

# Chapter 7: Medicare Part D Prescription Drug Coverage in Patients With CKD

- Approximately 71% of chronic kidney disease (CKD) patients are enrolled in Medicare Part D, including both the stand-alone and Medicare Advantage plans. The Part D enrollment rate for this group is slightly higher than in the general Medicare population (66%), but lower than for the ESRD population (77%; Figure 7.1).
- As compared to Whites (22%), higher proportions of Asian (70%) and Black/ African American (52%) CKD patients qualify for Part D coverage with the Low-income Subsidy (LIS; Figure 7.3).
- The percentage of beneficiaries who receive the LIS is higher for CKD patients across all age and race categories than among the general Medicare population (Figures 7.2 and 7.3).
- In 2014, per patient per year (PPPY) Medicare Part D spending for CKD patients was 50% higher than for general Medicare beneficiaries, at \$4,198 as compared to \$2,806 (Figure 7.5a).
- Total Medicare spending for Part D-covered medications in 2014 was more than twice as high for CKD patients with the LIS (\$7,352) than for those without (\$3,262). Patient out-of-pocket costs represented only a 1% share of these total expenditures, as compared to 29% in each of the non-LIS populations (Figure 7.5b).
- Prescriptions for HMG-CoA Reductase Inhibitors (statins) and β-Adrenergic Blocking Agents (β blockers) were each filled by more than 50% of the CKD patient group during 2014, and over one third had at least one claim for opiate agonists, loop diuretics, proton-pump inhibitors, antidepressants, or angiotensin-converting enzyme inhibitors (ACEIs). By drug class, the Medicare Part D program spent the greatest amount on insulins, followed by antineoplastic agents (Tables 7.6 and 7.7).

#### Introduction

The optional Medicare Part D prescription drug benefit has been available to all beneficiaries since 2006. Part D benefits can be managed through a stand-alone prescription drug plan (PDP) or through a Medicare Advantage (MA) managed care plan, which provides medical as well as prescription benefits. CKD patients have the option to enroll in an MA plan; end-stage renal disease (ESRD) patients, in contrast, are precluded from entering an MA plan if they are not already enrolled in one when they reach ESRD. Enrollment data are available for beneficiaries with both types of plans, however actual spending data are only available for beneficiaries in stand-alone plans. In 2014, 45% of general Medicare beneficiaries were enrolled in a stand-alone Medicare Part D PDP, while

23% received coverage through an MA plan (Kaiser, 2016).

Before 2006, Medicare beneficiaries obtained drug coverage through various avenues—insurance plans, state Medicaid programs, pharmaceutical assistance programs, or samples received from physicians. Those with none of these options paid for their medications out-of-pocket. After 2006, the majority of Medicare enrollees obtained Part D coverage.

The premiums for Part D coverage are partially subsidized. Beneficiaries who delay voluntary enrollment yet lack other creditable coverage at least equivalent to Part D are charged higher premiums once they do enroll. Consequently, 66% of general Medicare beneficiaries, 71% of CKD patients, and 77% of ESRD patients were enrolled in Part D in 2014. Other Medicare-enrolled CKD patients choose to

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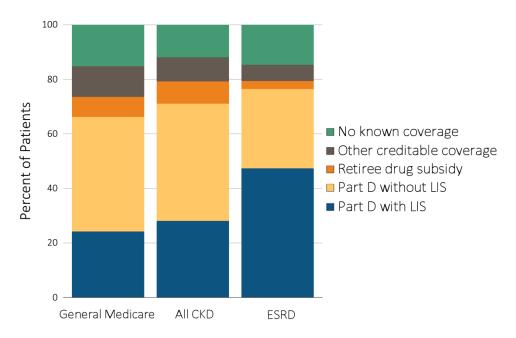
obtain outpatient medication benefits through retiree drug subsidy plans or other creditable coverage such as employer group health plans, other private coverage, or Veterans Administration benefits. Some enrollees remain uninsured and pay out-of-pocket for their outpatient prescription medications.

Between 2011 and 2014, the percentage of CKD patients with Part D coverage increased from 59% to 71%. In 2014, the proportion of CKD patients with no known coverage was 12%, lower than the 15% seen in the general Medicare population.

