

Chapter 10:

Prescription Drug Coverage in Patients with ESRD

- In this 2017 Annual Data Report (ADR) we introduce two new chapter features:
 - o To provide a more comprehensive examination of prescription coverage and medication use in endstage renal disease (ESRD) patients, we now add information from the Optum Clinformatics™ DataMart for persons with Medicare Advantage and commercial, managed care coverage.
 - Of the most common drug classes used by ESRD patients, this year we specifically investigate geospatial variation in analgesic use, including prescription nonsteroidal anti-inflammatory agents (NSAIDs) and opioids.
- Among beneficiaries with Medicare Part D enrollment, a higher proportion of those treated with hemodialysis (HD; 65.6%), peritoneal dialysis (PD; 53.2%), and kidney transplant (50.7%) received the Low-income Subsidy (LIS) than did the general Medicare population (30.7%; Figure 10.1).
- In 2015, per patient per year (PPPY) insurance spending on prescriptions for ESRD patients with stand-alone Part D plans was 3.8 times higher than the general Medicare population (\$11,389 vs. \$3,027). Prescription spending was also 3.3 times higher for these patients in Medicare Advantage plans (\$6,139 vs. \$1,836), and 11.8 times higher in managed care plans (\$8,790 vs. \$744; Figure 10.5.a-c).
- Of patients enrolled in stand-alone Part D plans, dialysis patients had a higher PPPY spending on prescriptions than did transplant patients (HD, \$12,589; PD, \$11,828; Transplant, \$8,038). Conversely, dialysis patients had a lower PPPY spending on prescriptions than did transplant patients in Medicare Advantage plans (\$5,596 vs. \$9,181) and managed care coverage (\$7,794 vs. \$10,199; Figure 10.5.a-c).
- In both the general Medicare and ESRD populations, PPPY Part D spending was 2.7-3.7 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 10.5.b). LIS beneficiaries' out-of-pocket costs represented only 0.6-1.3% of total Part D expenditures, compared to 23.3-27.8% in the non-LIS populations (Figure 10.5.d).
- In 2015, ESRD patients were most frequently prescribed ion-removing agents, β -adrenergic blocking agents, antibacterials, analgesics, antipyretics, and lipid-lowering agents (Tables 10.6).
- Ion-removing agents, cinacalcet, antidiabetic agents, antivirals, and immunosuppressive agents had the highest total costs of medications prescribed to ESRD patients (Tables 10.7).
- In the United States (U.S.), 8.3% of ESRD patients used prescription, nonsteroidal anti-inflammatory agents (NSAIDs); geographic rates ranged from 3.1% in Vermont to 11.4% in California (Figure 10.6).
- Approximately 50.3% of Medicare ESRD patients used opioid agonists, ranging from 38.1% in New York to 59.2% in Alabama (Figure 10.7).

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.

In this year's chapter, we add comparable information on prescription drug use and associated costs from the Optum Clinformatics™ database for persons enrolled in Medicare Advantage, and through a large commercial, managed care insurance payer. These data promote a more complete assessment of prescription drug use in ESRD—in 2015, 45% of general Medicare beneficiaries were enrolled in a stand-alone PDP, while 24% received coverage through a Medicare Advantage plan (Kaiser, 2017). Additionally, Optum Clinformatics™ data for beneficiaries with managed care insurance provides insight into a younger and employed population, also enhancing our assessment of this topic.

In the 2016 ADR, we reported the spending and utilization rate of the top 15 drug classes used by ESRD patients. Beginning this year we will also annually select a different drug class for a more detailed investigation of medication use patterns. Given that pain is a common symptom experienced by ESRD patients, we begin with analgesics, focusing on prescription nonsteroidal anti-inflammatory agents (NSAIDs) and opioid analgesics.

A parallel examination of prescription drug use and associated costs in patients with CKD can be found in Volume 1, Chapter 7, <u>Prescription Drug Coverage in Patients with CKD</u>.

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 past 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 now introduce Optum Clinformatics™ data to augment and refine our assessment of prescription utilization and associated costs for both the Medicare Advantage population and a managed care population.

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 percent ESRD population, using the period prevalent, as-treated actuarial model (model 1, described in ESRD Reference Table K).

To create comparable results for beneficiaries selected from Optum Clinformatics[™] data, we applied the same eligibility algorithm as for the Medicare population. Beneficiaries were required to be covered by either a Medicare Advantage plan or managed care insurance on January 1 of the calendar year of interest. Those with Medicare Advantage at the beginning of the year were classified as the Medicare Advantage population; otherwise, they were classified as the commercially insured, managed care population. Dialysis and transplant cohorts were identified by claims-based diagnosis codes; there was insufficient information in the datasets to distinguish HD and PD patients. All of beneficiaries in the Optum Clinformatics[™] dataset had prescription drug coverage.

