Chapter 12: Part D Prescription Drug Coverage in Patients With ESRD

- In this year's Annual Data Report (ADR) we focus on beneficiary data from 2014. The per patient per year (PPPY) Medicare Part D spending for those with end-stage renal disease (ESRD) ($8,420) was three times higher than for the population of all general Medicare beneficiaries ($2,830). Hemodialysis (HD) patients had the highest PPPY Medicare Part D spending, at $9,089, compared to $8,188 and $6,284 for those receiving peritoneal dialysis and kidney transplant (Figure 12.5a).
- Among beneficiaries with Part D enrollment, a higher proportion of those treated with HD (66%), peritoneal dialysis (PD; 55%), and kidney transplant (52%) receive the Low-income Subsidy (LIS) than in the overall general Medicare population (31%; Figure 12.1).
- Across general Medicare and ESRD populations, PPPY Part D spending was 2.8-3.7 times greater for beneficiaries with LIS benefits than for those without. This difference reflects both higher utilization among those with LIS benefits and the higher share of spending covered by Medicare for LIS beneficiaries (Figure 12.5b).
- LIS beneficiaries' out-of-pocket costs represented only 1% of total Part D expenditures, compared to 27-30% in the non-LIS populations (Figure 12.5b).
- Phosphate-binding agents, β-adrenergic blocking agents, and opiate agonists were each prescribed to more than half of dialysis patients during 2014, and over one third of dialysis patients had at least one claim for HMG-CoA Reductase Inhibitors, dihydropyridines, and proton-pump inhibitors. Phosphate-binding agents ranked first in Medicare Part D spending, followed by cinacalcet, and insulins (Tables 12.6a and 12.6b).

Introduction

2016 will mark ten years of operation for the Medicare Part D prescription drug benefit. Over that time period, Part D has become an important component of Medicare as whole. Given the clinical and socioeconomic status of the ESRD population, this benefit has been particularly significant. Before this program began on January 1, 2006, some Medicare beneficiaries were able to obtain drug coverage through various private insurance plans, state Medicaid programs, or the Department of Veterans Affairs. Others received partial support through pharmaceutical-assistance programs or free samples available from their physicians. However, many beneficiaries with ESRD did not have reliable coverage, and incurred substantial out-of-pocket expenses for their medications. Given that very few ESRD beneficiaries are enrolled in Medicare Advantage plans that provide both medical and prescription coverage, most obtain Part D benefits through a stand-alone prescription drug plan (PDP).

Enrollment in Part D is not mandatory; non-Part D Medicare enrollees may choose to obtain outpatient medication benefits through other creditable coverage sources that provide benefits equivalent to or better than Part D. These include employer group health plans, retiree health plans, Veterans Administration benefits, and state kidney programs. Those without an alternative source of coverage pay for their prescriptions out-of-pocket. The proportion of Medicare-covered beneficiaries with ESRD who have no known source of drug coverage is highest in the PD and transplant populations. Given that more of these

patients are employed (relative to HD patients), it is likely that some have sources of prescription drug coverage not currently tracked by Medicare.

Beneficiaries dually-enrolled in Medicare and Medicaid are automatically eligible for Part D under the Low-income Subsidy (LIS) benefit. Non-Medicaid eligible beneficiaries can also qualify for the LIS based on limited assets and income. The LIS provides full or partial waivers for many out-of-pocket cost-sharing requirements, including premiums, deductibles, and copayments, and provides full or partial coverage during the coverage gap ("donut hole"). The LIS also provides assistance for the premiums, deductibles, and co-payments of the Medicare Part D program. Some Medicare enrollees are automatically deemed eligible for LIS and do not need to file an application (referred to as "deemed LIS beneficiaries"). Such beneficiaries include persons dually eligible for both Medicaid and Medicare, those receiving supplemental security income, and those participating in Medicare savings programs (e.g., Qualified Medicare Beneficiaries (QMB) and Qualified Individuals (QI)). Other Medicare beneficiaries with limited incomes and resources who do not automatically qualify for LIS (non-deemed beneficiaries) can apply for the LIS and have their eligibility determined by their state Medicaid agency or the Social Security Administration.

In 2014, 62% of Medicare-covered beneficiaries with ESRD enrolled in Part D received the LIS benefit, compared to 31% of the general Medicare Part D population. By modality, 66%, 55%, and 52% of enrolled HD, PD, and transplant patients qualified for the LIS. By race, White dialysis patients were the least likely to qualify for LIS benefits.

Phosphate-removing agents comprise the most common Part D medication class taken by dialysis patients (by percentage of beneficiaries with at least one prescription filled), while cardiovascular agents (β-adrenergic blocking agents, HMG-CoA reductase inhibitors, and dihydropyridines) account for three of the top five. The list of medications by total Medicare Part D spending[1] is topped by phosphate-removing agents and and cinacalcet.