Part D does not cover all medications prescribed to Medicare enrollees. Several drug categories—such as over-the-counter medications, anorexia and weight loss or gain medications, prescription vitamins (except for prenatal vitamins), and cough and cold medications—are excluded from the Part D program formulary. This creates a lack of support for some drugs commonly prescribed to treat CKD, including oral iron, ergocalciferol, and cholecalciferol. In January, 2013, Medicare Part D coverage was expanded to include benzodiazepines with no restrictions, and barbiturates when prescribed for specific indications.

Before the Medicare Part D program began, beneficiaries dually-enrolled in Medicare and Medicaid received prescription benefits under state Medicaid programs. The Part D program offers a substantial Low-income Subsidy (LIS) benefit to enrollees with limited assets and income, including those who are dually-enrolled. 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 Part D coverage gap (commonly referred to as the "donut hole"). In 2014, 40% of CKD patients enrolled in Part D qualified for the LIS, compared with 37% of general Medicare beneficiaries and 62% of ESRD patients (see Figure 7.1). Among Medicare Part D enrollees with CKD, 81% of Asian beneficiaries received the LIS, compared to 67% of Blacks/African Americans and 32% of Whites. Part D spending for identified CKD patients, which represents the sum of the Medicare covered amount and the Low-income Subsidy amount, rose from \$5.2 billion in 2011 to \$7.7 billion in 2014—an increase of 49%, compared to the lesser cost growth of 26% and 65% for general Medicare and ESRD patients.

vol 1 Figure 7.1 Sources of prescription drug coverage in Medicare enrollees, by population, 2014



Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; LIS, Medicare Low-income Subsidy; Part D, Medicare prescription drug coverage benefit.

Out-of-pocket (OOP) Part D costs for CKD patients were higher than for general Medicare beneficiaries, at \$624 versus \$438 per person per year (PPPY) in 2014. However, the out-of-pocket share of total expenditures borne by CKD patients was slightly lower than that experienced by the general Medicare population due to a higher rate of LIS coverage for this group.

Under the Affordable Care Act, the coverage gap ("donut" hole) in the Part D benefit will be phased out by 2020. As part of the phase-out, pharmaceutical manufacturers have provided a 50% discount to non-LIS beneficiaries on the price of brand-name drugs purchased while in the coverage gap, and the Part D plans have paid an additional 2.5% of brand-name costs in the gap. Plans also have paid 28% of the cost of generics purchased by non-LIS beneficiaries in the coverage gap.

## Part D Coverage Plans

The Centers for Medicare and Medicaid Services provide prescription drug plans (PDPs) with guidance on structuring a "standard" Part D PDP. The upper portion of Table 7.1 shows the standard benefit design for PDPs in 2009 and 2014. In 2014, for example,

beneficiaries shared costs with the PDP (as coinsurance or copayments) until the combined total reached \$2,850 during the initial coverage period. After reaching this level, beneficiaries went into the coverage gap, or "donut hole," where they paid 100% of costs.

In 2011 the government began providing non-LIS recipients reaching the coverage gap with more assistance each year. In 2014, beneficiaries received a 50% discount on brand name drugs from manufacturers plus 2.5% coverage from their Part D plans, and plans paid 28% of generic drug costs in the gap. Beneficiaries who paid a yearly out-of-pocket drug cost of \$4,550 reached the catastrophic coverage phase, in which they then had only a small copayment for their drugs until the end of the year.

PDPs have the latitude to structure their plans differently than the model presented here; companies offering non-standard plans must show that their coverage is at least actuarially equivalent to the standard plan. Many have developed plans with 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.

vol 1 Table 7.1 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	\$6,153.75	\$6,455.00
(including the coverage gap). Catastrophic coverage begins after this point.	Ş0,133.73	<del>,</del> 0,433.00
Catastrophic coverage benefit	\$2.40	°\$2.55
Generic/preferred multi-source drug	\$6.00	°\$6.35
Other drugs		<sup>a</sup> 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	\$4,350.00	\$4,550.00
(maximum out-of-pocket costs prior to catastrophic coverage, excluding plan premium)		

<sup>&</sup>lt;sup>a</sup>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 <a href="http://www.q1medicare.com/PartD-The-2014-Medicare-Part-D-Outlook.php">http://www.q1medicare.com/PartD-The-2014-Medicare-Part-D-Outlook.php</a>.

