Chapter 10: Prescription Drug Coverage in Patients with ESRD

- In this 2018 Annual Data Report (ADR), we introduce new chapter features:
    - Because of the continuing prescription opioid epidemic, this year we retain the section of analgesic use and update the map of non-steroidal anti-inflammatory agents (NSAIDs) and opioid use in the United States using 2016 data.
    - Because of increasing use of high-cost antivirals nationally, this year we specifically investigate the spending and utilization rates of antivirals, including prescription antiretrovirals, nucleosides and nucleotides, and protease inhibitors.
- Among beneficiaries with Medicare Part D enrollment, a higher proportion of those treated with hemodialysis (HD; 65.5%), peritoneal dialysis (PD; 52.3%), and kidney transplant (50.3%) received the Low-income Subsidy (LIS) than did the general Medicare population (30.2%; Figure 10.1).
- In 2016, per patient per year (PPPY) Medicare Part D spending on prescriptions for end-stage renal disease (ESRD) patients with stand-alone Part D plans was 4.1 times higher than among the general Medicare population ($13,310 vs. $3,559; Figure 10.5.a).
- Of patients enrolled in stand-alone Part D plans, dialysis patients had a higher PPPY spending on prescriptions than did transplant patients (HD, $14,922; PD, $13,882; transplant, $8,693; Figure 10.5.a).
- In both the general Medicare and ESRD populations, PPPY Part D spending was 2.8-3.6 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. LIS beneficiaries' out-of-pocket costs represented only 0.6-1.2% of total Part D expenditures, compared to 21.6-26.9% in the non-LIS populations (Figure 10.5.b).
- In 2016, ESRD patients were most frequently prescribed ion-removing agents, β-adrenergic blocking agents (beta blockers), antibacterials, analgesics, antipyretics, and lipid-lowering agents (Table 10.6).
- The highest costing medications for ESRD patients were ion-removing agents, cinacalcet, antidiabetic agents, antivirals, and immunosuppressive agents (Table 10.7).
- In the United States, the overall proportions of ESRD patients using prescription NSAIDs and opioids were 8.3% and 49.0%, respectively (Figures 10.6 and 10.7).
- In 2016, approximately 5.8%, 5.6%, and 24.1% of HD, PD, and transplant patients had at least one filled prescription antiviral; PPPY Medicare Part D spending among these users was $918, $844, and $2,104, respectively (Figures 10.9 and 10.10).

Introduction

Pharmaceutical therapy is an important component of ESRD treatment. The contribution of medications to positive health outcomes, combined with the clinical and socioeconomic status of ESRD patients, makes their prescription drug benefits particularly significant. This chapter assesses prescription drug coverage, prescription drug-related costs, and patterns of prescription drug use for ESRD patients in several health systems. As in prior Annual Data Reports (ADR), Medicare Part D claims data from stand-alone prescription drug plans (PDPs) are used to describe Part D enrollment patterns and spending by Medicare beneficiaries.

Starting in 2017, we annually select a different drug class for a more detailed investigation of medication use patterns. In the 2017 ADR, we reported analgesics used by ESRD patients. Because of the continuing opioid epidemic, we continue that analysis this year, but we have also added a section on prescription antivirals, a category with high, and growing costs.

A parallel examination of prescription drug use and associated costs in patients with CKD can be found in Volume 1, Chapter 8: *Prescription Drug Coverage in Patients with CKD*.

Methods

In this chapter, we traditionally examine Medicare data to describe Part D enrollment and prescription utilization for Medicare beneficiaries. Our cohort contained 100% of the ESRD population receiving HD, PD, or with a functioning kidney transplant. Enrollment data were available for both traditional Medicare (fee-for-service) enrollees and Medicare Advantage enrollees; however, actual claims and spending data were only available for beneficiaries of traditional Medicare. Thus, our estimates for Part D enrollment applied to all Medicare beneficiaries, but the reporting of prescription utilization and associated costs applied only to Medicare fee-for-services Part D enrollees.

We included in our analyses the general Medicare beneficiaries who enrolled in both Medicare Parts A and B in the calendar year of interest. To create HD, PD, and kidney transplant cohorts, we identified all point prevalent and incident patients. Point prevalent cohorts included all patients alive and enrolled in Medicare on January 1 of the calendar year, with ESRD onset at least 90 days earlier; treatment modality was identified on January 1. Incident cohorts included all patients alive and enrolled in Medicare exactly 90 days after ESRD onset, between January 1 and December 31 of the index year; modality was identified on this date. We based Part D costs for ESRD patients on the 100% ESRD population, using the period prevalent, as-treated actuarial model (Model 1, described in ESRD Reference Table K).

In this chapter, we defined insurance spending as plan payments. For example, we calculated Medicare Part D spending as the sum of the Medicare net payment and the Low-income Subsidy (LIS) amount, which reduces the out-of-pocket obligations of qualifying beneficiaries. Patient obligations (out-of-pocket costs) were defined as the sum of the deductible and co-payment.

Medicare Part D Coverage Plans

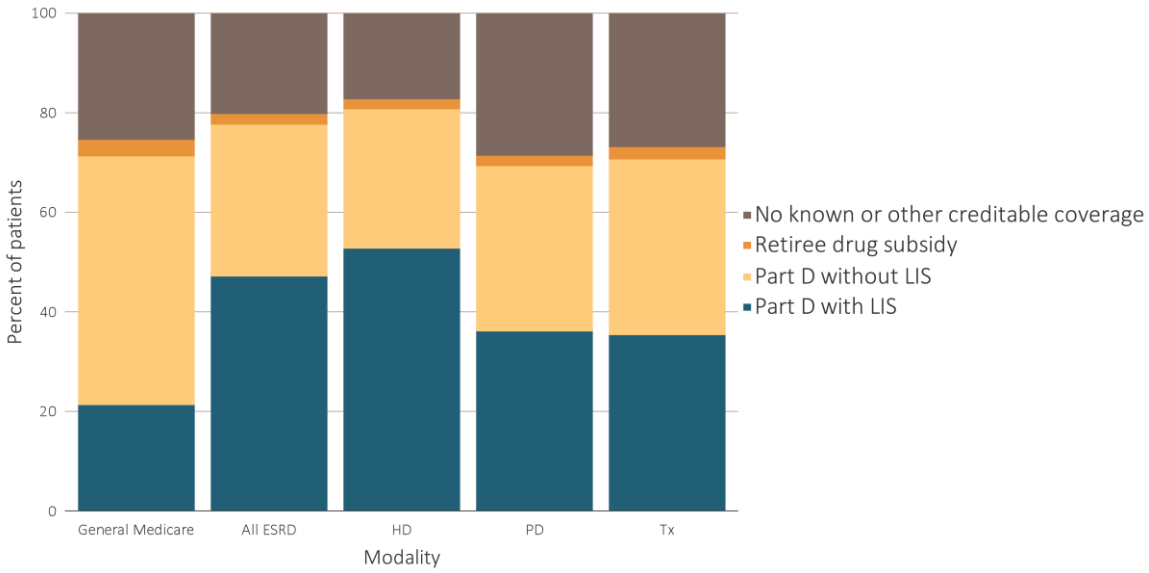
After more than a decade of availability, the Medicare Part D prescription drug benefit has become an integral component of Medicare coverage. Before this program began on January 1, 2006, some Medicare beneficiaries were able to obtain drug coverage through various private insurance plans, state Medicaid 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 (Medicare Advantage prescription drug plan, MA-PD), most obtain Part D benefits through a stand-alone PDP.

Enrollment in Part D is not mandatory. Non-Part D Medicare enrollees may 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 non-participants without an alternative source of coverage pay for their prescriptions out-of-pocket.

In 2016, 71.6% of the general Medicare population enrolled in a Medicare Part D prescription drug plan. Medicare-covered beneficiaries with ESRD exceeded the Part D enrollment rate of the general Medicare population, with 78.0% participation. The differences in benefit use between the ESRD and general Medicare cohorts extended to other areas. About 60.9% of Medicare beneficiaries with ESRD who enrolled in Part D received the LIS benefit, compared to only 30.2% of the general Medicare Part D population (Figure 10.1).

Other factors varied by renal replacement modality—81.1% of HD, 69.7% of PD, and 71.0% of kidney transplant patients enrolled in Part D (Figure 10.1). By modality, 65.5%, 52.3%, and 50.3% of enrolled HD, PD, and transplant patients qualified for the LIS.

vol 2 Figure 10.1 Sources of prescription drug coverage in Medicare ESRD enrollees, by population, 2016



Data source: 2016 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2016. 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.