In 2014, total estimated Medicare Part D expenditures for ESRD and general Medicare Part D enrollees were $2.7 billion and $58.1 billion. Between 2011 and 2014, total Part D spending increased by 63% and 91% for HD and PD patients, compared to 26% for general Medicare beneficiaries; for transplant patients, total Part D spending rose by 63%. In 2014, regardless of LIS status, Medicare Part D spending for HD, PD, and transplant patients averaged $9,089, $8,188, and $6,284 PPPY, compared to only $2,830 for general Medicare beneficiaries. Out-of-pocket Part D costs for beneficiaries with ESRD were slightly higher than for general Medicare beneficiaries, at $441 versus $423.

The Medicare Part D program functions in concert with Medicare Part B. Part B covers medications administered in physician offices, including some of those administered during hemodialysis (e.g. intravenous antibiotics that are not associated with dialysis-related infections), and most immunosuppressant medications required following a kidney transplant. Immunosuppression coverage continues as long as the transplant recipient maintains Medicare eligibility. Entitlement may end three years post-transplant or be continued due to disability or age. Beneficiaries whose kidney transplant is not covered by Medicare, but who become Medicare-eligible due to age or disability can enroll in and receive their immunosuppressant medications through Part D. Prescription drugs not covered for beneficiaries under Part B may be covered by Part D, depending upon whether the drug is included on the plan formulary. Until January 2011, costs of erythropoietin stimulating agents, IV vitamin D, iron, and antibiotic agents administered during dialysis were separately reimbursable under Medicare Part B. Since 2011, coverage for these products has been included in the monthly bundled payment to dialysis providers. Part B costs are thus not displayed

[1] In this chapter, Medicare Part D spending represents the sum of the Medicare covered amount and the Low- income Subsidy amount.

in chapter figures, as they have been in previous ADRs.

Part D Coverage Plans

CMS provides participating prescription drug plans (PDPs) with guidance on structuring a "standard" Part D PDP. The upper portion of Table 12.1 illustrates the standard benefit design for PDPs in 2009 and 2014. In 2014, for example, beneficiaries shared costs with the PDP through co-insurance or copayments until the combined total during the initial coverage period reached $2,850. After reaching this threshold, beneficiaries entered a coverage gap, or "donut hole," where they were then required to pay 100% of their prescription costs.

In each year since 2010, the U.S. government has been providing increasing assistance to those reaching this coverage gap. In 2014, beneficiaries received a 52.5% discount on brand name medications from drug manufacturers, and Part D plans paid 28% of generic drug costs for those in the gap (Q1 Medicare, 2014). Beneficiaries who reached annual out-of-pocket drug costs of $4,550 entered the catastrophic coverage phase, in which they then paid only a small copayment for any additional prescriptions until the end of that year (Table 12.1).

PDPs have the latitude to structure their plans differently from the example presented, but companies offering non-standard plans must demonstrate that their coverage is at least actuarially equivalent to the standard plan. Many have developed plans featuring no deductibles, or with drug copayments instead of the 25% co-insurance, and some plans provide generic and/or brand name drug coverage during the coverage gap (Table 12.1; Q1 Medicare, 2014).

vol 2 Table 12.1 Medicare Part D parameters for defined standard benefit, 2009 & 2014

	2009	2014
Deductible		
After the deductible is met, the beneficiary pays 25% of total prescription costs up to the initial coverage limit.	$295.00	$310.00
Initial coverage limit		
The coverage gap ("donut hole") begins at this point. The beneficiary pays 100% of their prescription costs up to the out-of-pocket threshold	$2,700.00	$2,850.00
Out-of-pocket threshold		
The total out-of-pocket costs including the "donut hole"	$4,350.00	$4,550.00
Total covered Part D prescription out-of-pocket spending		
(including the coverage gap). Catastrophic coverage begins after this point.	$6,153.75	$6,455.00
Catastrophic coverage benefit	$2.40	[a]$2.55
Generic/preferred multi-source drug	$6.00	[a]$6.35
Other drugs		[a]plus a 52.50% brand name medication discount
2014 Example:		
$310 (deductible)	$295.00	$310
+(($$2850-$310)*25%)(initial coverage)	$601.25	$635.00
+(($6455-$2850)*100%)(coverage gap)	$3,453.75	$3,605.00
Total (maximum out-of-pocket costs prior to catastrophic coverage, excluding plan premium)	**$4,350.00**	**$4,550.00**

[a]*The catastrophic coverage amount is the greater of 5% of medication cost or the values shown in the chart above. In 2014, beneficiaries were charged $2.55 for those generic or preferred multisource drugs with a retail price less than $51 and 5% for those with a retail price over $51. For brand name drugs, beneficiaries paid $6.35 for those drugs with a retail price less than $127 and 5% for those with a retail price over $127. Table adapted from http://www.q1medicare.com/PartD-The-2014-Medicare-Part-D-Outlook.php.*

The share of beneficiaries with ESRD that enrolled in Part D increased annually between 2011 and 2014 (Table 12.2). Total enrollment was higher in the dialysis population, than in the general Medicare population, but the growth between 2011 and 2014 was somewhat slower among beneficiaries on dialysis. Both the level and trend in enrollment among beneficiaries with transplants mirrored that in the general Medicare population.