The proportion of beneficiaries that enrolled in Medicare Part D rose between 2011 and 2014 among general Medicare beneficiaries, patients with CKD, and those with ESRD (Table 7.2). In each year,

enrollment was slightly higher for those with CKD than in the general Medicare population; enrollment has been highest for beneficiaries with ESRD.

vol 1 Table 7.2 General Medicare, CKD, & ESRD patients enrolled in Part D (%)

	General Medicare	All CKD	All ESRD
2011	55.7	59.3	69.9
2012	57.6	60.5	71.7
2013	65.7	69.3	75.2
2014	66.3	71.1	76.5

Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; Part D, Medicare prescription drug coverage benefit.

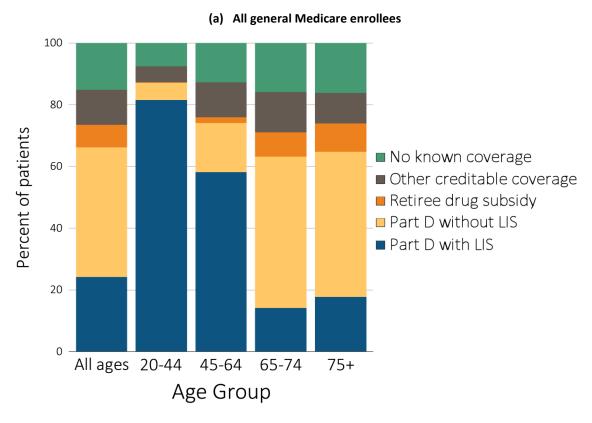
#### **Part D Enrollment Patterns**

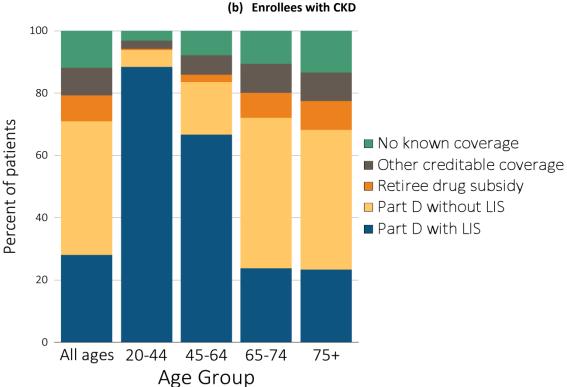
Approximately 71% of CKD patients enrolled in Medicare Part D (including both stand-alone and MA plans) in 2014, slightly higher than Part D enrollment by those in the general Medicare population (66%) and lower than enrollment by those in the ESRD population (77%). Compared to beneficiaries in the general population, however, a higher percentage of CKD patients qualified for the LIS (Figure 7.1).

Among both general Medicare beneficiaries and those with CKD, the percentage of beneficiaries

enrolled in Part D generally declines with age. In the 75+ age group, similar proportions of general Medicare and CKD patients were enrolled in Part D, at 65–68%. The proportion of beneficiaries with LIS declined with age in both populations with the exception of general Medicare population aged 75 and older, but CKD patients in all age categories were more likely to receive this subsidy (Figure 7.2). Eightynine percent of CKD patients aged 20–44 received the LIS in 2014.

vol 1 Figure 7.2 Sources of prescription drug coverage in Medicare enrollees, by age, 2014



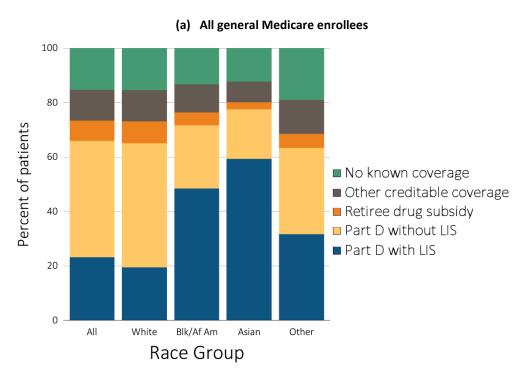


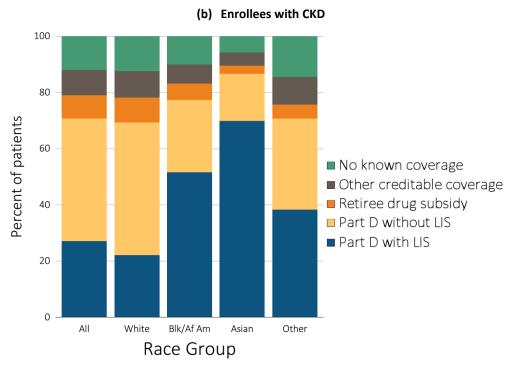
Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: CKD, chronic kidney disease; LIS, Medicare low income subsidy; Part D, Medicare prescription drug coverage benefit.