The share of beneficiaries with ESRD who enrolled in Part D increased annually between 2011 and 2016 (Table 10.1). Total enrollment was higher in the dialysis population than in the general Medicare population, but the growth between 2011 and 2016 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 10.1 Percentage of general Medicare & ESRD patients enrolled in Part D

Year	General Medicare (%)	All ESRD (%)	Hemodialysis (%)	Peritoneal dialysis (%)	Transplant (%)
2011	60.1	69.3	73.3	61.2	59.0
2012	61.8	71.3	75.2	63.5	61.4
2013	67.2	75.2	78.9	67.2	66.0
2014	69.1	76.5	79.9	68.6	68.2
2015	70.4	77.3	80.6	69.2	69.7
2016	71.6	78.0	81.1	69.7	71.0

Data source: 2016 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2016. 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.

The Centers for Medicare & Medicaid Services (CMS) provides participating PDPs with guidance on structuring a "standard" Part D PDP. The upper portion of Table 10.2 illustrates the standard benefit design for PDPs in 2011 and 2016. In 2016, for example, beneficiaries shared costs with the PDP through co-insurance or co-payments until the combined total during the initial coverage period reached $3,310. After reaching this threshold, beneficiaries entered a coverage gap, or "donut hole," where they were then required to pay 100% of their prescription costs.

Under the Affordable Care Act, in each year since 2010 the U.S. government has been providing increasing assistance to those reaching this coverage gap. In 2016, beneficiaries received a 50% discount on brand name drugs from manufacturers plus 5% coverage from their Part D plans; plans also paid 42% of generic drug costs in the gap (Q1 Medicare, 2016). Beneficiaries who reached annual out-of-pocket drug costs of $4,850 entered the catastrophic coverage phase, in which they then paid only a small co-payment for any additional prescriptions until the end of that year (Table 10.2).

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 co-payments instead of the 25% co-insurance, and some plans provide generic and/or brand name drug coverage during the coverage gap (Table 10.2; Q1 Medicare, 2016).

vol 2 Table 10.2 Medicare Part D parameters for defined standard benefit, 2011 & 2016

	2011	2016
Deductible After the deductible is met, the beneficiary pays 25% of total prescription costs up to the initial coverage limit.	$310	$360
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	$2,840	$3,310
Out-of-pocket threshold The total out-of-pocket costs including the "donut hole"	$4,550	$4,850
Total covered Part D prescription out-of-pocket spending Catastrophic coverage begins after this point (including the coverage gap) *	$6,448	$7,063
Generic/preferred multi-source drug	$2.50	$2.95
Other drugs	$6.30	$7.40
2016 Example:		
$360 (deductible)$320 (deductible)	$310	$360
+(($3,310-$360)*25%)(initial coverage) +(($2,960-$320)*25%)(initial coverage)	$633	$738
+(($7,063-$3,310)*100%)(coverage gap)+(($6,680-$2,960)*100%)(coverage gap)	$3,608	$3,753
Total (maximum out-of-pocket costs prior to catastrophic coverage, excluding plan premium)	$4,550	$4,850

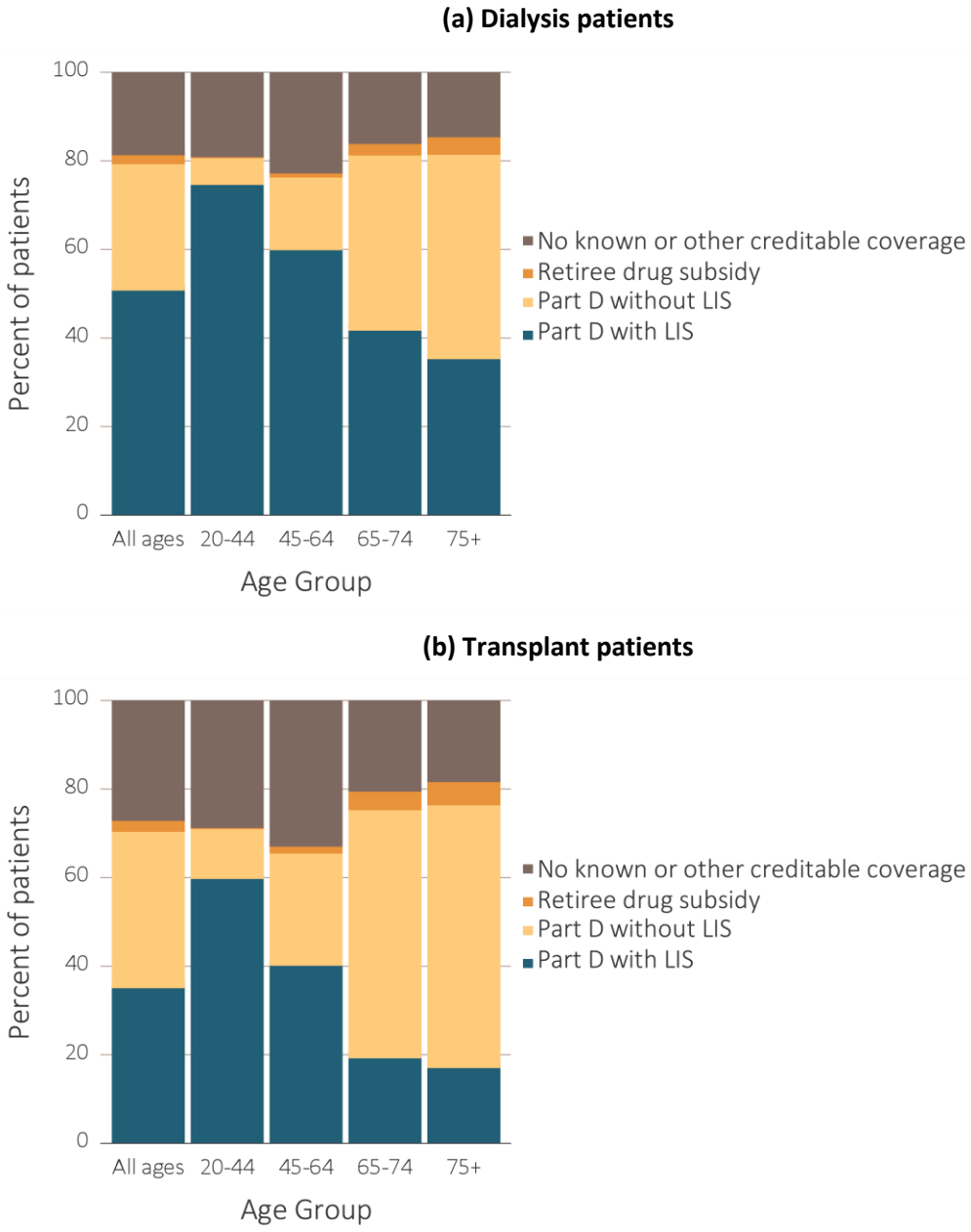
Data Source: Table adapted from http://www.q1medicare.com/PartD-The-2016-Medicare-Part-D-Outlook.php. **The catastrophic coverage amount is the greater of 5% of medication cost or the values shown in the chart above. In 2016, beneficiaries were charged $2.95 for those generic or preferred multisource drugs with a retail price less than $59 and 5% for those with a retail price over $59. For brand name drugs, beneficiaries paid $7.40 for those drugs with a retail price less than $148 and 5% for those with a retail price over $148. In 2016, beneficiaries received a 50% discount on brand name drugs from manufacturers plus 5% coverage from their Part D plans; plans also paid 42% of generic drug costs in the gap. Abbreviation: Part D, Medicare prescription drug coverage benefit.*

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 HD (e.g. intravenous (IV) 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 (ESAs), 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 spending for these medications is displayed in ESRD Reference Table K.1, but the cost of the bundled drugs are not broken out from the outpatient dialysis spending category.

Medicare Part D Enrollment Patterns

Beneficiaries with ESRD obtain prescription drug coverage from a variety of sources, and these vary widely by the beneficiary's age (Figure 10.2). Receipt of the LIS decreased substantially with age in both populations. In each age category, transplant patients were markedly less likely than those on dialysis to receive the LIS benefit.