vol 2 Table 12.2 General Medicare & ESRD patients enrolled in Part D (%)

	General Medicare	All ESRD	Hemodialysis	Peritoneal dialysis	Transplant
2011	60	70	74	62	59
2012	62	72	76	64	62
2013	67	75	79	67	66
2014	69	77	80	69	68

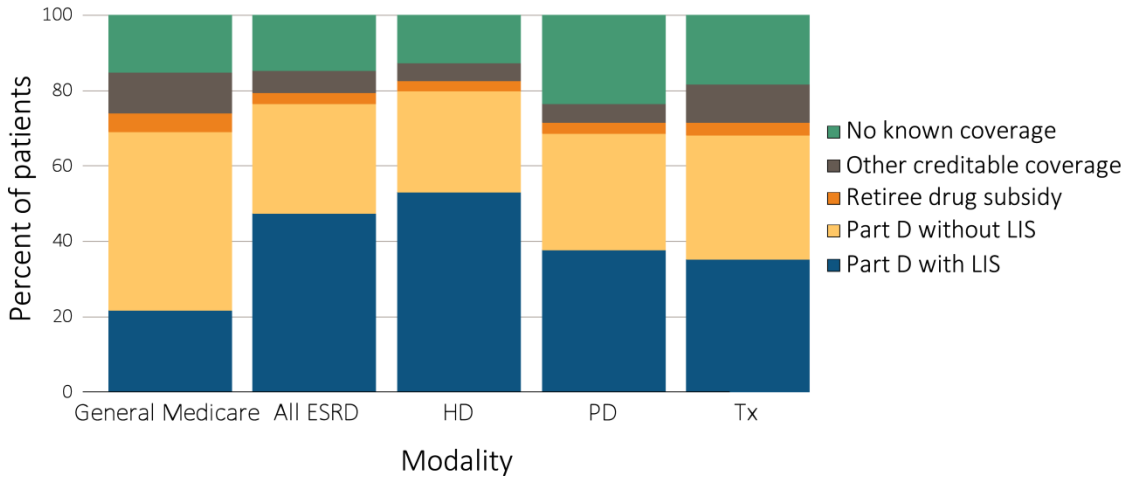
Data source: 2011-2014 Medicare data, point prevalent Medicare enrollees alive on January 1. Medicare data: general Medicare, 5% Medicare sample (ESRD, hemodialysis, peritoneal dialysis, and transplant, 100% ESRD population). Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage.

Part D Enrollment Patterns

In 2014, 69% of the general Medicare population enrolled in a Medicare Part D prescription drug plan. Medicare-covered beneficiaries with ESRD exceed the Part D enrollment rate of the general Medicare population, with 77% participation. Enrollment varies by renal replacement modality: 80% of HD, 69% of PD, and 68% of kidney transplant patients enrolled in Part D.

More HD, PD, and transplant patients with Part D receive the LIS—66%, 55%, and 52%, compared to 31% of the general Medicare population. About 15% of ESRD beneficiaries have no identified prescription drug coverage. By modality, PD and transplant patients are least likely to have known coverage (see Figure 12.1).