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. Patients' obligations 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.

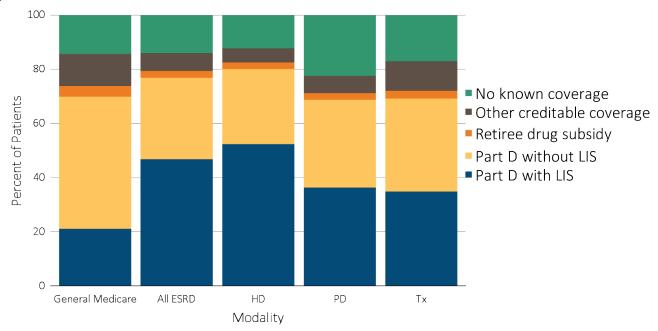
Enrollment in Part D is not mandatory. Non-Part D Medicare enrollees may obtain outpatient medication benefits through other creditable coverage sources that provide benefits equivalent to or better than Part D. These include employer group health plans, retiree health plans, Veterans Administration benefits, and

state kidney programs. Those non-participants without an alternative source of coverage pay for their prescriptions out-of-pocket.

In 2015, 70.4% 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 77.4% participation. The differences in benefit use between the ESRD and general Medicare cohorts extended to other areas. About 61.1% of Medicare beneficiaries with ESRD who enrolled in Part D received the LIS benefit, compared to only 30.7% of the general Medicare Part D population.

Other factors varied by renal replacement modality—80.7% of HD, 69.3% of PD, and 69.7% of kidney transplant patients enrolled in Part D (Figure 10.1). By modality, 65.6%, 53.2%, and 50.7% of enrolled HD, PD, and transplant patients qualified for the LIS. About 13.4% of ESRD beneficiaries had no identified prescription drug coverage, with PD and transplant patients most likely to have unknown coverage (Figure 10.1). Given that more of these patients were employed relative to those receiving HD, it is likely that some had sources of prescription drug coverage not currently tracked by Medicare.

vol 2 Figure 10.1 Sources of prescription drug coverage in Medicare ESRD enrollees, by population, 2015



Data source: 2015 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2015. 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 2015 (Table 10.1). Total enrollment was higher in the dialysis population than in the general Medicare population, but the growth between 2011 and 2015 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

	General Medicare (%)	All ESRD (%)	Hemodialysis (%)	Peritoneal dialysis (%)	Transplant (%)
2011	60.1	69.4	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	68.7	68.2
2015	70.4	77.4	80.7	69.3	69.7

Data source: 2011-2015 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.

The Centers for Medicare and Medicaid Services (CMS) provides participating prescription drug plans (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 2010 and 2015. In 2015, for example, beneficiaries shared costs with the PDP through co-insurance or co-payments until the combined total during the initial coverage period reached \$2,960. 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 2015, beneficiaries received a 50% discount on brand name drugs from manufacturers plus 5%

coverage from their Part D plans; plans also paid 35% of generic drug costs in the gap (Q1 Medicare, 2015). Beneficiaries who reached annual out-of-pocket drug costs of \$4,700 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 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 copayments 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, 2015).

vol 2 Table 10.2 Medicare Part D parameters for defined standard benefit, 2010 & 2015

	2010	2015
Deductible	\$310	\$320
After the deductible is met, the beneficiary pays 25% of total prescription costs up to the initial coverage limit.		
Initial coverage limit	\$2,830	\$2,960
The coverage gap ("donut hole") begins at this point.		
The beneficiary pays 100% of their prescription costs up to the out-of-pocket threshold		
Out-of-pocket threshold	\$4,550	\$4,700
The total out-of-pocket costs including the "donut hole"		
Total covered Part D prescription out-of-pocket spending	\$6,440.00	\$6,680.00
Catastrophic coverage begins after this point (including the coverage gap).		
Catastrophic coverage benefit	\$2.50	*\$2.65
Generic/preferred multi-source drug	\$6.30	*\$6.60
Other drugs		plus a 55% brand-name medication discount
2015 Example:		
\$320 (deductible)	\$310.00	\$320
+((\$2960-\$320)*25%) (initial coverage)	\$630.00	\$660.00
+((\$6680-\$2960)*100%) (coverage gap)	\$3,610.00	\$3,720.00
Total	\$4,550.00	\$4,700.00
(maximum out-of-pocket costs prior to catastrophic coverage, excluding plan premium)		

^{*}The catastrophic coverage amount is the greater of 5% of medication cost or the values shown in the chart above. In 2015, beneficiaries were charged \$2.65 for those generic or preferred multisource drugs with a retail price less than \$53 and 5% for those with a retail price over \$53. For brand name drugs, beneficiaries paid \$6.6 for those drugs with a retail price less than \$132 and 5% for those with a retail price over \$132. Table adapted from http://www.q1medicare.com/PartD-The-2015-Medicare-Part-D-Outlook.php.