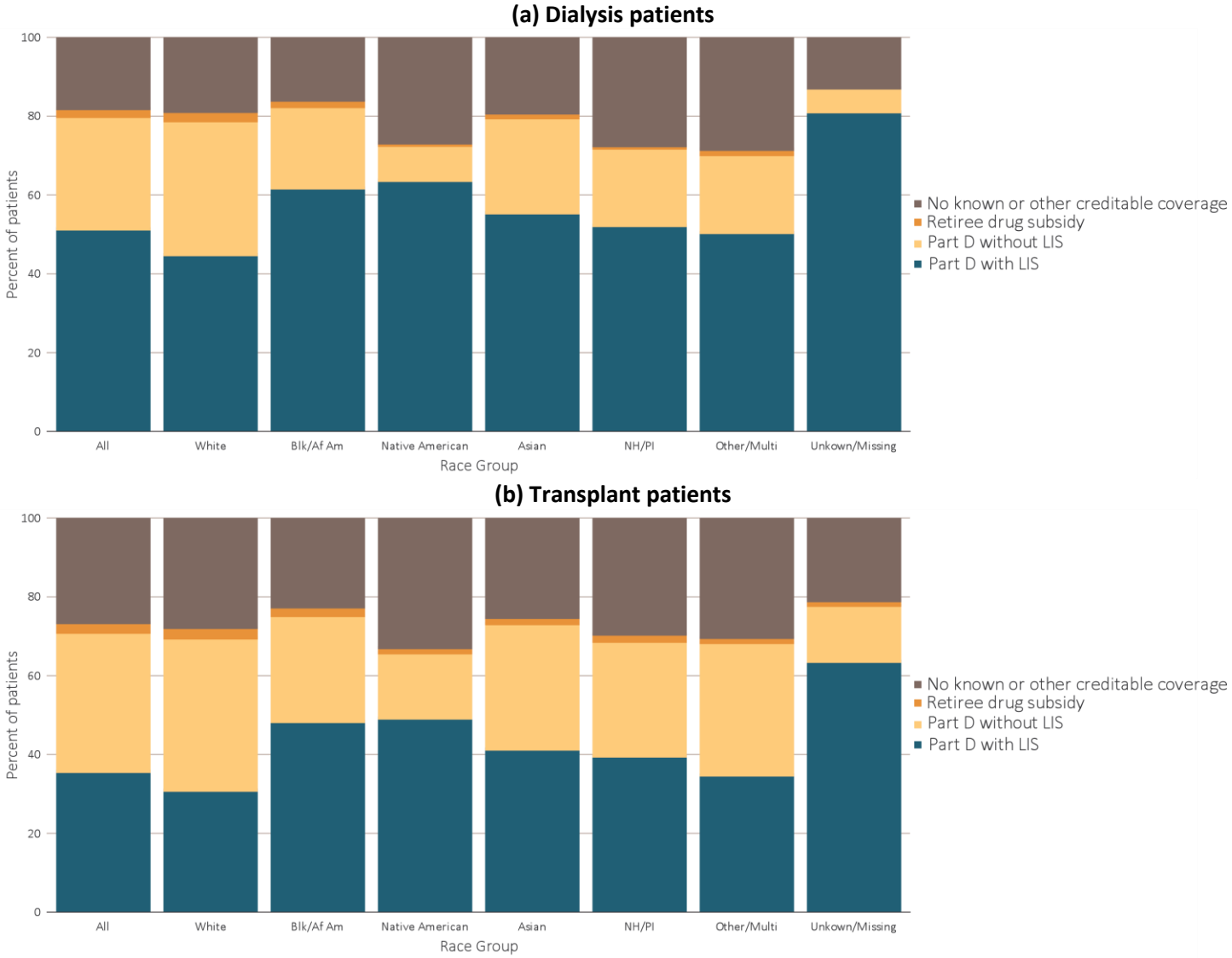
vol 2 Figure 10.2 Sources of prescription drug coverage in Medicare ESRD enrollees, by age & modality, 2016



Data source: 2016 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2016. Abbreviations: ESRD, end-stage renal disease; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage. ESRD patients aged under 20 were not presented. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage; LIS, Low-income Subsidy.

Overall, 79.9% of dialysis patients were enrolled in Part D. A higher percentage of dialysis patients who identified as Black/African American enrolled in Part D (82.4%) compared to those who identified as White (78.9%), Native American/Alaska Native (72.6%), or Asian (79.6%). About 71.0% of transplant patients enrolled in Part D. By race, 69.6% of White, 75.3% of Black, 65.8% of Native American/Alaska Native, and 73.2% of Asian transplant patients enrolled. A larger share of dialysis patients with Part D coverage had the LIS (64.3%), compared to 50.3% of transplant patients (Figure 10.3).

vol 2 Figure 10.3 Sources of prescription drug coverage in Medicare ESRD enrollees, by race/ethnicity & modality, 2016



Data source: 2016 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2016. 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.

Table 10.3 reports the percentage of general Medicare and ESRD enrollees who were eligible for the LIS, stratified by age and race. Please note that the numbers of Native American/Alaska Native, Hawaiian Native/Pacific Islander, Other/multiple race, and Unknown/missing race beneficiaries in each age category are comparatively small.

vol 2 Table 10.3 Percentage of Medicare Part D enrollees with the Low-income Subsidy, by age & race, 2016

	General Medicare (%)	All ESRD (%)	Hemodialysis (%)	Peritoneal dialysis (%)	Transplant (%)
All	30.2	60.9	65.5	52.3	50.3
White					
All ages	23.6	53.4	58.2	45.6	44.5
20-44	88.5	88.3	91.7	88.3	82.5
45-64	51.7	70.8	76.6	64.1	57.5
65-74	14.4	39.0	48.1	23.4	20.9
75+	17.8	33.3	37.0	16.6	17.8
Black/African American					
All ages	56.3	73.3	75.4	68.9	64.3
20-44	93.0	92.7	94.2	91.2	88.1
45-64	74.9	80.9	83.4	74.1	70.5
65-74	41.2	58.2	62.5	40.4	39.2
75+	47.2	57.6	59.7	36.0	37.5
Native American/Alaska Native					
All ages	67.1	85.3	88.1	82.4	74.8
20-44	93.8	95.2	97.1	95.8	86.1
45-64	81.3	90.0	91.4	89.3	84.8
65-74	54.3	75.0	81.0	46.5	56.2
75+	55.6	74.7	78.8	64.3	56.5
Asian					
All ages	61.8	66.6	71.9	54.1	56.5
20-44	90.7	87.5	91.0	85.7	83.2
45-64	65.1	72.4	77.6	59.2	65.0
65-74	52.5	56.9	65.4	39.4	42.8
75+	69.9	64.7	69.1	47.5	41.8
Hawaiian Native/Pacific Islander					
All ages	NA	70.6	73.9	60.5	57.6
20-44	NA	90.2	91.5	89.7	85.6
45-64	NA	78.5	82.0	63.6	63.3
65-74	NA	57.4	62.0	39.7	44.7
75+	NA	60.5	63.6	53.2	36.6
Other/multiple race					
All ages	29.9	61.5	72.5	65.4	50.9
20-44	86.9	85.2	93.4	94.1	76.8
45-64	47.2	68.4	82.9	78.6	53.3
65-74	20.9	47.5	60.8	31.6	38.4
75+	32.2	45.9	53.5	22.2	36.4
Unknown/missing					
All ages	28.9	86.9	94.0	81.5	81.7
20-44	91.6	94.8	97.7	100.0	96.7
45-64	28.9	87.7	92.8	72.7	80.3
65-74	18.9	71.5	89.5	50.0	66.1
75+	83.1	93.8	100.0	NA	100.0