Patterns of coverage by race were similar in the both the general Medicare population and for beneficiaries with CKD (Figure 7.3). Compared to Whites, a higher portion of Asian and Black

beneficiaries had Part D coverage with the LIS. Across all races, the percentage of beneficiaries with the LIS was higher for CKD patients than among the entire general Medicare group

vol 1 Figure 7.3 Sources of prescription drug coverage in Medicare enrollees, by race, 2014





Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: Blk/Af Am, Black/African American; CKD, chronic kidney disease; LIS, Medicare Low-income Subsidy; Part D, Medicare prescription drug coverage benefit.

Table 7.3 reports the percent of general Medicare and CKD enrollees who were eligible for the LIS,

stratified by both age and race.

vol 1 Table 7.3 Medicare Part D enrollees (%) with the Low-income Subsidy, by age & race, 2014

	General Medicare	All CKD	
	Part D with Low-income Subsidy	Part D with Low-income Subsidy	
White			
All ages	30.0	31.9	
20-44	92.9	94.0	
45-64	76.0	77.1	
65-74	17.2	26.4	
75+	21.5	27.1	
Black/African Am	nerican		
All ages	67.6	66.7	
20-44	95.3	94.1	
45-64	85.7	84.7	
65-74	49.0	56.4	
75+	57.9	63.6	
Asian			
All ages	76.5	80.6	
20-44	91.9	100.0	
45-64	85.1	85.9	
65-74	68.4	74.3	
75+	80.1	82.3	
Other races			
All ages	50.1	54.3	
20-44	92.8	90.5	
45-64	79.2	83.7	
65-74	34.4	40.8	
75+	47.5	54.7	

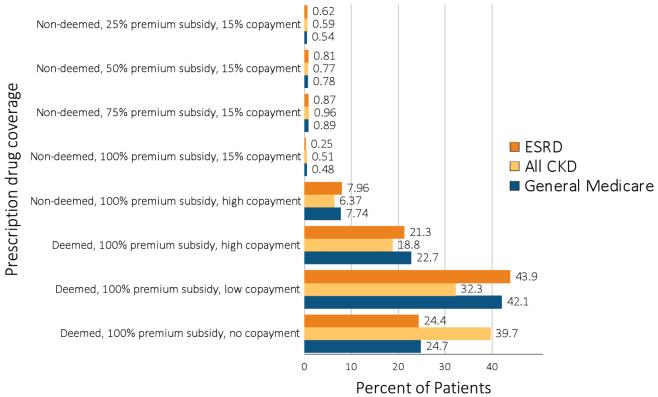
Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: CKD, chronic kidney disease; Part D, Medicare prescription drug coverage benefit.

Several categories of Medicare beneficiaries automatically qualify for LIS and Part D benefits, and are considered to be "deemed". These individuals include full-benefit Medicare/Medicaid dual eligible individuals, partial dual eligible individuals, Qualified Medicare Beneficiaries (QMB-only), Specified Lowincome Medicare Beneficiaries (SLMB-only), Qualifying Individuals (QI), and people who receive Supplemental Security Income (SSI) benefits but not Medicaid. Other Medicare beneficiaries with limited incomes and resources who do not automatically

qualify for LIS (non-deemed) can apply for LIS and have their eligibility determined by their State Medicaid agency or the Social Security Administration.

The distribution of Part D enrollees receiving the LIS across benefit categories (premium subsidy, copayment) is described in Figure 7.4. The largest group of LIS recipients who had CKD were eligible for a full premium subsidy: 18.8% had a high copay, 32.3% had a low copay, and 39.7% had no copay.

vol 1 Figure 7.4 Distribution of Low-income Subsidy categories in Part D general Medicare, CKD, & ESRD patients, 2014



Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; Part D, Medicare prescription drug coverage benefit.