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, 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

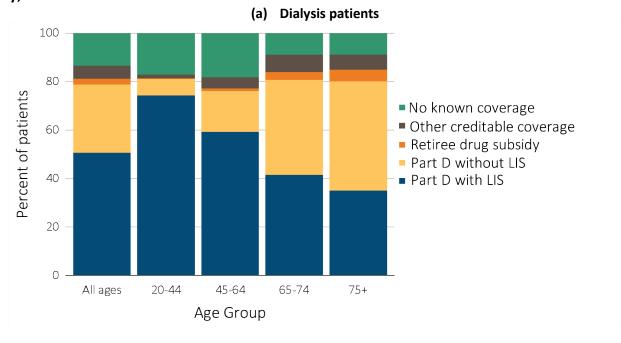
Beneficiaries with ESRD obtain prescription drug coverage from a variety of sources, and these vary

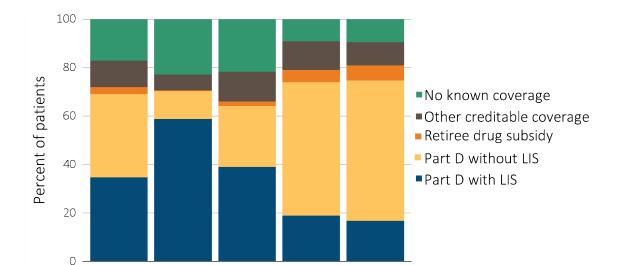
All ages

20-44

widely by the beneficiary's age (Figure 10.2). 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 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, 2015





(b) Transplant patients

Data source: 2015 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2015. 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.

75+

65-74

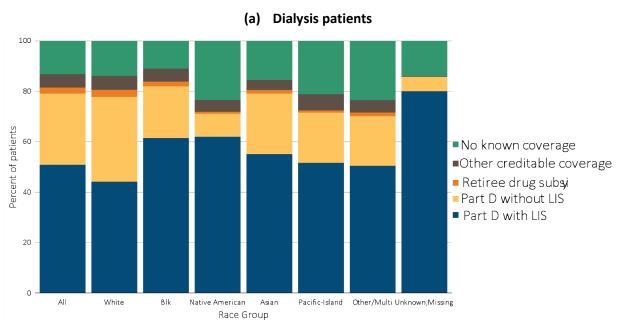
45-64

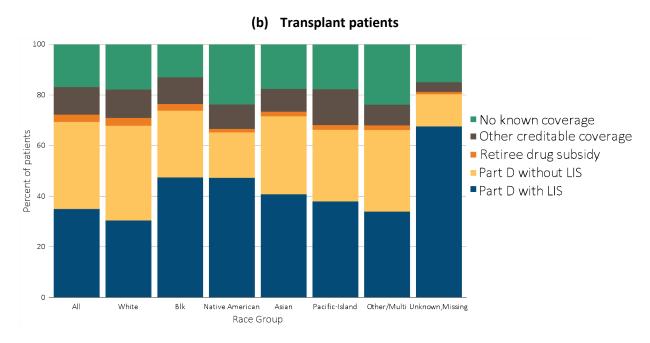
Age Group

Overall, 79.5% 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 (78.2%), Native American/Alaska Native (71.5%), or Asian (79.5%; Figure 10.3.a). About 87.2% of Native Americans/Alaska Natives, 75.2% of Blacks, and 69.8% of Asians with Part D coverage qualified for the LIS benefit, compared to 57.0% of Whites; Blacks were the

least likely to have no known prescription drug coverage. About 69.7% of transplant patients enrolled in Part D. By race, 68.3% of White, 74.2% of Black, 65.7% of Native American/Alaska Native, and 72.0% of Asian transplant patients enrolled. A larger share of Native American/Alaska Native (72.6%), Black (64.4%) and Asian (57.2%) transplant patients with Part D coverage had the LIS, compared to 45.1% of White transplant patients (Figure 10.3.b).

vol 2 Figure 10.3 Sources of prescription drug coverage in Medicare ESRD enrollees, by race/ethnicity & modality, 2015





Data source: 2015 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2015. 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, 2015