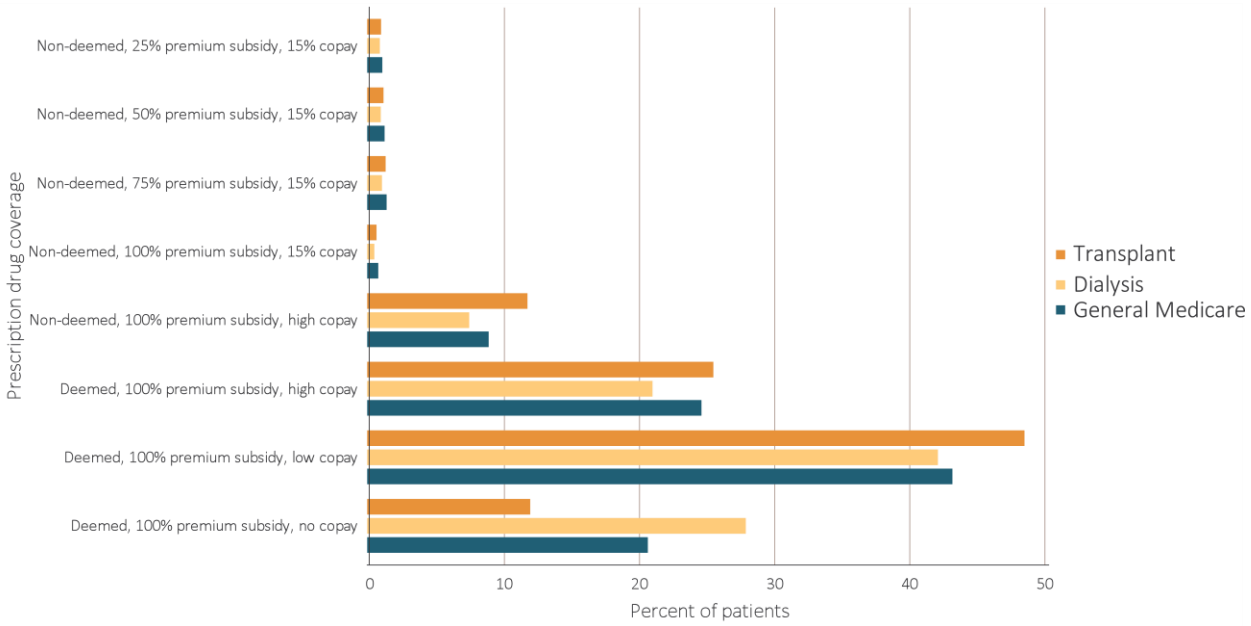
Data source: 2016 Medicare data, point prevalent Medicare enrollees alive on January 1, 2016. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage. ESRD patients aged under 20 were not presented.

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 co-payments, 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 Social Security income, and those participating in Medicare savings programs (e.g., Qualified Medicare Beneficiaries and Qualified Individuals). 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 2016, 90.4% of dialysis patients with Part D LIS coverage were deemed LIS beneficiaries, compared to 85.4% of transplant, and 87.9% of general Medicare beneficiaries (Figure 10.4).

vol 2 Figure 10.4 Distribution of Low-income Subsidy categories in Part D general Medicare & ESRD patients, 2016



Data source: 2016 Medicare data, point prevalent Medicare enrollees alive on January 1, 2016. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage.

Insurance Spending for Prescriptions

In recent years, Medicare Part D spending for beneficiaries with ESRD increased by 1.1 times from $1.8 billion in 2011 to $3.7 billion in 2016 (Table 10.4). These amounts did 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). Medicare spending on outpatient dialysis, which included medications covered by the ESRD bundle, is presented in USRDS ESRD *Reference Table K.1*. Medicare Part D spending in 2016 was 2.1, 2.5, and 1.9 times as great as in 2011 for HD, PD, and kidney transplant patients. These rates of increase far outpaced the 50% spending growth that occurred in

the general Medicare population. The increase of overall Medicare Part D spending for ESRD patients arose from the increase in the prevalence of ESRD and from the increase in Medicare part D spending per capita. However, the per capita increases were much greater for ESRD than for Medicare in general. The $3,122 per capita for general Medicare was 16% greater than the $2,691 per capita in 2011. However, for ESRD patients, the per capita increases ranged from 51% for transplant patients ($5,348 and $8,089) to 78% for hemodialysis patients ($8,080and $14,383). The reasons for this disparity in drug cost growth are unexplained.

vol 2 Table 10.4 Estimated Medicare Part D spending for enrollees, 2011-2016

	General Medicare		All ESRD		Hemodialysis		Peritoneal Dialysis		Transplant	
Year	Medicare spending (in billions)	Medicare spending (PPPY)	Medicare spending (in billions)	Medicare spending (PPPY)	Medicare spending (in billions)	Medicare spending (PPPY)	Medicare spending (in billions)	Medicare spending (PPPY)	Medicare spending (in billions)	Medicare spending (PPPY)
2011	$46.0	$2,691	$1.8	$7,417	$1.4	$8,080	$0.1	$8,006	$0.3	$5,348
2012	$40.1	$2,594	$2.0	$7,873	$1.6	$8,647	$0.1	$8,433	$0.3	$5,522
2013	$52.1	$2,586	$2.3	$8,316	$1.8	$9,155	$0.1	$8,665	$0.3	$5,881
2014	$58.1	$2,831	$2.7	$9,601	$2.1	$10,464	$0.2	$9,669	$0.4	$7,274
2015	$63.4	$3,027	$3.2	$11,387	$2.5	$12,583	$0.2	$11,826	$0.5	$8,057
2016	$68.8	$3,122	$3.7	$12,740	$2.9	$14,383	$0.2	$13,082	$0.5	$8,089

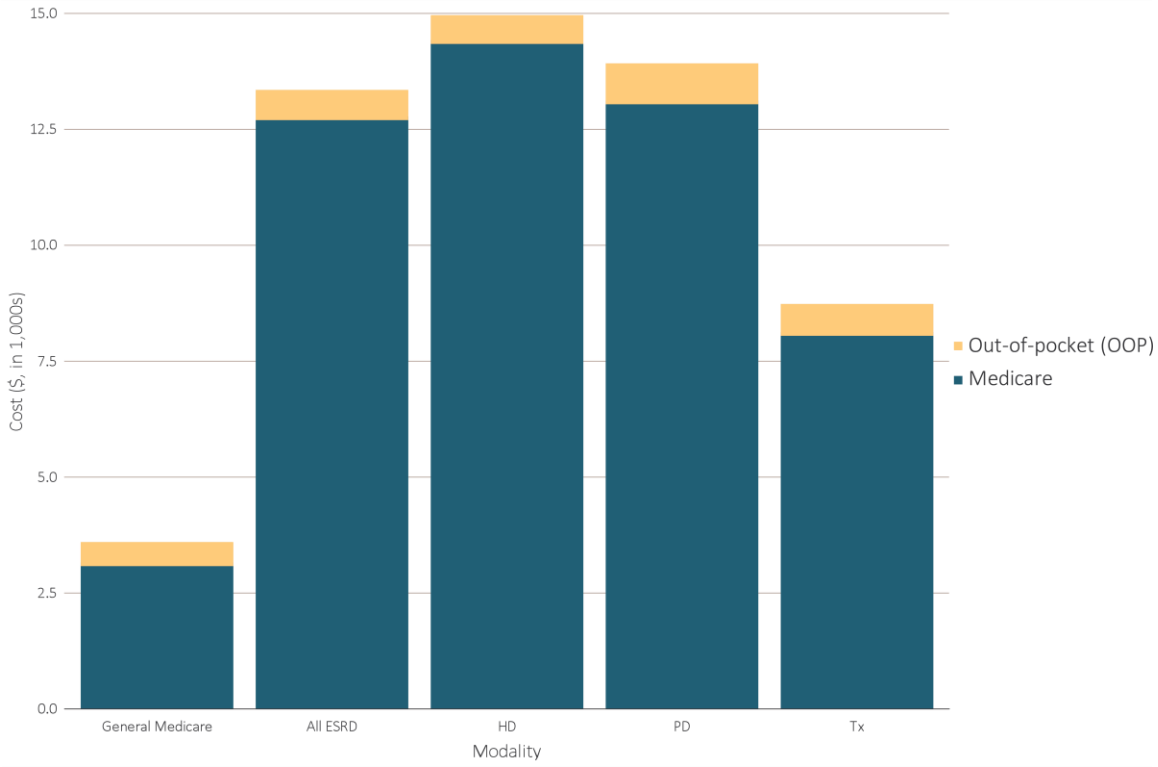
Data source: 2011-2016 Medicare data, period prevalent Medicare enrollees alive on January 1, excluding those in Medicare Advantage Part D plans and Medicare secondary payer, using as-treated actuarial model (see ESRD Methods chapter for analytical methods). Part D spending represents the sum of the Medicare covered amount and the Low-income Subsidy amount. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage; PPPY, per person per year.