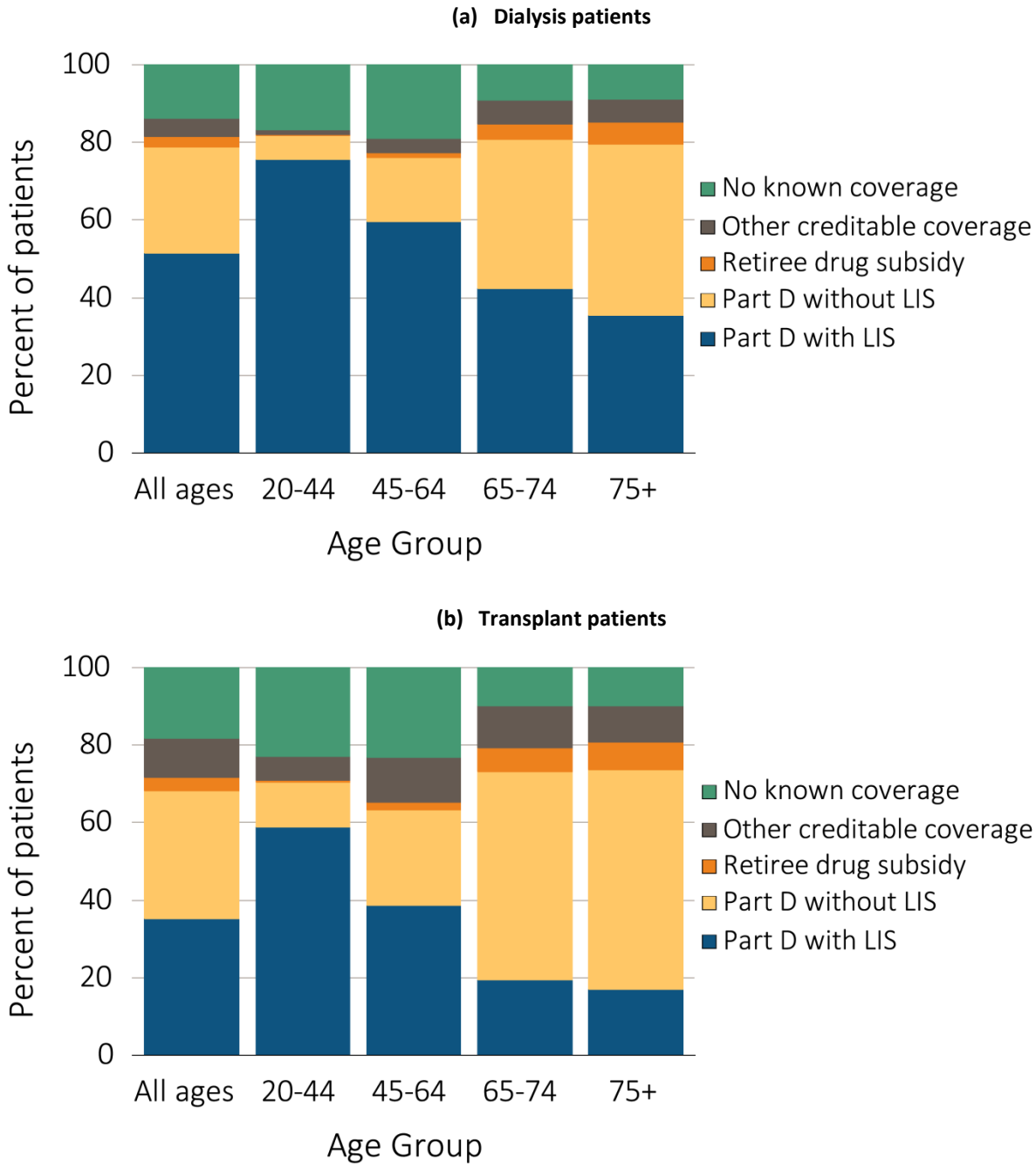
vol 2 Figure 12.1 Sources of prescription drug coverage in Medicare ESRD enrollees, by population, 2014



Data source: 2014 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage; PD, peritoneal dialysis; Tx, kidney transplant.

Beneficiaries with ESRD obtain prescription drug coverage from a variety of sources, and the sources vary widely by age (Figure 12.2). Total enrollment from any known source varied modestly across age groups. However, receipt of the LIS decreased substantially with age in both populations. Finally, in each age category transplant patients are markedly less likely than those on dialysis to receive the LIS benefit.

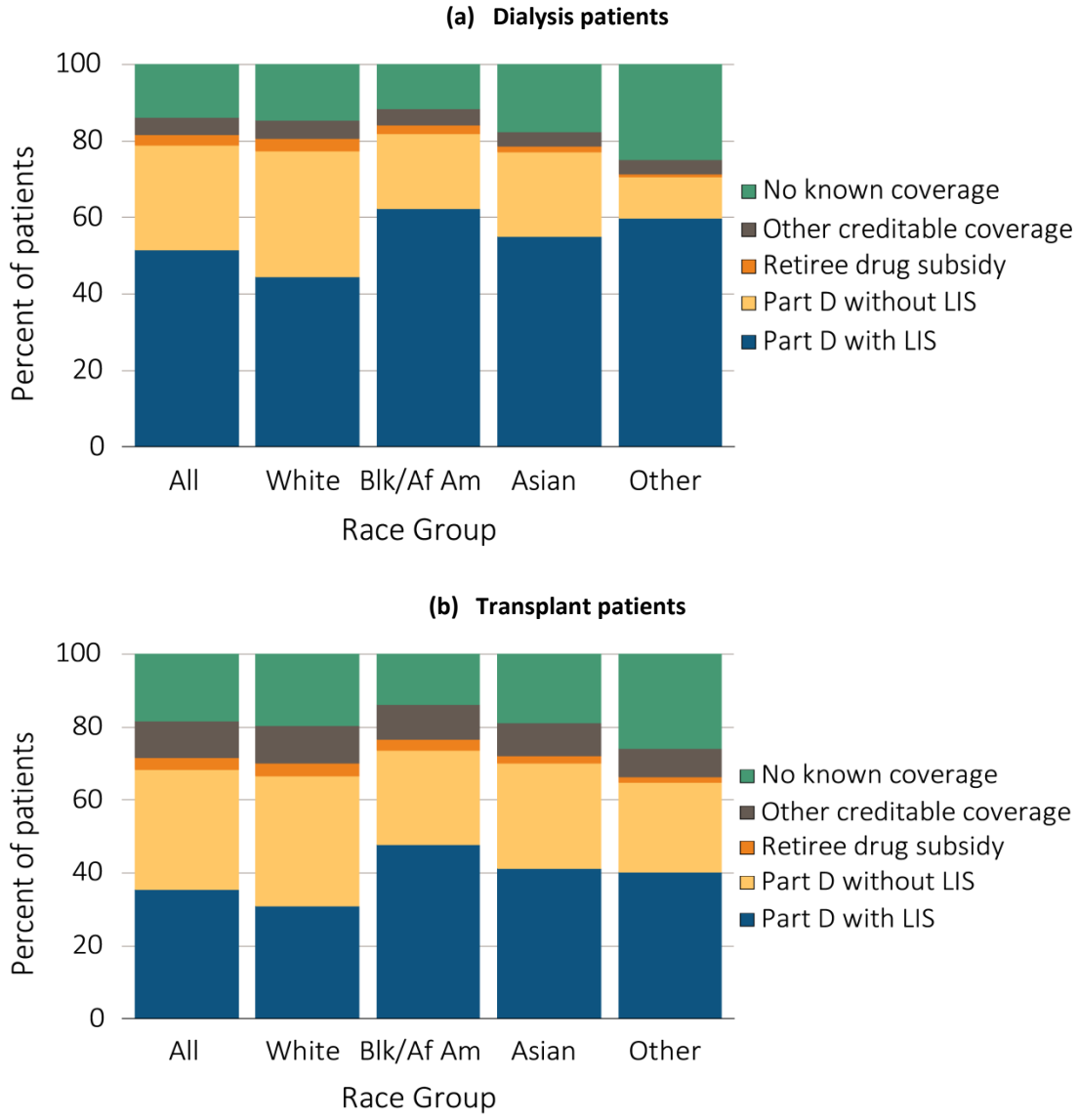
vol 2 Figure 12.2 Sources of prescription drug coverage in Medicare ESRD enrollees, by age & modality, 2014



