

CMS Coverage Lift on PET Beta Amyloid Imaging Impact on mAb Treatment and Beneficiary Out-Of-Pocket (OOP) Spending

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Objective

This study aims to examine impact of the National Coverage Determination (NCD) 220.6.20 removal of the once per lifetime limit on PET beta amyloid imaging (PET), focusing on beneficiary healthcare utilization and OOP cost.

Introduction

- CMS announced the NCD lift on beta-amyloid PET scans limits in October 2023.
- These PET scans are crucial for early amyloid detection, access to, and management of anti-amyloid monoclonal antibodies (mAbs) treatment in beneficiaries with Alzheimer's disease (AD) diagnosis.
- The average cost of a PET scan without insurance is ~\$3,000 per test.
- This rule change provides promise of increased access to novel anti-amyloid treatments and lower beneficiary OOP costs for those with an AD diagnosis.

Methods

- This study analyzed the 100% Medicare Research Identifiable Files (RIFs) from 2021 to 2023.
- Patients were selected if they had paid claims with PET imaging during the study period.
- Demographic information was identified using the Medicare Beneficiary Summary File (MBSF).
- Descriptive statistics examine beneficiaries who had PET imaging and those who received both PET and mAb treatment.
- Fisher's exact test utilized to compare OOP costs pre and post October rule change.

Figure 1 – Distribution of beneficiaries PET imaging frequency compared to their OOP costs.

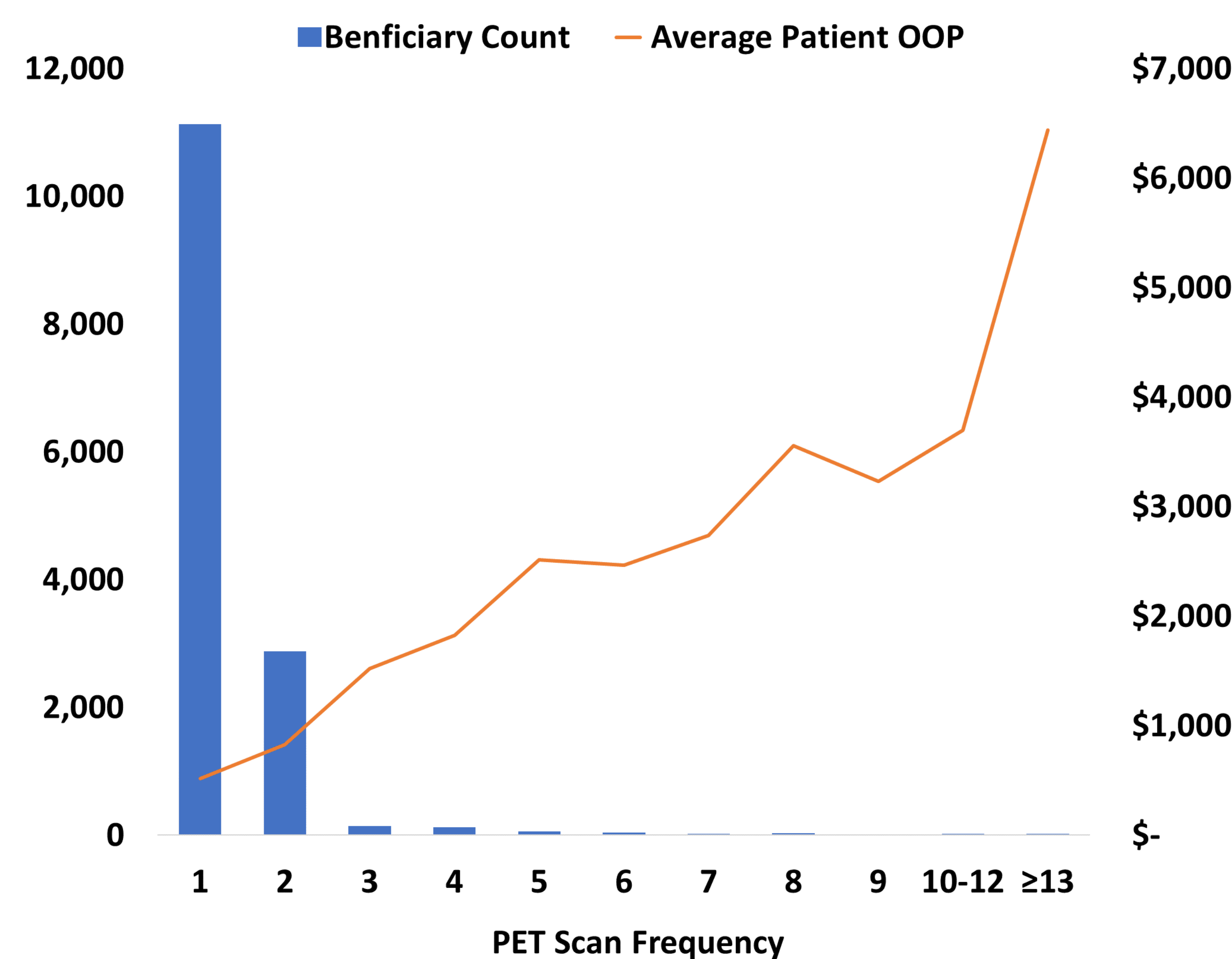
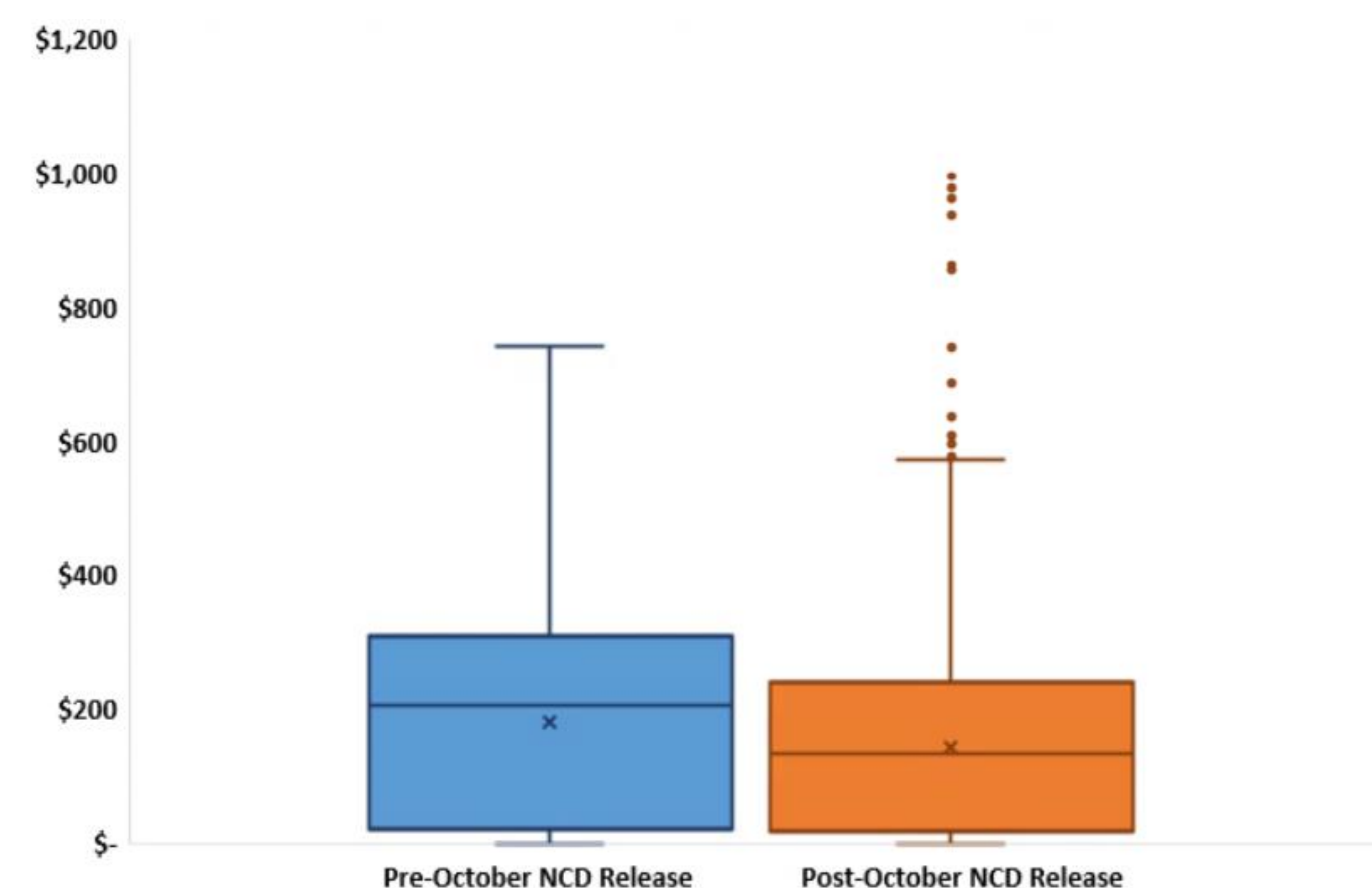