Per patient per year Medicare Part D spending was 4.1 times greater for beneficiaries with ESRD than for general beneficiaries in the Medicare population. As a proportion of total prescription spending, however, out-of-pocket costs were lower for beneficiaries with ESRD than all general beneficiaries (4.3% vs. 12.3%). However, since total prescription spending was so much higher for beneficiaries with ESRD, out-of-pocket spending was still higher for beneficiaries with ESRD than the general population. By modality, total prescription spending was higher for dialysis patients than transplant patients in those covered by stand-alone Part D plans (HD,$14,922; PD, $13,882; transplant, $8,693; Figure 10.5.a).

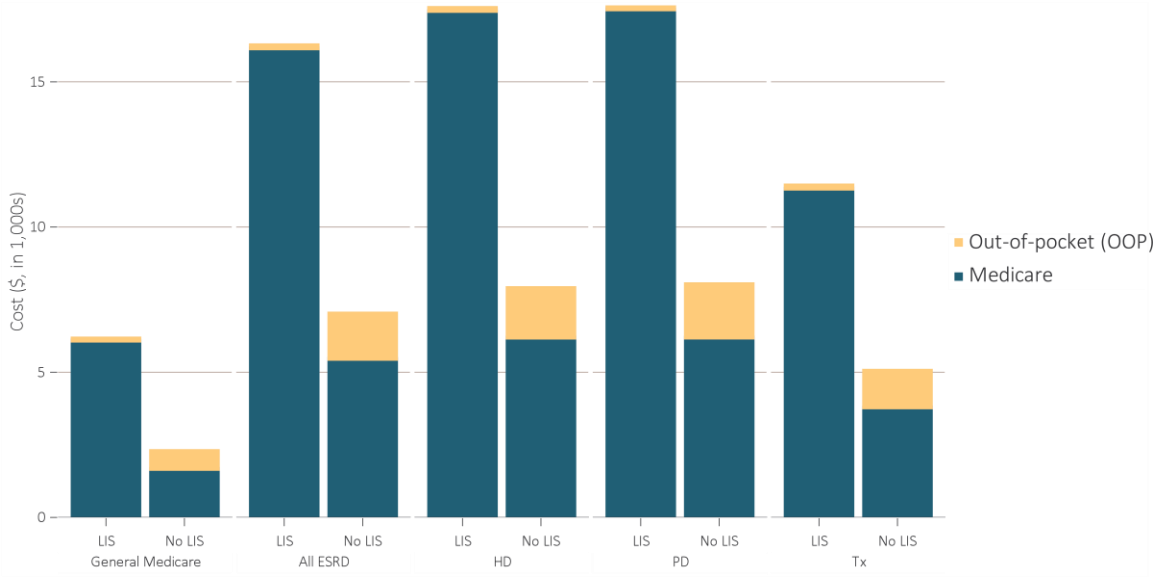
Across general Medicare and ESRD populations, PPPY Medicare Part D spending was 2.8-3.6 times greater for beneficiaries with LIS benefits than for those without. In the LIS population, however, out-of-pocket costs represented only 0.6-1.2% of total prescription spending, compared to 21.6-26.9% among general Medicare and ESRD beneficiaries who did not receive the subsidy. PPPY Medicare Part D spending was 2.7 and 3.3 times greater for those with ESRD than for general Medicare beneficiaries in the LIS and non-LIS populations (Figure 10.5.b).

vol 2 Figure 10.5 Per person per year Medicare Part D spending & out-of-pocket costs for enrollees, 2016

(a) Medicare



(b) Medicare by Low-income Subsidy status



Data source: Medicare Part D claims for Part D enrollees with traditional Medicare (Parts A & B). Costs are per person per year for calendar year 2016, using as-treated actuarial model (see ESRD Methods chapter for analytical methods). Medicare Part D spending represents the sum of the Medicare covered amount and the Low-income Subsidy amount. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage.

Total PPPY insurance spending for prescriptions (excluding patient obligations) varied by coverage, age, sex, and race (Table 10.5). Overall, Medicare Part D spending for beneficiaries with ESRD was higher than in the general population. For both the general and ESRD cohorts, PPPY Medicare Part D spending was highest in Medicare Part D with LIS ($6,087 and $16,153). Generally, younger beneficiaries aged 20-44 or 45-64 years, had higher costs than older patients. Medicare Part D spending varied only modestly by sex.

vol 2 Table 10.5 Per person per year Medicare Part D spending for enrollees, 2016

	General ($)		All ESRD ($)		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	6,087	1,670	16,153	5,460	17,440	6,191	17,495	6,192	11,321	3,788
20-44	6,134	2,745	16,410	4,899	18,782	6,341	18,069	5,650	10,413	3,191
45-64	8,028	2,895	17,484	6,364	18,943	7,406	18,080	6,452	11,856	4,239
65-74	5,212	1,585	14,807	5,674	15,700	6,606	15,241	6,622	11,163	3,893
75+	4,497	1,558	12,095	4,413	12,759	4,808	12,079	5,236	8,146	2,784
Sex										
Male	6,161	1,819	16,452	5,519	17,751	6,156	18,541	6,419	11,833	4,027
Female	6,035	1,560	15,811	5,370	17,091	6,246	16,562	5,849	10,639	3,429
Race										
White	6,214	1,650	15,624	5,320	17,167	6,140	17,672	6,312	10,861	3,667
Black/African American	6,415	2,062	17,068	5,949	17,985	6,338	17,098	5,504	12,492	4,459
Native American/Alaska Native	5,082	3,071	10,539	5,050	10,771	5,677	13,301	4,464	8,969	2,999
Asian	5,137	1,283	15,767	5,457	17,277	6,294	19,176	6,809	10,491	3,709
Native Hawaiian/Pacific-Islander	NA	NA	16,751	4,524	17,739	4,949	17,168	5,372	10,981	3,219
Other race	5,345	1,601	14,552	4,552	16,145	7,059	16,651	5,468	11,564	3,011
Unknown/missing	4,730	1,579	16,472	6,723	19,646	9,259	23,122	13,923	9,618	5,954

Data source: Medicare Part D claims. Costs are per person per year for calendar year 2016, using as-treated actuarial 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. Abbreviations: ESRD, end-stage renal disease; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage.

Prescription Drug Classes

In this section, we rank the top 15 drug classes used by ESRD patients based on the percentage of beneficiaries with at least one claim for a drug within the class during 2016. ESRD patients were most frequently prescribed ion-removing agents, β-adrenergic blocking agents (beta blockers), antibacterials, analgesics, and lipid-lowering agents (Table 10.6).

vol 2 Table 10.6 Top 15 drug classes received by ESRD cohorts, by modality, 2016

	Hemodialysis		Peritoneal dialysis		Transplant	
Rank	**Drug class**	**%**	**Drug class**	**%**	**Drug class**	**%**
1	Ion-removing agents	71.5	Ion-removing agents	61.9	Antibacterials	73.9
2	B-Adrenergic blocking agents	64.1	B-Adrenergic blocking agents	61.5	β-Adrenergic blocking agents	63.0
3	Antibacterials	57.9	Antibacterials	58.7	Antiulcer agents and acid suppressants	58.8
4	Analgesics and antipyretics	57.3	Lipid-lowering agents	48.5	Lipid-lowering agents	56.8
5	Lipid-lowering agents	51.0	Calcium-channel blocking agents	48.1	Calcium-channel blocking agents	50.7
6	Calcium-channel blocking agents	48.2	Analgesics and antipyretics	46.4	Analgesics and antipyretics	48.2
7	Renin-angiotensin-aldosterone system inhibitors	46.3	Renin-angiotensin-aldosterone system inhibitors	44.1	Adrenals	47.1
8	Antiulcer agents and acid suppressants	37.9	Antiulcer agents and acid suppressants	39.8	Antidiabetic agents	39.0
9	Antidiabetic agents	36.9	Diuretics	35.5	Renin-angiotensin-aldosterone system inhibitors	35.7
10	Anticonvulsants	32.7	Antidiabetic agents	33.6	Diuretics	33.3
11	Hypotensive agents	32.4	Anti-infectives	32.9	Psychotherapeutic agents	25.2
12	Psychotherapeutic agents	32.2	Psychotherapeutic agents	28.2	Diabetic consumables	24.6
13	Cinacalcet	31.9	Hypotensive agents	27.4	Antivirals	24.4
14	Antithrombotic agents	31.0	Cinacalcet	26.7	Anticonvulsants	22.7
15	Anxiolytics, sedatives, and hypnotics	25.1	Anticonvulsants	25.0	Antithrombotic agents	20.2

Data source: Medicare Part D claims. Ion-removing agents include phosphate-binding agents, potassium-binding agents, etc. Hypotension agents include alpha-2-agonist and vasodilators. Diabetic consumables refer to blood glucose test strips, blood glucose meters/sensors, lancets, needles, pen needles, etc. Abbreviations: ESRD, end-stage renal disease; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage.