Data source: 2014 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: ESRD, end-stage renal disease; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage.

Overall, approximately 79% of dialysis patients were enrolled in Part D. A higher percentage of dialysis patients who identified as Black/African American enrolled in Part D (82%) compared to those who identified as White (77%) or Asian (77%; Figure 12.3a). Seventy-six percent of Blacks and 71% of Asians with Part D coverage qualified for the LIS benefit, compared to 58% of Whites; Blacks were the least likely to have no known prescription drug coverage. Sixty-eight percent of transplant patients enrolled in Part D. By race, 67% of Whites, 74% of Blacks, and 70% of Asian transplant patients enrolled. A larger share of Black (65%) and Asian (59%) transplant patients with Part D coverage have the LIS, compared to 46% of White transplant patients (Figure 12.3b).

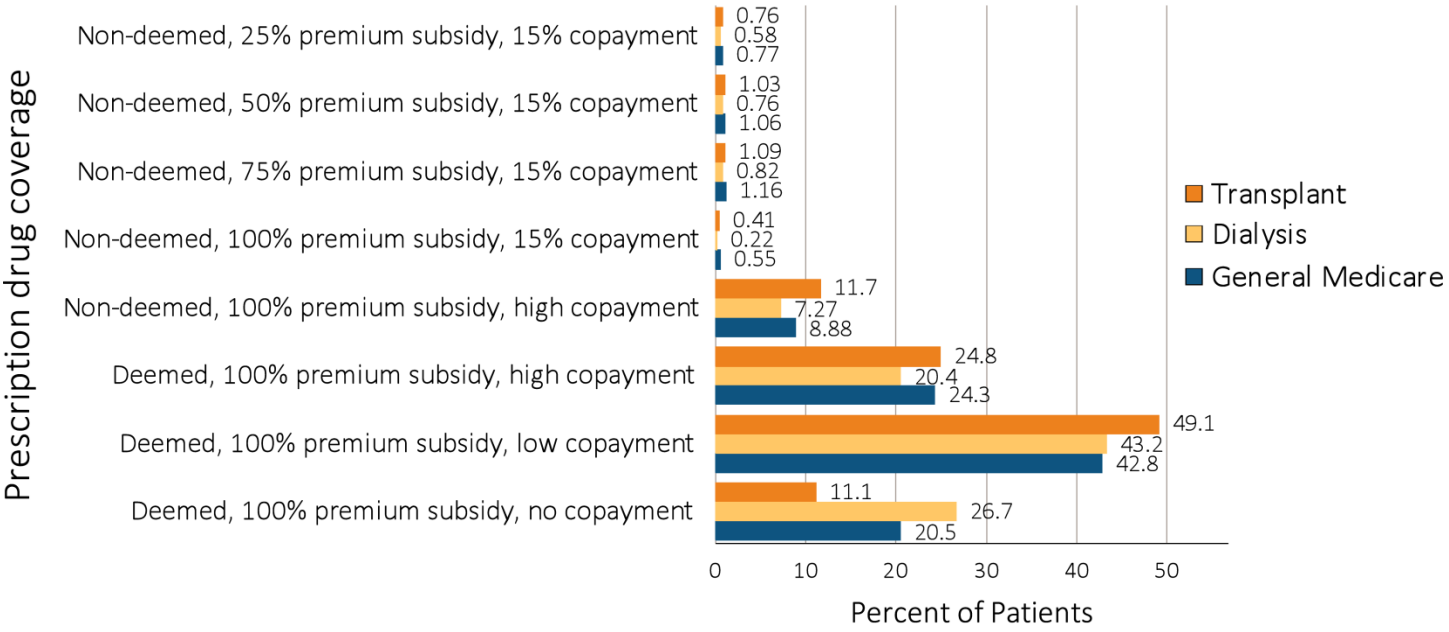
vol 2 Figure 12.3 Sources of prescription drug coverage in Medicare ESRD enrollees, by race/ethnicity & modality, 2014