## **Spending Under Stand-alone Part D Plans**

In 2014, total Part D spending reached \$50.5 billion. Expenditures for beneficiaries with CKD or ESRD were \$10.4 billion—about 21% of total Part D prescription drug spending. Data over a four-year period shows a

consistent trend of increasing costs, by \$3.6 billion between 2011 and 2014 (Table 7.4). ESRD costs were \$2.7 billion in 2014, but did not include drugs paid for under the ESRD prospective payment system (e.g. ESAs, IV vitamin D, and iron) or those medications billed to Medicare Part B (e.g. immunosuppressants).

vol 1 Table 7.4 Total estimated Medicare Part D spending for enrollees (in billions), 2011-2014

	<b>General Medicare</b>	All CKD	All ESRD
2011	40.1	5.2	1.6
2012	35.7	4.8	2.0
2013	45.7	6.8	2.3
2014	50.5	7.7	2.7

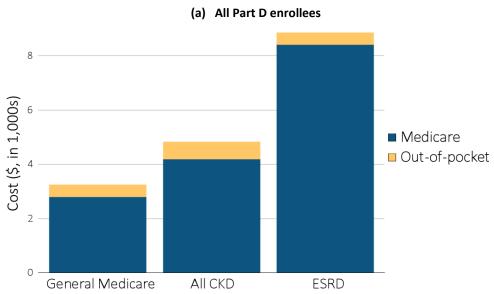
Data source: Medicare Part D claims. Medicare totals include Part D claims for Part D enrollees with traditional Medicare (Parts A & B). CKD totals include Medicare CKD patients, as determined from claims. ESRD totals include all Part D claims for Medicare ESRD patients with Medicare Part D stand-alone prescription drug plans. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; Part D, Medicare prescription drug coverage benefit.

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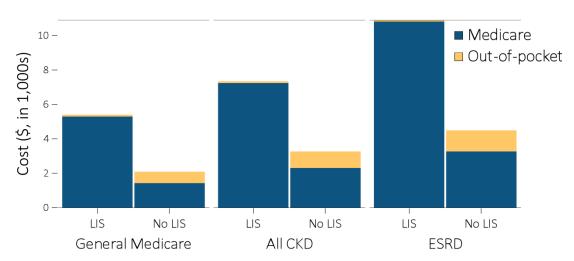
In 2014, PPPY Part D spending for CKD patients was 50% higher than for general Medicare beneficiaries, at \$4,198 compared to \$2,806. Out-of-pocket costs were 42% higher for beneficiaries with CKD than among the general Medicare population. Due to the much higher proportion of LIS in the ESRD population, out-of-pocket costs represented a smaller share of total spending (5%) than in the other two groups (13% for CKD, and 14% for general Medicare; Figure 7.5a).

Total spending for Part D-covered medications in 2014 was more than twice as high for beneficiaries with the LIS than for those without (Figure 7.5b). In the LIS population, however, out-of-pocket costs represented only 1% of these total expenditures, compared to 27-30% in each of the non-LIS populations.

vol 1 Figure 7.5 Per person per year Medicare Part D spending & out-of-pocket costs for enrollees, 2014



#### (b) Part D enrollees by Low-income Subsidy status



Data source: Medicare Part D claims. Medicare totals include Part D claims for Part D enrollees with traditional Medicare (Parts A & B). CKD totals include Medicare CKD patients as determined from claims. ESRD totals include all Part D claims for Medicare ESRD patients with Medicare Part D stand-alone prescription drug plans. Costs are per person per year for calendar year 2014. Medicare Part D spending is the sum of the Medicare covered amount and the Low-income Subsidy amount. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; Part D, Medicare prescription drug coverage benefit.

#### CHAPTER 7: MEDICARE PART D PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH CKD

Total PPPY Medicare Part D spending varied widely between those with and without the LIS (Table 7.5), excluding patient obligations. Overall, expenditures were highest in both categories for beneficiaries with ESRD. Total PPPY Medicare-paid Part D costs for LIS and non-LIS recipients varied from \$5,302 and \$1,447 PPPY in the general Medicare population to \$7,249 and \$2,318 among patients with CKD, and to \$10,826

and \$3,286 among those with ESRD. By race, PPPY spending was highest for Whites in the general Medicare and CKD LIS populations, but highest for Blacks and Asians in the general Medicare and CKD non-LIS populations, respectively. In each of the three populations, spending was highest in the age 45-64 category, regardless of LIS status.