	General Medicare (%	All ESRD (%)	Hemodialysis (%)	Peritoneal dialysis (%)	Transplant (%)
White	N=1640171	N= 308137	N= 200447	N= 22761	N= 62861
All ages	24.2	53.6	58.2	46.8	45.1
20-44	88.2	87.5	90.7	87.5	81.9
45-64	52.0	70.1	75.9	63.6	57.1
65-74	14.5	39.1	48.0	24.3	20.9
75+	18.4	33.5	37.1	17.5	18.0
Black/African American	N=231027	N= 163167	N= 127716	N= 8407	N= 21580
All ages	57.2	73.6	75.6	69.0	64.4
20-44	92.8	92.2	93.8	89.3	87.5
45-64	74.8	80.3	82.7	73.3	69.8
65-74	41.6	58.5	62.8	40.2	39.2
75+	48.5	58.6	60.5	35.1	38.9
Native American/Alaska Native	N=8154	N= 4740	N= 3601	N= 267	N= 734
All ages	68.0	84.4	87.7	80.5	72.6
20-44	92.7	93.1	94.7	92.4	85.0
45-64	82.2	88.2	90.5	80.8	81.6
65-74	55.4	75.8	81.6	63.8	55.5
75+	56.7	75.1	80.3	54.5	54.7
Asian	N=50113	N= 20108	N= 13323	N= 1886	N= 4229
All ages	62.9	66.8	72.0	54.3	57.2
20-44	90.5	86.4	89.4	83.6	83.1
45-64	65.0	71.8	77.3	55.5	65.4
65-74	53.7	56.9	64.7	40.1	43.7
75+	70.7	65.8	70.0	50.4	41.5
Hawaiian Native/Pacific Islander	n/a	N= 4937	N= 3797	N= 386	N= 638
All ages	n/a	70.2	73.6	60.1	57.5
20-44	n/a	88.4	89.3	87.5	85.1
45-64	n/a	76.8	80.5	61.7	64.4
65-74	n/a	57.3	62.0	40.2	44.4
75+	n/a	62.1	65.3	56.3	29.4
Other/multiple race	N=37936	N= 1491	N= 619	N=66	N=694
All ages	30.5	61.2	72.4	69.7	51.6
20-44	85.5	81.4	88.7	83.3	75.0
45-64	45.1	67.4	82.4	88.9	53.8
65-74	21.1	47.5	59.5	33.3	39.9
75+	33.8	45.7	56.3	25.0	32.8
Unknown/missing	N=24737	N= 596	N=305	N=25	N=189
All ages	28.8	87.4	93.8	88.0	84.1
20-44	90.5	93.8	97.6	91.7	98.4
45-64	26.6	88.3	94.6	100.0	78.5
65-74	18.9	74.8	86.8	60.0	70.8
75+	79.8	85.0	83.3		90.0

Data source: 2015 Medicare data, point prevalent Medicare enrollees alive on January 1, 2015. 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

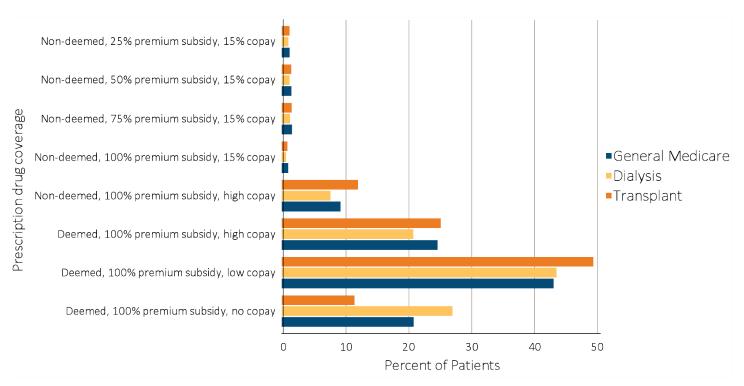
Beneficiaries dually enrolled in Medicare and Medicaid are automatically eligible for Part D under the Low-income Subsidy (LIS) benefit. Non-Medicaid eligible beneficiaries can also qualify for the LIS based on limited assets and income. The LIS provides full or partial waivers for many out-of-pocket 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 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 2015, 90.4% of dialysis patients with Part D LIS coverage were deemed LIS beneficiaries, compared to 85.0% of transplant, and 87.6% 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, 2015



Data source: 2015 Medicare data, point prevalent Medicare enrollees alive on January 1, 2015. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage.

Insurance Spending for Prescriptions

In recent years, total Part D spending for beneficiaries with ESRD increased by 81.7%, from \$1.8 billion in 2011 to \$3.2 billion in 2015 (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 the USRDS ESRD <u>reference table K.1</u>. Between 2011 and 2015, total estimated Part D spending increased by 1.8, 2.2 and 1.8 times for HD, PD, and kidney transplant patients. These rates of increase far outpaced the 40% spending growth that occurred in the general Medicare population.

vol 2 Table 10.4 Total estimated Medicare Part D spending for enrollees, in billions, 2011-2015

	General Medicare (\$)	All ESRD (\$)	Hemodialysis (\$)	Peritoneal Dialysis (\$)	Transplant (\$)
2011	46.0	1.8	1.4	0.1	0.2
2012	40.1	2.0	1.6	0.1	0.3
2013	52.1	2.3	1.8	0.1	0.3
2014	58.1	2.7	2.1	0.2	0.4
2015	63.4	3.2	2.5	0.2	0.5

Data source: 2011-2015 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.