Data source: 2014 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: Blk/Af Am, Black or African American; ESRD, end-stage renal disease; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage.

In 2014, 90% of dialysis patients with Part D LIS coverage were deemed LIS beneficiaries, compared to 85% and 88% of transplant and general Medicare beneficiaries (Figure 12.4).

vol 2 Figure 12.4 Distribution of Low-income Subsidy categories in Part D general Medicare & ESRD patients, 2014



Data source: 2014 Medicare data, point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage.

Within each racial category, the share of general Medicare beneficiaries who receive the LIS decreases with age but increases among those aged 75 and older (see Table 12.3). This increase in receipt of the LIS among the oldest beneficiaries is not seen in the ESRD population, except among Asians (note that samples of Asian patients by age category are relatively small).

vol 2 Table 12.3 Medicare Part D enrollees (%) with the Low-income Subsidy, by age & race, 2014

	General Medicare	All ESRD	Hemodialysis	Peritoneal dialysis	Transplant
White					
All ages	24.7	54.4	58.8	48.1	46.4
20-44	88.2	88.1	91.6	88.3	82.3
45-64	51.7	70.3	76.1	64.4	57.1
65-74	14.7	39.7	48.6	24.7	21.3
75+	19.0	34.1	37.5	17.5	18.0
Black/African American					
All ages	57.9	74.4	76.3	71.2	64.9
20-44	92.8	92.3	94.3	90.3	85.9
45-64	74.5	80.4	82.8	74.6	69.2
65-74	42.2	59.5	63.7	40.6	40.3
75+	49.7	59.5	61.2	36.1	39.1
Asian					
All ages	64.1	68.7	73.2	57.1	58.8
20-44	89.8	87.0	89.5	83.7	83.1
45-64	65.4	73.5	78.3	58.9	66.0
65-74	55.5	58.3	65.2	40.6	45.3
75+	71.3	66.9	70.7	54.0	41.2
Other race					
All ages	37.8	78.6	85.3	78.8	62.2
20-44	88.5	91.2	95.9	96.5	76.4
45-64	56.3	83.2	89.0	82.8	67.9
65-74	25.9	67.9	77.2	54.0	48.8
75+	38.1	66.5	75.0	37.5	40.4

Data source: 2014 Medicare data, point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: ESRD, end-stage renal disease; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage.

Spending Under Stand-alone Part D Plans

In recent years, total Part D spending for beneficiaries with ESRD increased by 65%, from $1.64 billion in 2011 to $2.71 billion in 2014 (Table 12.4). These amounts do not include costs of medications subsumed under the ESRD prospective payment system (e.g. ESAs, IV vitamin D, and iron) or billed to Medicare Part B (e.g. immunosuppressants). Between 2011 and 2014, total estimated Part D spending increased by 63%, 91%, and 63% for HD, PD, and kidney transplant patients. These rates of increase far outpaced the 26% spending growth that occurred in the general Medicare population.

vol 2 Table 12.4 Total estimated Medicare Part D spending for enrollees, in billions, 2011-2014