vol 1 Table 7.5 Per person per year Part D spending (\$) for enrollees, by Low-income Subsidy status, 2014

	<b>General Medicare</b>		All CKD		All ESRD	
	Part D with Low-income Subsidy	Part D remaining enrollees	Part D with Low-income Subsidy	Part D remaining enrollees	Part D with Low-income Subsidy	Part D remaining enrollees
Age						
All	5,302	1,447	7,249	2,318	10,826	3,286
20-44	5,255	2,060	10,655	3,074	11,386	2,640
45-64	7,115	3,122	10,928	4,156	11,783	3,859
65-74	4,572	1,386	7,343	2,801	9,728	3,474
75+	4,030	1,329	5,426	1,952	7,826	2,643
Sex						
Male	5,310	1,556	7,694	2,476	10,925	3,349
Female	5,296	1,367	6,978	2,161	10,718	3,190
Race						
White	5,510	1,446	7,506	2,302	10,510	3,318
Black	4,881	1,513	6,563	2,344	11,325	3,167
Asian	4,858	1,278	7,339	2,750	11,105	3,369
Other race	4,728	1,396	6,708	2,745	7,956	3,319

Data source: Medicare Part D claims. All Medicare patients with Medicare Part D stand-alone prescription drug plans. CKD determined from claims. ESRD patients with Medicare Part D stand-alone prescription drug plans. Costs are per person per year for calendar year 2014. Medicare Part D PPPY is the sum of the Medicare covered amount and the Low-income Subsidy amount. LIS status is determined from the Part D enrollment. A person is classified as LIS if they are eligible for the LIS for at least one month during 2014. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; Part D, Medicare prescription drug coverage benefit.

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# **Prescription Drug Classes**

Ranking of the top 15 prescription drug classes used by patients is based on the percentage of beneficiaries with at least one claim for a drug. The list is led by cardiovascular therapies (statins, beta blockers, and diuretics). Over one third of CKD patients received opioid agonists, proton-pump inhibitors antidepressants, angiotensin-converting enzyme inhibitors, or dihydropyridines (Table 7.6).

vol 1 Table 7.6 Top 15 drug classes received by Part D-enrolled CKD patients, by percent of patients 2014

Rank	Drug class	Percent of patients
1	HMG-CoA Reductase Inhibitors (statins)	59%
2	β-Adrenergic Blocking Agents	57%
3	Opiate Agonists	46%
4	Loop Diuretics	39%
5	Proton-pump Inhibitors	38%
6	Antidepressants	35%
7	Angiotensin-Converting Enzyme Inhibitors	34%
8	Dihydropyridines	33%
9	Quinolones	27%
10	Thyroid Agents	25%
11	Angiotensin II Receptor Antagonists	24%
12	Anticonvulsants, Miscellaneous	23%
13	Adrenals	21%
14	Replacement Preparations	20%
15	Insulins	20%

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

Insulins ranked first in total Medicare drug expenditures for CKD patients, followed closely by antineoplastic agents. These two drug classes

accounted for 13% and 10% of total Medicare Part D spending, respectively

vol 1 Table 7.7 Top 15 drug classes received by Part D-enrolled CKD patients, by Medicare Part D spending, 2014

Percent of total

Rank	Drug class	Medicare Part D spending (\$ in millions)	Medicare Part D spending
1	Insulins	\$1,017.81	13%
2	Antineoplastic Agents	\$758.01	10%
3	Antipsychotics	\$288.85	4%
4	Proton-pump Inhibitors	\$252.85	3%
5	Dipeptidyl Peptidase IV (DDP-4) Inhibitors	\$240.78	3%
6	Corticosteroids	\$225.37	3%
7	HMG-CoA Reductase Inhibitors (statins)	\$223.01	3%
8	Antiretrovirals	\$209.87	3%
9	HCV antivirals	\$206.89	3%
10	Opiate Agonists	\$200.95	3%
11	Anticoagulants	\$181.25	2%
12	Anticonvulsants, Miscellaneous	\$178.52	2%
13	Antimuscarinics/Antispasmodics	\$169.03	2%
14	Antidepressants	\$167.42	2%
15	Angiotensin II Receptor Antagonists	\$155.01	2%

Data source: Medicare Part D claims. CKD 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.

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## Notes