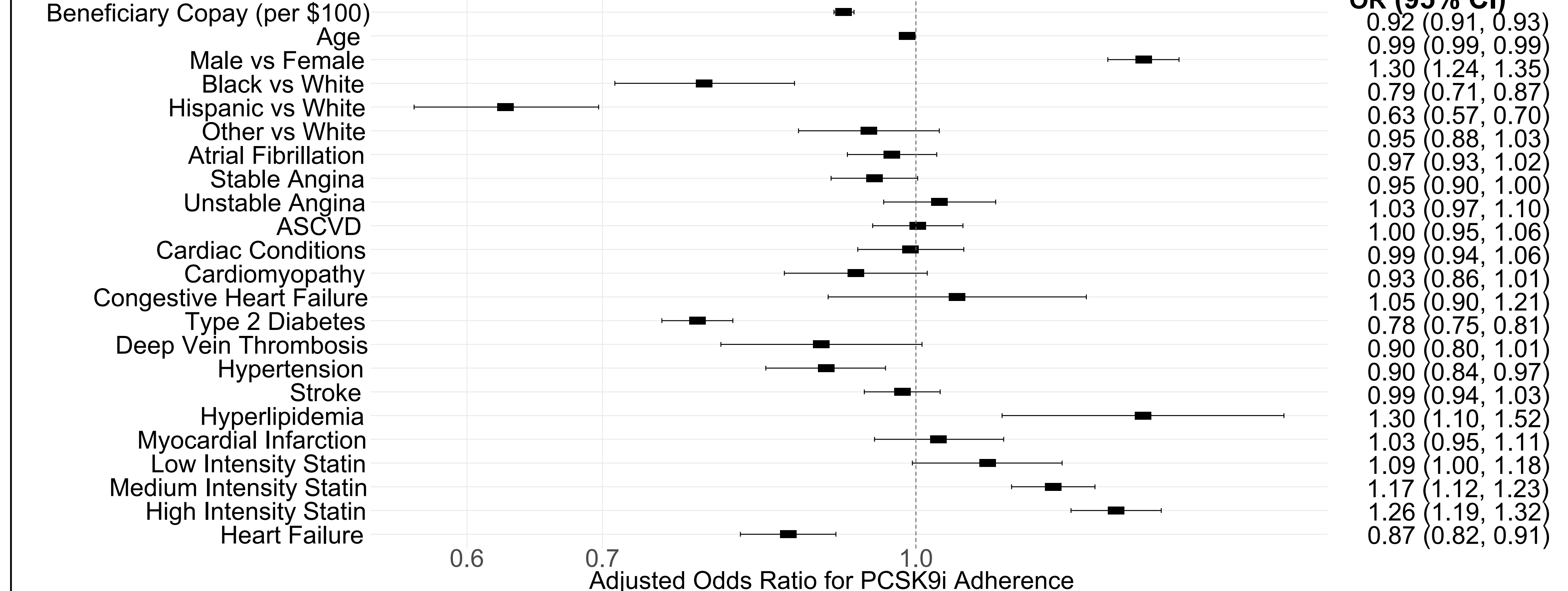
**Figure 1:** Trends in Medicare and patient Copayment from 2016-2021



**Figure 2:** Trends in Adherence and Persistence from 2016-2021



**Figure 3:** Association Between Beneficiary Copay and PCSK9i Adherence



## Conclusions

- From 2016 to 2020, the mean monthly Medicare spending decreased by around 60%, whereas the mean monthly beneficiary out-of-pocket cost decreased by approximately 32%.
- The reductions of PCSKi list prices were associated with a substantial decrease in Medicare spending over time, but this change was reflected more strongly in third-party costs than in patient affordability.
- Patient adherence and persistence to PCSK9i increased over time, suggesting that reduced financial burden may have positively influenced adherence and persistence.
- Multivariable logistic regression model showed that higher patient copays were associated with lower adherence, supporting a negative relationship between cost-sharing and real-world medication use.

## Limitations

- The study used Medicare Fee-for-Service Part D claims, which may limit generalizability to commercially insured patients and other Medicare subgroups.
- Adherence and persistence were derived from administrative pharmacy claims, which may not fully capture dosing/injection use and can introduce measurement error.

## References

1. Regeneron Pharmaceuticals. *Highlights of Prescribing Information* (alirocumab). 2021.
2. Amgen. *Highlights of Prescribing Information* (evolocumab). 2017.
3. Pagliarulo N. Regeneron, Sanofi cut PCSK9 list price, matching earlier move by rival Amgen. *BiopharmaDive*. 2019.
4. Dangi-Garimella P. Amgen announces 60% reduction in list price of PCSK9 inhibitor evolocumab. 2018.

## Author Contact and Disclosures

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