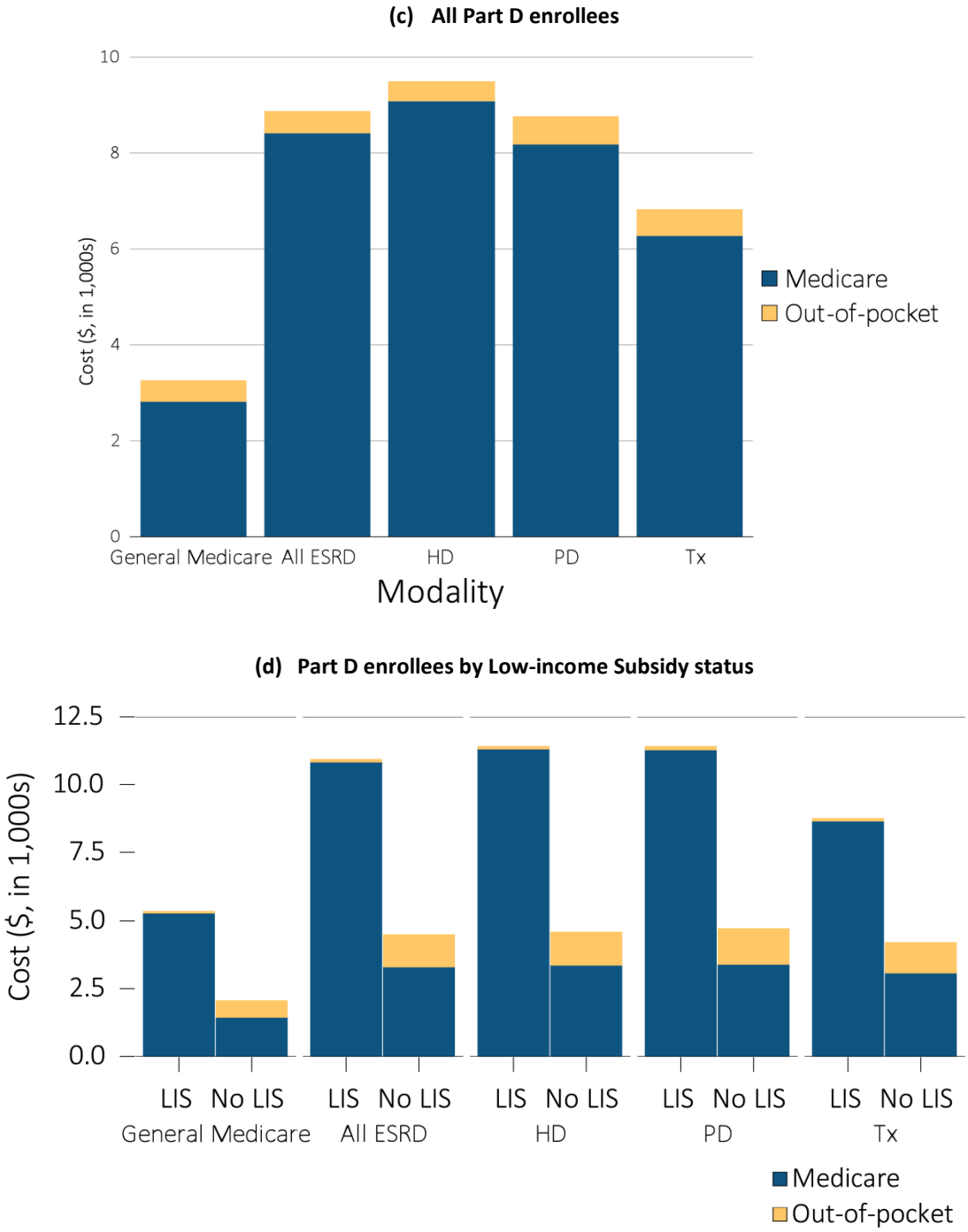
	General Medicare	All ESRD	Hemodialysis	Peritoneal dialysis	Transplant
2011	45.96	1.64	1.29	0.09	0.21
2012	40.08	2.00	1.59	0.12	0.23
2013	52.08	2.27	1.79	0.14	0.27
2014	58.07	2.71	2.10	0.17	0.35

Data source: 2011-2014 Medicare data, period prevalent Medicare enrollees alive on January 1, excluding those in Medicare Advantage Part D plans and Medicare secondary payer, using as-treated model (see ESRD Methods chapter for analytical methods). Part D spending represents the sum of the Medicare covered amount and the Low- income Subsidy amount.

By ESRD modality, HD patients had the highest PPPY Medicare Part D spending at $9,089, compared to $8,188 for those with PD and $6,284 for transplant patients. PPPY Part D spending was three times greater for beneficiaries with ESRD ($8,420) than for general Medicare beneficiaries ($2,830). As a proportion of total costs, however, out-of-pocket costs were lower for beneficiaries with ESRD, representing 4%, 7%, and 8% percent of PPPY costs for HD, PD, and transplant patients, compared to 13% in the general Medicare population (Figure 12.5a). A higher proportion of beneficiaries with ESRD received the LIS relative to the general Medicare population, which substantially reduced out-of-pocket obligations.

Across general Medicare and ESRD populations, PPPY Part D spending was 2.8-3.7 times greater for beneficiaries with LIS benefits than for those without. In the LIS population, however, out-of-pocket costs represented only 1% of total expenditures, compared to 27-30% among general Medicare and ESRD populations that did not receive the subsidy. PPPY Part D spending was 2.1 and 2.3 times greater for beneficiaries with ESRD than for general Medicare beneficiaries in the LIS and non-LIS populations (Figure 12.5b).

vol 2 Figure 12.5 Per person per year Medicare Part D spending & out-of-pocket costs for enrollees, 2014



Data source: 2014 Medicare data, period prevalent Medicare enrollees alive on January 1, 2014, excluding those in Medicare Advantage Part D plans and Medicare secondary payer, using as-treated model (see ESRD Methods chapter for analytical methods). Part D spending represents the sum of the Medicare covered amount and the Low- income Subsidy amount.

