Effect of Medicare Part D Coverage On Adherence With Disease Modifying Drug Therapy for Multiple Sclerosis

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BACKGROUND
Since 1993, six immunomodulation drugs, also known as disease modifying drugs (DMDs), have been approved by the FDA for use in the treatment of multiple sclerosis (MS). However, persistency and adherence can be a challenge for many patients.1 1 Higher out-of-pocket (OOP) costs have been shown to be related to higher drug abandonment rates and lower persistency in a variety of disease states, but research is still needed to better determine the relationship between OOP costs and adherence and persistency with DMD therapy.2 3 4 5 6

The Coverage Gap in the Medicare Part D program imposes a significant increase in OOP burden for most beneficiaries.

OBJECTIVES
The objective of this analysis was to assess the impact of the Medicare Part D coverage levels on medication utilization behaviors among beneficiaries taking DMDs for the treatment of MS.

METHODS
The study design was a retrospective observational analysis. Data
- 5% random sample of Medicare beneficiaries in the United States for the year 2008.
- Research identifiable files (RIFs) were obtained from the Centers for Medicare and Medicaid Services.
- RIFs used in the analyses included beneficiary summary files, medical claims files (outpatient and institutional), and prescription drug event claim files (Part D claims).

RESULTS
A total of 4,180 beneficiaries were identified as having MS and meeting the general inclusion criteria. MS beneficiaries were:
- More likely than other beneficiaries to be eligible due to disability (68% versus 21%, P<0.001).
- Less likely to be paying full or 15% coinsurance levels than other beneficiaries (33% versus 56%, P<0.001).

1,600 beneficiaries had MS and took a DMD during 2008.
- Age was related to DMD use (62% for <45 years of age; 42% for ages 45-64; 25% for ages 65-74; and 8% for ages 75-84, P<0.001).

Sample Selection Criteria
Medicare beneficiaries were included in this analysis if they were:
- Covered by Medicare Parts A (hospital), B (physician/outpatient), and D (drugs) for at least 3 months during the analysis year.
- Not enrolled in a Medicare Advantage program for any months during the year.
- Classified as having MS based on at least two medical claims with an ICD-9 code for MS (340.xx) that occurred at least 60 days apart during the year or in previous years.
- Not receiving nursing home care during year.
- Not diagnosed with end-stage-renal disease (ESRD).

Operational Definitions
- Low income subsidy (LIS) status was used as a proxy for OOP burden.3 4 5 6
- No subsidy – patients with lower copay levels with and without premium subsidy.
- Reduced copay – patients with lower copay levels with and without premium subsidy.
- Full copay – fully subsidized patients.

Copay level was significantly related to likelihood of beneficiary reaching the coverage gap and catastrophic benefit phases.
- Full copay beneficiaries were less likely to reach the catastrophic benefit phase than were reduced copay or no copay beneficiaries (75.5%, 84.3% and 81.6%, respectively, P<0.001).
- OOP burden appears to be greater for full copay beneficiaries with 37.2% stopping therapy before the gap.

Copay level and OOP burden were significantly related to lower rates of adherence and higher rates of non-persistency with DMD therapies.
- Regardless of benefit phase reached, beneficiaries with more than the highest copay levels reached the gap pre-benefit phase (P=0.005, P=0.017, P=0.001).
- Beneficiaries not reaching the gap were less compliant in the pre-gaps than those reaching the gap or catastrophic phases.

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REFERENCES

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CONCLUSIONS
- OOP burden appears to be associated with an adverse impact on both adherence and persistency behaviors.
- Actual OOP burden may be greater for beneficiaries with reduced copay than for full copay beneficiaries.

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