Figure 2 – The average OOP for amyloid PET scans pre-October 2023 NCD release was significantly higher than the OOP post-October 2023 (\$182 vs \$144, Fisher's exact, $p < 0.0001$).



Results

Table 1 – Demographics information of beneficiaries with a history of PET beta amyloid imaging and imaging with mAb treatment.

Characteristics	PET History (n,%)	PET with mAb Treatment (n,%)
Total	14,460	308
AD Diagnosis	1,613 (11%)	255 (83%)
Mean Age	74.3 ± 8.25	75.4 ± 5.25
Gender		
Male	7,384 (51%)	142 (46%)
Race		
White	12,006 (83%)	286 (93%)
Black	1,203 (8%)	* (*%)
Asian	270 (2%)	0 (0%)
Hispanic	280 (2%)	0 (0%)
Other	701 (5%)	15 (5%)
Socio-Economic		
LIS Status	1,800 (12%)	* (*%)
Dual Eligible	1,687 (12%)	* (*%)
Prior COVID-19 Diagnosis	1,706 (12%)	43 (14%)

- This study included 14,460 unique beneficiaries with at least one paid PET beta amyloid imaging claim between 2021 and 2024.
- Though there is a small portion of beneficiaries who have both paid PET and mAbs (308, 2%), the percentage of mAb claims increased substantially post-October PET rule change compared to pre-October 2023 (13% vs 55%).
- Majority of beneficiaries had only 1 PET scan (77%) with an average OOP of \$516 while those with 2 or more PET scans (23%) had an average OOP of \$1,031.
- Most PET claims were captured post-October 2023 (51%) compared to the full study period pre-October 2023 (49%).
- The beneficiary OOP for PET scans post-October 2023 was significantly lower than the beneficiary OOP pre-October 2023 (\$144 vs \$182).

Conclusions

Alzheimer's Disease (AD) impacts approximately 6.5 million Americans. These findings suggest the CMS rule change results in improved access to amyloid PET scans which are essential for diagnosis and monitoring of anti-amyloid mAbs treatments in beneficiaries with AD. These results also suggest the alleviation of the OOP cost burden on patients receiving treatment.

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