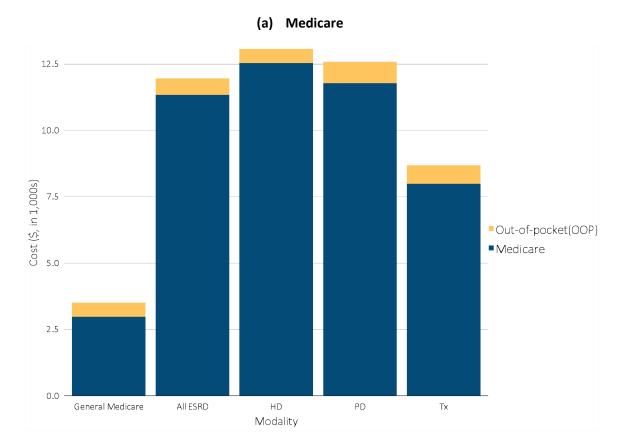
Per patient per year insurance spending was 3.8, 3.3 and 11.8 times greater for beneficiaries with ESRD than for general beneficiaries in the Medicare, Medicare Advantage, and managed care insurance populations. As a proportion of total costs, however, out-of-pocket costs were lower for beneficiaries with ESRD than all general beneficiaries (Medicare, 4.4% vs. 12.6%; Medicare Advantage, 12.0% vs. 18.8%; managed care, 7.9% vs. 19.0%). However, since total spending was so much higher for beneficiaries with ESRD, total out-of-pocket spending was still higher for beneficiaries with ESRD than the general population (Figures 10.5.a-c).

By modality, prescription spending was higher for dialysis patients than transplant patients in those covered by stand-alone Part D plans (HD,\$12,589; PD, \$11,828; Transplant, \$8,038), while prescription

spending was lower for dialysis patients than transplant patients in those with Medicare Advantage (\$5,596 vs. \$9,181) and managed care coverage (\$7,794 vs. \$10,199; Figures 10.5.a-c).

Across general Medicare and ESRD populations, PPPY Part D spending was 2.7-3.7 times greater for beneficiaries with LIS benefits than for those without. In the LIS population, however, out-of-pocket costs represented only 0.6-1.3% of total expenditures, compared to 23.3-27.8% among general Medicare and ESRD beneficiaries who did not receive the subsidy. PPPY Part D spending was 2.4 and 3.0 times greater for those with ESRD than for general Medicare beneficiaries in the LIS and non-LIS populations (Figure 10.5.d).

vol 2 Figure 10.5 Per person per year insurance & out-of-pocket costs for enrollees, 2015



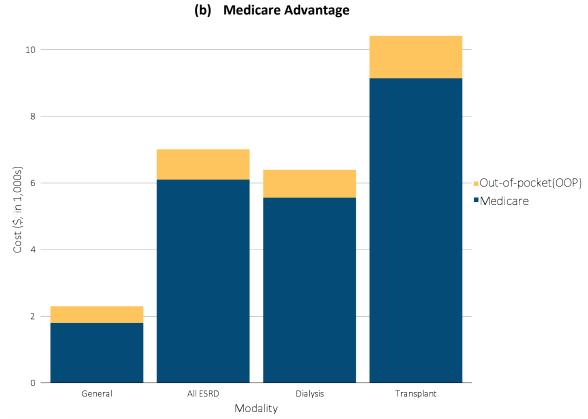
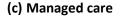
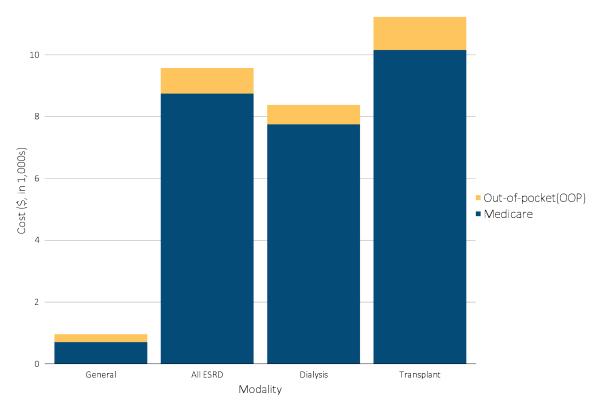