The highest costing medications for ESRD patients were ion-removing agents, cinacalcet, antidiabetic agents, antivirals, and immunosuppressive agents (Table 10.7). Ion-removing agents incurred the greatest costs for dialysis patients, at about 40% of overall Medicare Part D spending. Antivirals ranked highest in cost for transplant patients with Medicare Part D.

vol 2 Table 10.7 Top 15 drug classes received by different ESRD cohorts, by modality and Medicare Part D spending, 2016

	Hemodialysis			Peritoneal Dialysis			Transplant		
Rank	Drug class	Spending (in millions)	%	Drug class	Spending (in millions)	%	Drug class	Spending (in millions)	%
1	Ion-removing agents	$1,145.3	39.8	Ion-removing agents	$94.3	41.3	Antivirals	$124.7	26.5
2	Cinacalcet	$701.3	24.4	Cinacalcet	$51.7	22.6	Antidiabetic Agents	$86.1	18.3
3	Antidiabetic agents	$214.1	7.4	Antidiabetic agents	$23.0	10.1	Cinacalcet	$56.0	11.9
4	Antivirals	$183.5	6.4	Antivirals	$14.6	6.4	Immunosuppressive Agents	$22.3	4.7
5	Antineoplastic agents	$71.9	2.5	Antineoplastic agents	$5.6	2.5	Adrenocortical Insufficiency	$12.2	2.6
6	Vasodilating agents	$34.0	1.2	Antilipemic agents	$3.1	1.4	Antilipemic Agents	$11.8	2.5
7	Caloric agents	$32.1	1.1	Antiulcer agents and acid suppressants	$2.1	0.9	Antiulcer Agents and Acid Suppressants	$10.1	2.1
8	Antilipemic agents	$31.5	1.1	Antibacterials	$1.8	0.8	Serums	$9.5	2.0
9	Analgesics and antipyretics	$30.8	1.1	Vasodilating agents	$1.7	0.8	Antineoplastic Agents	$8.5	1.8
10	Antiulcer agents and acid Suppressants	$29.4	1.0	Analgesics and antipyretics	$1.6	0.7	Hematopoietic Agents	$8.0	1.7
11	Anticonvulsants	$29.2	1.0	Anticonvulsants	$1.6	0.7	Antibacterials	$7.8	1.7
12	Antibacterials	$26.1	0.9	Antithrombotic agents	$1.4	0.6	Anticonvulsants	$7.0	1.5
13	Anti-inflammatory agents	$23.5	0.8	Pituitary	$1.3	0.6	Antithrombotic Agents	$6.5	1.4
14	Antithrombotic agents	$22.5	0.8	Disease-modifying antirheumatic agents	$1.2	0.5	Analgesics and Antipyretics	$6.0	1.3
15	Psychotherapeutic agents	$21.8	0.8	Anti-inflammatory agents	$1.2	0.5	Psychotherapeutic Agents	$5.8	1.2

Data source: Medicare Part D claims. Medicare Part D spending represents the sum of the Medicare covered amount and the Low-income Subsidy amount. Ion-removing agents include phosphate-binding agents, potassium-binding agents, etc. Hypotension agents include alpha-2-agonists and vasodilators. Diabetic consumables refer to blood glucose test strips, blood glucose meters/sensors, lancets, needles, pen needles, etc. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage.

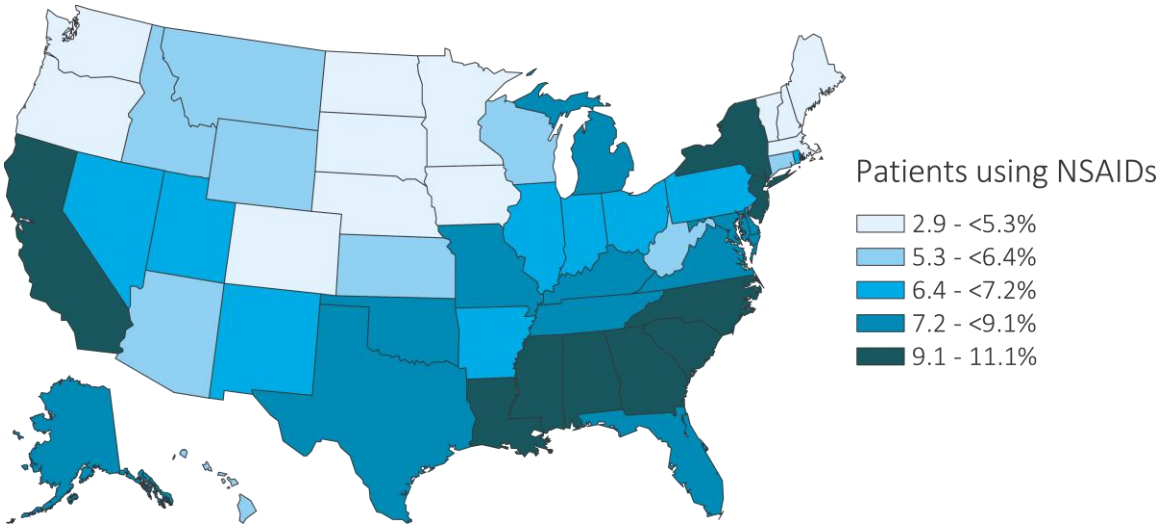
Medications for Pain Management

Pain is a common symptom experienced by patients with ESRD (Murtagh et al, 2007). In this section, we examine two main drug classes used for pain management—nonsteroidal anti-inflammatory agents (NSAIDs) and opioid analgesics. The former are often obtained over the counter, therefore, any estimates based on prescription claims alone likely significantly underestimate their use. Each of these classes of agents has unique adverse effects that occur at a higher frequency among ESRD patients than the general population (e.g., gastrointestinal bleeding, respiratory depression; Pham et al., 2009). Figures 10.6 and 10.7 display the state-specific proportions of ESRD Medicare Part D patients prescribed NSAIDs and opioid analgesics in 2016.

The overall national proportion of prescription NSAID use in ESRD patients was 8.3%. California, southern states, and the District of Columbia demonstrated the highest use. These rates are almost certainly an underestimate of actual use, however, as NSAIDs are more commonly purchased on a non-prescription, over-the-counter basis.

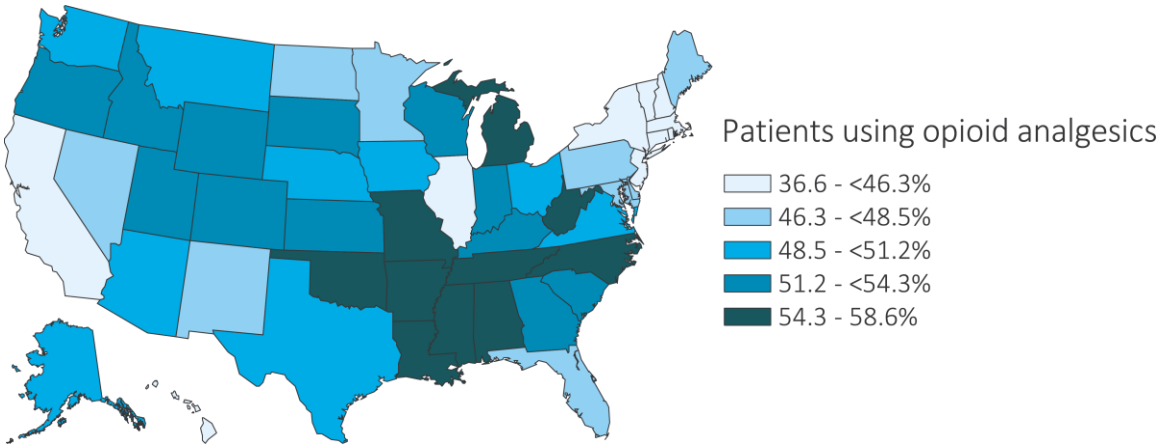
The proportion of patients using opioid analgesics was very high, at 49.0%. Use was greatest in the south central region (Alabama, Louisiana, Oklahoma, and Mississippi). These state differences could reflect varying prevalence of coexisting conditions, pain management practices, and preferences by state.

vol 2 Figure 10.6 Estimated utilization rate of prescription NSAIDs by state, Medicare ESRD patients, 2016



Data source: Medicare Part D claims. ESRD patients with Medicare Part D stand-alone prescription drug plans. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage; NSAIDs, nonsteroidal anti-inflammatory agents. NSAID filled under Medicare Part D represent a fraction of actual NSAID use.

vol 2 Figure 10.7 Estimated utilization rate of opioid analgesics by state, Medicare ESRD Patients, 2016



Data source: Medicare Part D claims. ESRD patients with Medicare Part D stand-alone prescription drug plans. Abbreviation: ESRD, end-stage renal disease.