Total PPPY Medicare Part D spending varied by age, sex, and race (Table 12.5). Generally, younger beneficiaries aged 20-44 or 45-64, had higher costs than older patients. Medicare Part D spending varied only modestly by sex and race.

vol 2 Table 12.5 Per person per year Part D spending ($) for enrollees, by Low-income Subsidy status, 2014

	General Medicare		All ESRD		Hemodialysis		Peritoneal dialysis		Transplant	
	Part D with LIS	Part D without LIS	Part D with LIS	Part D without LIS	Part D with LIS	Part D without LIS	Part D with LIS	Part D without LIS	Part D with LIS	Part D without LIS
Age										
All	5,265	1,437	10,826	3,286	11,323	3,358	11,287	3,402	8,655	3,080
20-44	5,341	2,104	11,386	2,640	12,908	3,464	11,564	2,780	6,902	1,551
45-64	6,861	2,163	11,783	3,859	12,310	4,075	11,595	3,727	9,529	3,272
65-74	4,457	1,371	9,728	3,474	9,957	3,560	9,434	3,577	9,016	3,274
75+	4,026	1,331	7,826	2,643	8,075	2,653	7,021	2,877	6,905	2,632
Sex										
Male	5,283	1,542	10,925	3,349	11,411	3,361	11,608	3,420	8,853	3,291
Female	5,253	1,358	10,718	3,190	11,228	3,354	10,987	3,373	8,394	2,753
Race										
White	5,461	1,436	10,510	3,318	11,056	3,405	11,416	3,487	8,499	3,084
Black/African American	5,133	1,512	11,325	3,167	11,745	3,204	10,875	2,914	8,884	3,105
Asian	4,523	1,220	11,105	3,369	11,523	3,537	12,539	3,523	9,086	2,996
Other race	4,617	1,365	7,956	3,319	7,713	3,764	10,034	3,699	8,381	2,765

Data source: 2014 Medicare data, period prevalent Medicare enrollees alive on January 1, 2014, excluding those in Medicare Advantage Part D plans and Medicare secondary payer, using as-treated model (see ESRD Methods chapter for analytical methods). Part D spending represents the sum of the Medicare covered amount and the Low- income Subsidy amount.

Prescription Drug Classes

The top 15 drug classes used by this population are ranked based on the percentage of beneficiaries with at least one claim for a drug within the class. Phosphate-binding agents were the most frequently prescribed Part D medication class in dialysis patients during 2014, and first as well in terms of Medicare Part D spending. Meanwhile, more than half of dialysis patients had at least one claim for β-adrenergic blocking agents and opiate agonists (Table 12.6). Cinacalcet and insulin were the second and third most costly classes of medications. Together, phosphate-binding agents and cinacalcet accounted for more than 50% of Part D spending (Table 12.7).

vol 2 Table 12.6 Top 15 drug classes received by Part D-enrolled dialysis patients, by percent of patients, 2014

Rank	Drug class	Percent of patients
1	Phosphate-binding Agents	72%
2	β-Adrenergic Blocking Agents	66%
3	Opiate Agonists	54%
4	HMG-CoA Reductase Inhibitors	47%
5	Dihydropyridines	46%
6	Proton-pump Inhibitors	42%
7	Insulins	32%
8	Cinacalcet	30%
9	Antidepressants	30%
10	Anticonvulsants	27%
11	Angiotensin-Converting Enzyme Inhibitors	27%
12	Direct Vasodilators	24%
13	Quinolones	22%
14	Central α-Agonists	19%
15	Platelet-aggregation Inhibitors	18%

Data source: Medicare Part D claims. Dialysis patients with Medicare Part D stand-alone prescription drug plans in the Medicare 5% sample.

Vol 2 Table 12.7 Top 15 drug classes received by Part D-enrolled dialysis patients, by spending, 2014

Rank	Drug class	Medicare Part D spending ($ in millions)	Percent of total Medicare Part D spending
1	Phosphate-binding Agents	$840.53	37.0%
2	Cinacalcet	$479.86	21.1%
3	Insulins	$160.58	7.1%
4	HIV Antiretrovirals	$72.73	3.2%
5	Nucleosides and Nucleotides	$60.02	2.6%
6	Antineoplastic Agents	$52.79	2.3%
7	Proton-pump Inhibitors	$41.02	1.8%
8	HCV antivirals	$37.50	1.7%
9	Opiate Agonists	$30.54	1.3%
10	Vasodilating Agents	$24.95	1.1%
11	Vasodilating Agents	$22.57	1.0%
12	Anticonvulsants	$21.25	0.9%
13	HMG-CoA Reductase Inhibitors	$21.10	0.9%
14	Antipsychotics	$20.14	0.9%
15	Corticosteroids	$20.09	0.9%

Data source: Medicare Part D claims. Dialysis patients with Medicare Part D stand-alone prescription drug plans in the Medicare 5% sample. Part D spending represents the sum of the Medicare covered amount and the Low- income Subsidy amount.

References

Q1 Medicare. *The 2014 Medicare Part D Prescription Drug Program.* Website. Retrieved August 30, 2015 from http://www.q1medicare.com/PartD-The-2014-Medicare-Part-D-Outlook.php