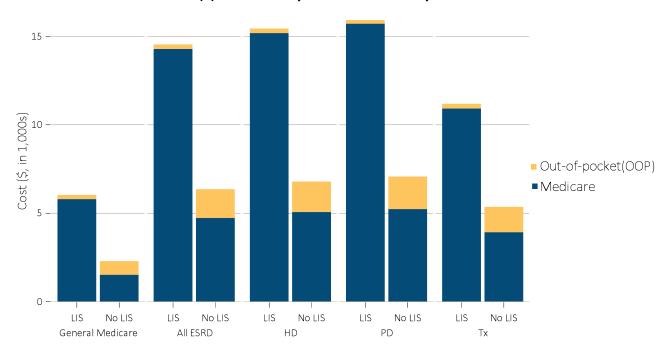
Figure 10.5 continued on next page.

vol 2 Figure 10.5 Per person per year insurance & out-of-pocket costs for enrollees, 2015 (continued)





(d) Medicare by Low-income Subsidy status



Data source: Medicare Part D claims and Optum Clinformatics™ claims. Medicare totals include Part D claims for Part D enrollees with traditional Medicare (Parts A & B)., Costs are per person per year for calendar year 2015, 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.

Total PPPY insurance spending for prescriptions (excluding patient obligations) varied by coverage, age, sex, and race (Table 7.5). Overall, spending for beneficiaries with ESRD was higher than in the general population. For both the general and ESRD cohorts, total PPPY prescription spending was highest in Medicare Part D with LIS (\$5,877 and \$14,364). Lowest spending for the general population cohorts occurred in managed care (\$744), and for the ESRD cohorts in Medicare

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Part D without LIS (\$4,812). Generally, younger beneficiaries aged 20-44 or 45-64, had higher costs than older patients. Insurance spending varied only modestly by sex. As there are differences between the Medicare and Optum Clinformatics™ beneficiary populations and in their methods of reporting costs, however, these results should be interpreted in those contexts.

vol 2 Table 10.5 Per person per year insurance spending for enrollees, 2015

(a) Medicare

		neral (\$)		ESRD (\$)		odialysis (\$)		eal dialysis (\$)		splant (\$)
	Part D	Part D	Part D	Part D	Part D	Part D	Part D	Part D	Part D	Part D
	with LIS	without LIS	with LIS	without LIS	with LIS	without LIS	with LIS	without LIS	with LIS	without LIS
Age										
All	5,877	1,600	14,364	4,812	15,263	5,146	15,791	5,311	10,995	4,006
20-44	5,839	2,510	14,574	4,670	16,584	5,994	16,000	5,091	9,433	3,027
45-64	7,909	2,934	15,623	5,675	16,549	5,944	16,321	5,720	12,027	4,856
65-74	4,965	1,514	12,993	4,947	13,605	5,472	13,572	5,640	10,645	3,928
75+	4,208	1,461	10,601	3,819	11,179	4,077	10,647	4,277	7,435	2,882
Sex										
Male	6,028	1,756	14,689	4,955	15,551	5,138	16,636	5,317	11,615	4,411
Female	5,771	1,484	13,997	4,596	14,945	5,159	15,030	5,302	10,172	3,384
Race		<u> </u>		_		_		_		
White	6,029	1,586	13,941	4,732	15,107	5,167	16,183	5,343	10,351	3,813
Black/African American	6,090	1,873	15,068	5,061	15,612	5,082	15,053	5,119	12,463	4,931
Native American/Alaska Native	4,774	2,605	9,218	4,533	9,204	5,185	11,767	4,355	8,438	3,607
Asian	4,637	1,268	14,511	5,031	15,575	5,622	16,953	5,640	10,895	4,144
Native Hawaiian/Pacific-Islander	NA	NA	14,898	4,085	15,685	3,929	17,203	4,875	9,126	4,053
Other race	4,973	1,599	12,478	4,856	14,175	6,161	12,446	4,726	10,868	4,397
Unknown/missing	4,723	1,534	13,829	3,347	15,155	3,870	20,957	33,966	10,907	4,149

Data source: Medicare Part D claims and Optum Clinformatics™ claims. Costs are per person per year for calendar year 2015, 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.