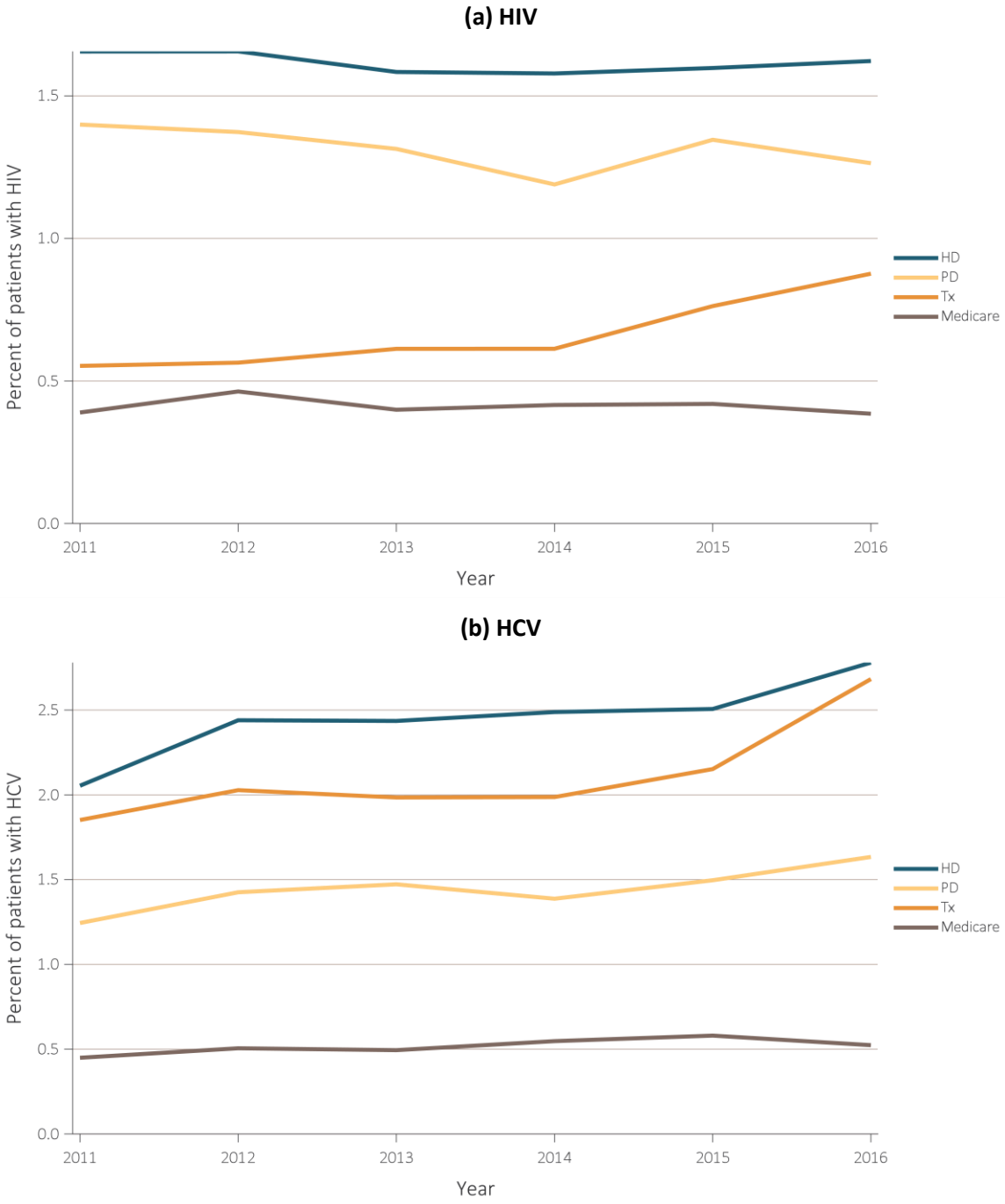
Antiviral Medications

ESRD patients are more vulnerable to viral infections than the general population (Figure 10.8). For example, the prevalence of the human immunodeficiency virus (HIV) is stable in dialysis patients, but increased considerably in transplant patients from 2011-2016 (Figure 10.8.a). The prevalence of hepatitis C (HCV) gradually increased in all ESRD modalities since 2011, and was highest in hemodialysis patients, followed by transplant patients and peritoneal dialysis patients (Figure 10.8.b). In this section, we examine use of prescribed antiviral medications in Medicare Part D enrollees and particularly assess three main drug classes used for antiviral management — prescription antiretrovirals, nucleosides and nucleotides, and protease inhibitors. These classes of agents are prescribed solely or in combination with others to treat HIV, herpes virus infections, HCV, and hepatitis B.

Figure 10.9 displays the proportions of Medicare Part D enrollees prescribed antivirals in 2011-2016. The proportion using antivirals was relatively stable in ESRD patients over the past six years, regardless of renal replacement therapy modality. In 2016, use was significantly higher in transplant patients compared to HD, PD, and the general population (24.1% versus 5.8%, 5.6%, and 4.9%).

Figure 10.10 displays the PPPY Medicare Part D spending on antivirals by ESRD modality from 2011 to 2016. There was a notable increase in PPPY Medicare Part D spending on antivirals in transplant patients, from $1,063 to a peak of $2,945 in 2014, with a sharp decline to $2,104 in 2016. Unlike transplant patients, Medicare Part D spending gradually increased in HD and PD patients, from $315 and $298 in 2011 to $918 and $844 in 2016, respectively. Medicare Part D spending on antivirals was higher in transplant patients than dialysis patients and general Medicare beneficiaries. Spending on protease inhibitors has also increased dramatically since 2013 in general Medicare beneficiaries as well as ESRD patients.

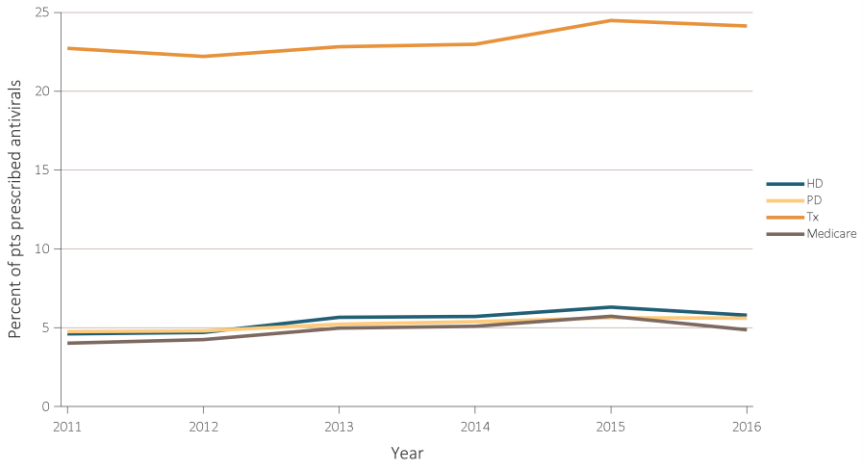
vol 2 Figure 10.8 Estimated prevalence of HIV and HCV in Medicare Part D enrollees, by ESRD modality, 2011-2016



