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

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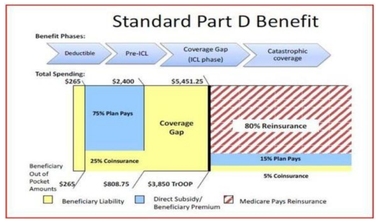
BACKGROUND

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, 2] 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. [3, 4, 5]

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% national 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).

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 copay*** = no subsidy; ***Reduced copay*** = patients with lower copay levels with and without premium subsidy; ***No copay*** = 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 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% coinsuranc 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*)

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 (57.5%, 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.

LIS Status	Latest Benefit Phase Reached		
	Pre-Gap	Gap	Catastrophic
Full copay	37.2%	5.3%	57.5%
Reduced copay	11.3%	4.4%	84.3%
No copay	9.7%	8.7%	81.6%
P value	< 0.001		

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 by beneficiaries, patients with no copay had higher PDC rates during the pre-gap benefit phase (*p=0.005, p=0.017, p<0.001).*
- Beneficiaries not reaching the gap were less compliant in the pre-gap phase than those reaching the gap or catastrophic phases.

Latest Benefit Phase Rearched	LIS Status	N	Proportion of Days Covered		
			Pre-Gap	Gap	Catastrophic
Beneficiaries reaching catastrophic phase with PDC measures for all three benefit phases	Full copay	205	86.0%	92.5%	93.0%
	Reduced copay	743	83.8%	88.4%	88.0%
	No copay	147	90.2%	93.5%	92.5%
	P value		*0.005*	*<0.001*	*<0.001*
Beneficiaries only reaching gap with PDC measures for pre-gap and gap phases	Full copay	16	74.5%	91.5%	
	Reduced copay	31	60.8%	93.3%	
	No copay	14	86.5%	92.9%	
	P value		*0.017*	*0.915*	
Beneficiaries not reaching gap with PDC measures for pre-gap phase	Full copay	141	61.8%		
	Reduced copay	116	83.5%		
	No copay	19	87.8%		
	P value		*<0.001*		

Copay level was not related to overall non-persistency with DMDs, but was related to stopping therapy in the gap phase (*p=0.010).*

Non-persistency was highest for full copay beneficiaries although this was not statistically significant.

- OoP burden appeared to be a major problem for patients only reaching the gap phase with 71.9% stopping therapy during the gap.

LIS Status	Stopped Therapy	
	Anytime	In Gap
Full copay	14.6%	7.1%
Reduced copay	12.6%	3.3%
No copay	12.5%	6.8%
P value	*0.649*	*0.010*

Latest Benefit Phase Reached	Stopped Therapy	
	Anytime	In Gap
Pre-gap	44.3%	
Gap	71.9%	71.9%
Catastrophic	7.1%	0.0%
P value	*< 0.001*	*< 0.001*

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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ACKNOWLEDGEMENT

Research funded by EMD Serono, Inc and Pfizer, Inc. EMD Serono, Inc. is an affiliate of Merck KGaA, Darmstadt, Germany. Work was conducted under Center for Medicare and Medicaid Services Data Use Agreement 21174.

Poster PRR-03 presented at the 24th Annual Meeting and Expo of the Academy of Managed Care Pharmacy (AMCP), April 18-20, 2012; San Francisco, CA, USA.