Table 10.5 continued on next page.

vol 2 Table 10.5 Per person per year insurance spending for enrollees, 2015 (continued)

(b) Medicare Advantage

	General (\$)	All ESRD (\$)	All Dialysis (\$)	Transplant (\$)
Age				
All	1,836	6,139	5,596	9,181
20-44	4,849	14,168	10,725	20,641
45-64	4,928	10,035	9,228	12,295
65-74	1,563	5,893	5,619	7,093
75+	1,421	4,125	4,050	5,387
Sex				
Male	1,836	5,932	5,186	9,915
Female	1,836	6,376	6,057	8,265
Race				
White	1,855	5,738	5,249	8,305
Black/African American	2,678	7,477	6,701	13,897
Asian	1,842	7,805	7,176	11,468
Unknown	1,689	5,590	5,321	6,756

(c) Managed care

	General (\$)	All ESRD (\$)	All Dialysis (\$)	Transplant (\$)
Age				
All	744	8,790	7,794	10,199
20-44	504	7,434	6,665	8,135
45-64	1,233	9,173	8,384	10,310
65-74	2,018	8,686	7,892	10,609
75+	2,711	5,792	5,466	8,616
Sex				
Male	738	9,147	8,206	10,540
Female	749	8,260	7,148	9,718
Race				
White	773	9,093	8,191	10,178
Black/African American	693	7,871	6,890	11,141
Asian	413	8,009	7,701	8,395
Unknown	764	8,909	7,051	10,592

Data source: Medicare Part D claims and Optum Clinformatics™ claims. Costs are per person per year for calendar year 2015, 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.

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 2015. The proportion of patients using each drug class was somewhat lower for Medicare Advantage and managed care enrollees in the ClinformaticsTM database than for those having Medicare Part D. These differences could arise from plan effects such as coverage or care management activities, or from patient selection in the younger and

healthier Clinformatics TM cohort. ESRD patients in all insured populations commonly used ion-removing agents, β -adrenergic blocking agents, antibacterials, analgesics, and lipid-lowering agents. As expected, immunosuppressive agents were the most frequently prescribed medication class to transplant patients with Medicare Advantage and managed care coverage. The use proportion for this drug class for Medicare transplant recipients were underestimated, as only a fraction of immunosuppressive agents were covered through Part D (Table 10.6).

vol 2 Table 10.6 Top 15 drug classes received by ESRD cohorts in different health plans, by modality, 2015
(a) Medicare

	Hemodialysis		Peritoneal Dialysis		Transplant			
Rank	Drug class	%	Drug class	%	Drug class	%		
1	Ion-removing agents	71.2	Ion-removing agents	61.7	Antibacterials	74.3		
2	β-adrenergic blocking agents	63.7	β-adrenergic blocking agents	60.3	β-Adrenergic blocking agents	63.0		
3	Antibacterials	58.7	Antibacterials	58.6	Antiulcer agents and acid suppressants	59.6		
4	Analgesics and antipyretics	58.4	Analgesics and antipyretics	47.5	Lipid-lowering agents	56.6		
5	Lipid-lowering agents	49.6	Lipid-lowering agents	47.3	Calcium-channel blocking agents	50.3		
6	Calcium-channel blocking agents	47.7	Calcium-channel blocking agents	46.3	Analgesics and antipyretics	49.2		
7	Antiulcer agents and acid suppressants	46.9	Renin-angiotensin-aldosterone system inhibitors	42.8	Adrenals	47.0		
8	Renin-angiotensin-aldosterone system inhibitors	38.5	Antiulcer agents and acid suppressants	39.7	Antidiabetic agents	39.1		
9	Antidiabetic agents	37.1	Antidiabetic agents	33.5	Renin-angiotensin-aldosterone system inhibitors	36.3		
10	Hypotensive agents	32.5	Anti-infectives	33.5	Diuretics	33.5		
11	Psychotherapeutic agents	31.7	Diuretics	32.7	Psychotherapeutic agents	25.3		
12	Anticonvulsants	31.4	Hypotensive agents	27.2	Antivirals	24.8		
13	Cinacalcet	30.9	Psychotherapeutic agents	27.2	Diabetic consumables	24.6		
14	Antithrombotic agents	30.2	Cinacalcet	25.6	Anticonvulsants	22.3		
15	Anxiolytics, sedatives, and hypnotics	26.8	Replacement preparations	25.1	Anti-infectives	20.4		

Table 10.6 continued on next page.

vol 2 Table 10.6 Top 15 drug classes received by ESRD cohorts in different health plans, by modality, 2015 (continued)

(b) Medicare Advantage

Dialysis Transplant

Rank	Drug class	%	Drug class	%
1	β-adrenergic blocking agents	44.8	Immunosuppressive agents	48.0
2	Lipid-lowering agents	41.0	Antibacterials	40.9
3	Analgesics and antipyretics	40.4	Adrenals	38.8
4	Antibacterials	40.2	β-adrenergic blocking agents	35.5
5	Ion-removing agents	37.2	Lipid-lowering agents	34.8
6	Calcium-channel Blocking agents	35.2	Antiulcer agents and acid suppressants	29.4
7	Antiulcer agents and acid suppressants	31.5	Calcium-channel Blocking agents	28.0
8	Antidiabetic agents	29.1	Analgesics and antipyretics	27.8
9	Diuretics	26.8	Renin-angiotensin-aldosterone system inhibitors	25.1
10	Renin-angiotensin-aldosterone system inhibitors	26.7	Antidiabetic agents	24.4
11	Diabetic consumables	24.8	Diabetic consumables	23.3
12	Antithrombotic agents	22.5	Diuretics	20.2
13	Hypotensive agents	22.0	Psychotherapeutic agents	15.6
14	Psychotherapeutic agents	21.9	Antithrombotic agents	14.5
15	Anticonvulsants	20.1	Anticonvulsants	13.9

