The Effect of Medicare Part D Coverage Gap and Out-of-Pocket Burden On The Use of Disease Modifying Drugs To Treat Multiple Sclerosis

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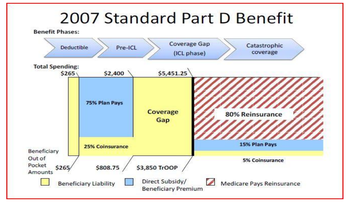
BACKGROUND

The prevalence of multiple sclerosis (MS) is estimated to be between 72 to 131 cases per 100,000 population world-wide, affecting approximately 400,000 people in the U.S.[1] Since 1993, six immunomodulating drugs, also known as disease modifying drugs (DMDs), have been approved by the FDA for use in MS therapy. Clinical trials have shown that treatment with disease modifying drugs (DMDs) can reduce the frequency of relapses and, for some therapies, slow disease progression.[2, 3, 4, 5] However, persistency and adherence can be a challenge for many patients.[7, 8] Higher out-of-pocket (OoP) costs have been shown to be related to higher prescription 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 persistence with DMD therapy.[9, 10, 11]

The Coverage Gap in 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 gap and OoP burden levels on medication utilization behaviors of Medicare beneficiaries taking DMDs for the treatment of MS.

METHODS

The study design was a retrospective observational analysis.

Data

- 5% national sample of Medicare beneficiaries in the United States for the year 2007.
- 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).

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. Classification used: Full co-pay = no subsidy; Reduced co-pay = patients with lower co-pay levels with and without premium subsidy; No co-pay = fully subsidized patients.
- Stopping therapy (non-persistency) was defined as having the last prescription fill or administration of therapy occur more than two months before the end of the calendar year.
- Adherence was measured as proportion of days covered (PDC) – the number of days of possession divided by the number of days covered by all prescriptions/administrations of the therapy.

RESULTS

A total of 1,493 beneficiaries were identified as having MS, taking a DMD and meeting all other sample selection criteria.

OoP burden varied significantly by LIS status:

LIS Status	% of Sample	Average Monthly OoP	
		Pre-Gap	Gap
Full co-pay	22%	$441	$1,324
Reduced co-pay	65%	$14	Not subject to gap
No co-pay	12%	$6	

OoP burden was significantly related to the latest benefit stage reached by beneficiaries taking DMDs.

- Full co-pay beneficiaries were more than twice as likely to remain in the pre-gap or the gap benefit phases than either the reduced co-pay or no co-pay groups *(p < 0.001)*.

LIS Status	Latest Benefit Stage Reached		
	Pre-Gap	Gap	Catastrophic
Full co-pay	8.1%	15.6%	76.2%
Reduced co-pay	3.5%	7.1%	89.4%
No co-pay	3.9%	3.9%	92.2%

p< 0.001

Some full co-pay and reduced co-pay beneficiaries appeared to manage their higher OoP burden through lower adherence and /or non-persistency.

- For beneficiaries reaching the gap benefit phase, OoP burden was significantly related to the number of months spent in the gap. Full co-pay beneficiaries averaged twice as many months in the gap as did no co-pay patients *(p < 0.001)*.
- Full co-pay beneficiaries and reduced co-pay beneficiaries were significantly *(p < 0.01)* more likely than no-co-pay beneficiaries to become non-persistent when they reached the gap benefit phase.

LIS Status	# Months		Stopped Therapy	
	Pre-Gap	Gap	Anytime	In Gap
Full co-pay	4.3	2.7	11.6%	8.30%
Reduced co-pay	3.8	1.8	12.5%	4.30%
No co-pay	3.6	1.3	9.9%	1.80%
	NS	*p< 0.001*	*NS*	*p< 0.01*

LIS Status	Proportion of Days Covered (PDC) For Time on DMD Therapy		
	All Patients	Patients Stopping Therapy	Patients Not Stopping Therapy
Full co-pay	69.80%	68.10%	82.30%
Reduced co-pay	81.00%	81.10%	80.50%
No co-pay	84.20%	83.80%	87.70%
	p< 0.001	*p< 0.001*	*NS*

CONCLUSIONS

- Most beneficiaries with MS reach the coverage gap early in the year and fairly quickly move to catastrophic coverage.
- Average time in the coverage gap is limited for most beneficiaries, but increases with OoP burden.
- Higher OoP burden is associated with a reduction in adherence and a decline in persistency with DMD therapy.

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