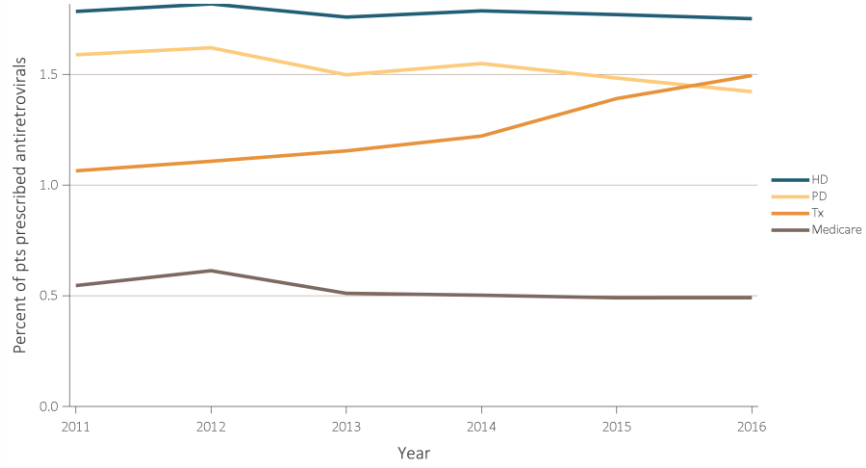
Data source: 2016 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2016. Abbreviations: ESRD, end-stage renal disease; HCV, hepatitis C; HD, hemodialysis; HIV, human immunodeficiency virus; Part D, Medicare Part D prescription drug coverage; PD, peritoneal dialysis; Tx, transplant.

vol 2 Figure 10.9 Estimated utilization rate of prescription antivirals in Medicare Part D enrollees, by ESRD modality, 2011-2016

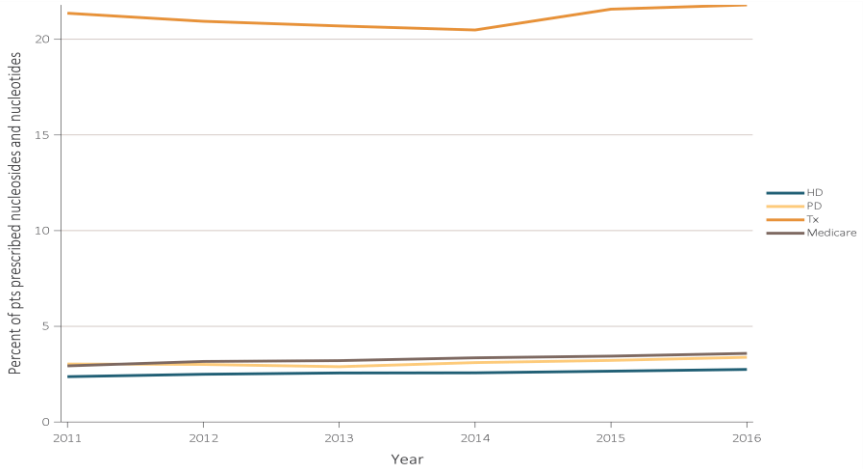
(a) All antivirals



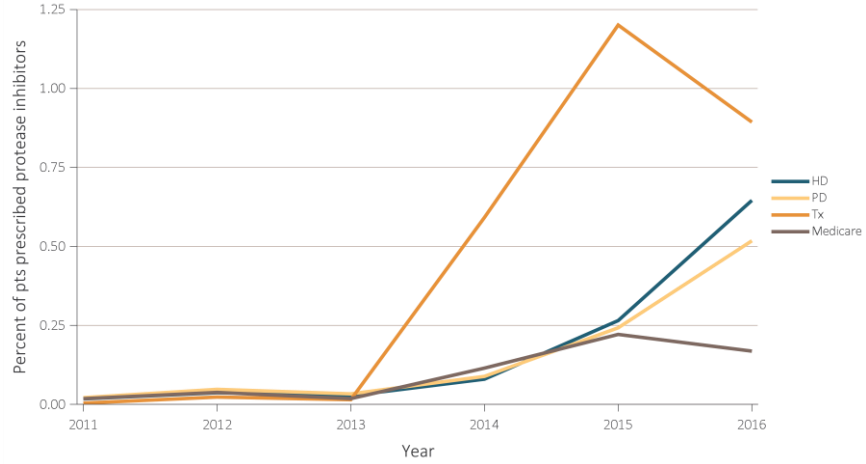
(b) Antiretrovirals



(c) Nucleosides and nucleotides

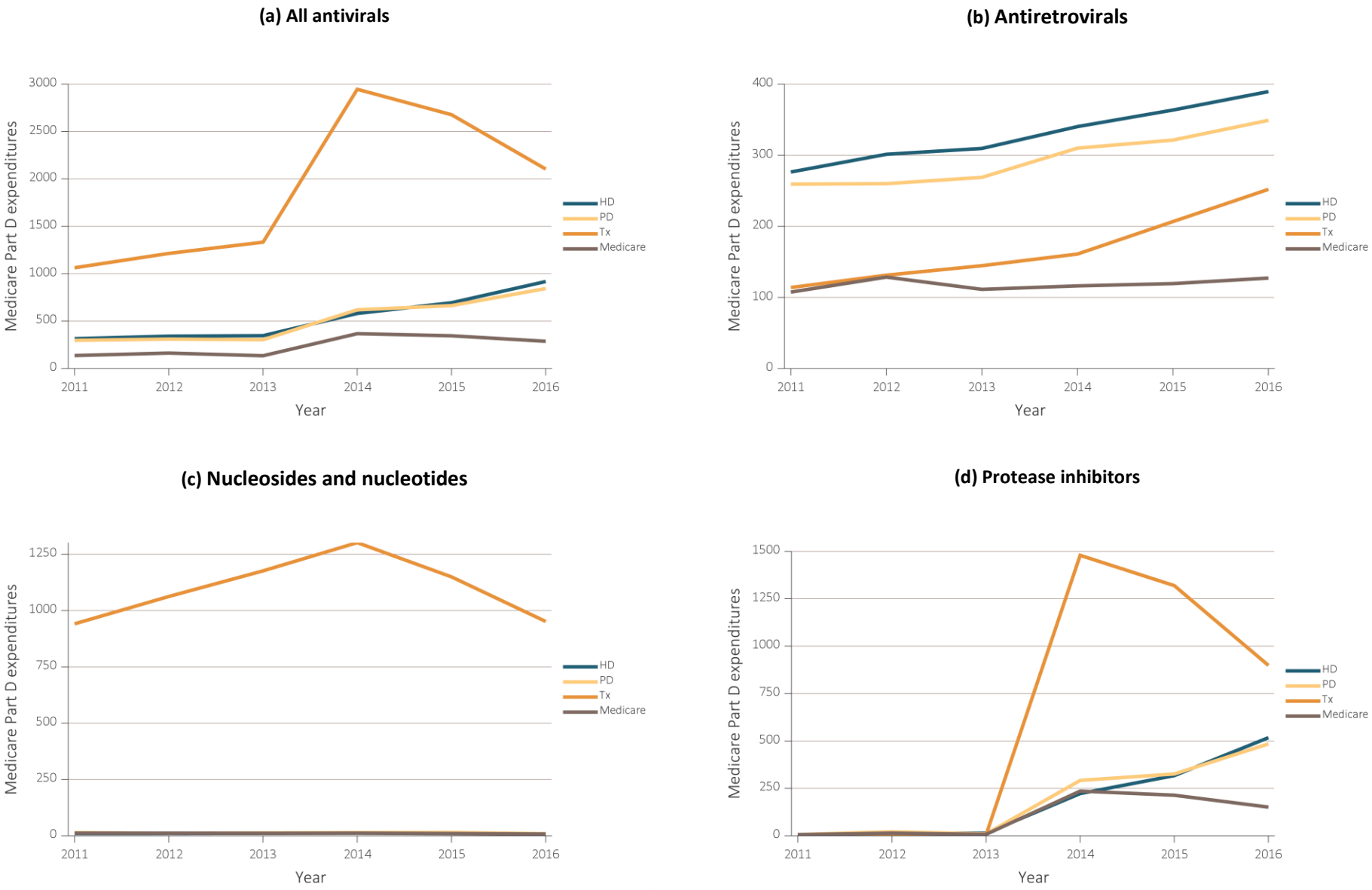


(d) Protease inhibitors



Data source: 2016 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2016. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; Part D, Medicare Part D prescription drug coverage; PD, peritoneal dialysis; Tx, kidney transplant.

vol 2 Figure 10.10 Estimated PPPY Medicare Part D spending of antivirals in Medicare Part D enrollees, by ESRD modality, 2011-2016



Data source: 2016 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2016. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; Part D, Medicare Part D prescription drug coverage; PD, peritoneal dialysis; PPPY, per person per year; Tx, kidney transplant.

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