

# Future Eligibility for Medicare Part D Medication Therapy Management among Dialysis Patients

Eric Weinhandl, MS<sup>1</sup>, Wendy St. Peter, Pharm D, BCPS, FASN<sup>1,2</sup>

<sup>1</sup>United States Renal Data System, Minneapolis Medical Research Foundation, <sup>2</sup>University of Minnesota, College of Pharmacy, Twin Cities

## Introduction

- Medicare Part D plan sponsors are required to provide medication therapy management (MTM) services to targeted beneficiaries.
- Beginning in 2013, the Centers for Medicare & Medicaid Services will designate end-stage renal disease (ESRD) as 1 of 9 core chronic condition targets for MTM.
- MTM services are to be provided to targeted beneficiaries to ensure that Part D-covered drugs are appropriately used and that therapeutic outcomes are optimized.
- Plans must offer at least a minimum level of MTM services, including an annual in-person or telehealth comprehensive medication review that is conducted by a pharmacist or some other qualified health care provider.
- One MTM eligibility criterion in 2012 is that the beneficiary is likely to incur >\$3,100 in gross drug costs during the year.
- In 2014, coverage of both calcimimetics (i.e., cinacalcet) and phosphate binders will shift from Part D to the ESRD Prospective Payment System (PPS) (a.k.a. the "dialysis bundle"), thereby lowering expected gross Part D drug costs for dialysis patients.
- Using data from 2009, we assessed the possible impact of this cost shift on MTM eligibility in dialysis patients.

## Methods

- The cohort comprised ESRD patients who were alive during all of 2009.
- Patients received dialysis treatment, carried Medicare Parts A and B as primary payer of health care services, and were enrolled in Medicare Part D during all of 2009.
- Only patients enrolled in standalone Part D plans were retained for analysis.
- Gross Part D drug costs were tabulated from plan payment, low-income subsidy (LIS), and out-of-pocket payment amounts.
- Oral agents presumed to be added to the ESRD PPS in 2014 included cinacalcet, calcium acetate, lanthanum carbonate, and sevelamer (carbonate or hydrochloride).
- Fills of these agents were identified by linking the National Drug Code (NDC) in the Part D event data to a corresponding Generic Product Identifier (GPI) code in the Medi-Span Master Drug Database.
- Proportions of patients in 2009 with gross Part D drug costs less than \$3100 were stratified by LIS receipt and dialysis provider, but were otherwise unadjusted.
- Logistic regression was used to estimate the adjusted odds ratios of gross Part D drug costs less than \$3100 in 2009. A small number of patients (N = 1003 [0.7%]) were excluded from the analysis because of missing data regarding ethnicity or primary cause of ESRD.

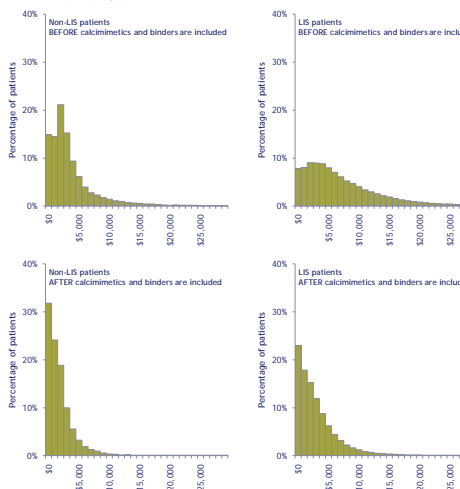
## Results

- With calcimimetics and phosphate binders included in Part D cost tabulations, gross Part D costs were \$7,897 and \$4,410 PPPY in LIS and non-LIS patients, respectively, in 2009.
- In this scenario, the percentages of LIS and non-LIS patients with costs less than \$3,100 were 26% and 52%, respectively.
- With calcimimetics and phosphate binders excluded from Part D cost tabulations, gross Part D costs were \$3,904 and \$2,599 PPPY in LIS and non-LIS patients, respectively.
- In this scenario, the percentages of LIS and non-LIS patients with costs less than \$3,100 were 57%, and 76%, respectively.
- With calcimimetics and phosphate binders excluded from Part D cost tabulations, the percentages of patients with costs less than \$3,100 were relatively similar across dialysis organizations, conditional upon LIS status.
- In a logistic regression model with exclusion of calcimimetics and phosphate binders from Part D cost tabulations, predictors of costs less than \$3,100 were age 18-44 vs. 45-64 years (odds ratio, 1.51); black (1.90) and Asian (1.47) vs. white race; Hispanic ethnicity (1.78); male sex (1.27); hypertension (2.02), glomerulonephritis (2.17), and cystic kidney disease (2.52) vs. diabetes as the primary cause of ESRD; and LIS receipt (3.36).

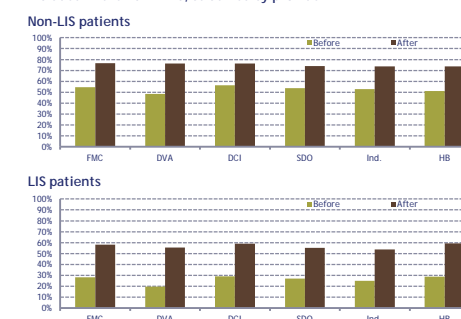
Characteristics of dialysis patients alive during all of 2009 and enrolled in Medicare Parts A, B, and D, stratified by provider

	Freemans (FMC)	Davita (DVA)	Dialysis Clinic, Inc. (DCI)	SDO	Ind.	HB
Sample size	44,836	37,329	5,300	13,320	18,333	21,860
Age (years)						
18-44	16.9%	17.4%	18.5%	16.1%	16.3%	19.1%
45-64	43.0%	42.8%	42.8%	42.1%	41.6%	42.8%
65-74	23.4%	23.2%	23.1%	23.8%	23.9%	21.1%
75+	16.7%	16.6%	15.6%	18.0%	18.2%	16.9%
Race						
White	49.8%	50.6%	43.9%	54.2%	55.8%	48.4%
Black	45.7%	42.7%	51.3%	36.6%	37.2%	44.5%
Native American	1.4%	2.0%	2.2%	0.8%	1.5%	2.3%
Asian	3.1%	4.6%	2.6%	8.3%	5.6%	4.7%
Sex						
Female	50.1%	48.1%	50.2%	49.5%	47.7%	45.3%
Male	49.9%	51.9%	49.8%	50.5%	52.3%	54.7%
Low-income subsidy (LIS)						
No	22.1%	20.1%	20.1%	19.1%	21.0%	20.8%
Yes	77.9%	79.9%	79.9%	80.9%	79.0%	79.2%
Mean Part D-covered medications taken per day, adjusted for age, race, and sex						
In non-LIS patients	3.63	3.74	3.92	3.66	3.75	3.69
In LIS patients	5.25	5.62	5.47	5.26	5.48	5.16

Gross Part D costs before and after calcimimetics and phosphate binders are included in the ESRD PPS, stratified by LIS receipt



Percentage of patients in 2009 with gross Part D costs less than \$3100, before and after calcimimetics and phosphate binders are included in the ESRD PPS, stratified by provider



Adjusted odds ratios of gross Part D costs less than \$3100 in 2009, after costs of calcimimetics and phosphate binders are excluded

	Crude costs PPPY in non-LIS patients (2011 / 2014 PPS)	Crude costs PPPY in LIS patients (2011 / 2014 PPS)	Adjusted odds ratio of costs < \$3100	95% interval	P-value
Age (years)					
18-44	\$3509 / \$1618	\$7977 / \$3309	1.51	1.46-1.56	< 0.01
45-64	\$4371 / \$2368	\$8466 / \$4099	1.00	Referent	
65-74	\$4713 / \$2828	\$7380 / \$4066	0.87	0.85-0.90	< 0.01
75+	\$4252 / \$2689	\$6512 / \$3903	0.86	0.83-0.89	< 0.01
Race					
White	\$4686 / \$2865	\$8173 / \$4274	1.00	Referent	
Black	\$3560 / \$1854	\$7696 / \$3597	1.90	1.85-1.95	< 0.01
Asian	\$4766 / \$2457	\$8245 / \$3992	1.47	1.39-1.55	< 0.01
Ethnicity					
Non-Hispanic	\$3561 / \$2178	\$7288 / \$3643	1.00	Referent	
Hispanic	\$4472 / \$2634	\$8026 / \$3966	1.78	1.72-1.84	< 0.01
Sex					
Female	\$4701 / \$2775	\$7921 / \$4089	1.00	Referent	
Male	\$4203 / \$2473	\$7874 / \$3717	1.27	1.25-1.30	< 0.01
Primary cause of ESRD					
Diabetes	\$4473 / \$2807	\$7927 / \$4350	1.00	Referent	
Hypertension	\$3905 / \$2228	\$7324 / \$3189	2.02	1.97-2.08	< 0.01
Glomerulonephritis	\$4528 / \$2189	\$8278 / \$3268	2.17	2.08-2.26	< 0.01
Cystic kidney disease	\$5011 / \$2268	\$8257 / \$3124	2.52	2.32-2.72	< 0.01
Other known cause	\$5335 / \$3394	\$9608 / \$5023	1.46	1.40-1.52	< 0.01
Duration of ESRD (years)					
<1	\$4133 / \$3942	\$6334 / \$4087	1.00	Referent	
1-2	\$4205 / \$3459	\$7258 / \$3590	1.02	0.99-1.05	0.27
3-5	\$4478 / \$2453	\$8498 / \$3994	0.99	0.95-1.02	0.47
≥4	\$5034 / \$2349	\$9083 / \$3560	1.07	1.03-1.11	< 0.01
Dialytic modality					
Hemodialysis	\$4398 / \$2581	\$7894 / \$3894	1.00	Referent	
Peritoneal dialysis	\$4538 / \$2790	\$7969 / \$4100	0.96	0.91-1.00	0.07
Low-income subsidy					
No	\$4410 / \$2599	NA	3.36	3.25-3.48	< 0.01
Yes	NA	\$7897 / \$3904	1.00	Referent	

## Conclusions

- Cinacalcet and phosphate binders account for almost half of gross Part D drug costs.
- Shifting coverage of these medications from Part D to the ESRD PPS in 2014 will reduce Part D expenditures to such an extent that the majority of dialysis patients will not qualify for MTM offered by Part D plan sponsors.
- Dialysis patients are a medically complicated population. Patients take an average of 10 to 12 medications, have multiple comorbid conditions, and see multiple physicians.
- The design of drug dosage regimens around the dialysis procedure is an added complexity.
- Logically, MTM services offered by a pharmacist or some other qualified provider should be provided in the dialysis unit, in collaboration with other dialysis team members, including nephrologists, nurses, dietitians, and social workers.
- In light of the significant medication-related problems and poor medication adherence that have been described in this patient population, provision of MTM services in dialysis units may improve outcomes and simultaneously reduce health care-related costs.
- CMS should consider possible mechanisms to encourage dialysis providers to offer MTM services in the context of the recently implemented ESRD PPS.