(c) Managed care

Dialysis Transplant

Rank	Drug class	%	Drug class	%
1	Ion-removing agents	44.0	Immunosuppressive agents	52.8
2	β-adrenergic blocking agents	42.6	Antibacterials	43.8
3	Analgesics and antipyretics	37.8	Adrenals	39.3
4	Antibacterials	36.6	β -adrenergic blocking agents	32.0
5	Calcium-channel Blocking agents	35.7	Lipid-lowering agents	30.2
6	Lipid-lowering agents	31.3	Calcium-channel Blocking agents	26.0
7	Renin-angiotensin-aldosterone system inhibitors	28.5	Renin-angiotensin-aldosterone system inhibitors	25.8
8	Antidiabetic agents	24.3	Analgesics and antipyretics	25.6
9	Diuretics	24.0	Antiulcer agents and acid suppressants	20.6
10	Hypotensive agents	22.9	Antidiabetic agents	15.3
11	Vitamin D	20.0	Diuretics	14.3
12	Antiulcer agents and acid suppressants	19.7	Vitamin D	13.1
13	Diabetic consumables	18.9	Diabetic consumables	13.0
14	Antithrombotic agents	14.9	Anxiolytics, sedatives, and hypnotics	11.9
15	Anxiolytics, sedatives, and hypnotics	14.5	Psychotherapeutic agents	11.7

Data source: Medicare Part D claims and Optum Clinformatics™ 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.

Ion-removing agents incurred the greatest costs for dialysis patients in all insured populations, at about 40% of total insurance spending. Antivirals ranked first for transplant patients with Medicare Part D, and immunosuppressive agents were highest for patients with Medicare

\$15.2

0.6

Advantage and managed care coverage. Other costly medications and classes for treatment of ESRD included cinacalcet, antidiabetic agents, and antivirals (Table 10.7).

vol 2 Table 10.7 Top 15 drug classes received by different ESRD cohorts, by modality and insurance spending, 2015

(a) Medicare

Hemodialysis **Transplant Peritoneal Dialysis** Costs % Costs Costs **Drug class Drug class** % **Drug class** % Rank Ion-removing agents \$1,005.1 Ion-removing agents **Antivirals** \$152.0 33.4 1 40.7 \$83.3 41.7 20.9 Antidiabetic agents 2 Cinacalcet \$546.0 22.1 Cinacalcet \$41.8 \$76.2 16.8 3 Antidiabetic agents \$192.0 7.8 Antidiabetic agents \$20.2 10.1 Cinacalcet \$40.3 8.9 4 Antivirals \$135.3 5.5 Antivirals \$11.1 5.5 Immunosuppressive agents \$21.8 4.8 \$57.8 2.3 \$4.4 2.2 Antiulcer agents and acid \$11.9 2.6 5 Antineoplastic agents Antineoplastic agents suppressants 6 Antiulcer agents and acid \$35.1 1.4 Lipid-lowering agents \$3.0 1.5 Lipid-lowering agents \$11.8 2.6 suppressants Analgesics and antipyretics \$32.2 1.3 Antiulcer agents and acid \$2.4 1.2 Adrenocortical Insufficiency \$8.5 1.9 7 suppressants Antibacterials \$2.1 8 Lipid-lowering agents \$31.9 1.3 1.1 **Antibacterials** \$7.7 1.7 Psychotherapeutic agents \$26.6 Analgesics and antipyretics \$1.6 8.0 Hematopoietic agents \$7.4 1.6 9 1.1 Vasodilating agents \$26.4 1.1 Serums \$1.5 8.0 Antineoplastic agents \$7.0 1.5 10 Antibacterials \$26.3 1.1 Pituitary \$1.5 0.8 Psychotherapeutic agents \$7.0 1.5 11 12 Anticonvulsants \$25.2 1.0 Vasodilating agents \$1.4 0.7 Serums \$6.4 1.4 Caloric agents Anticonvulsants 0.7 Anticonvulsants \$6.2 13 \$23.7 1.0 \$1.4 1.4 Anti-inflammatory agents \$20.5 8.0 Psychotherapeutic agents \$1.3 0.6 Analgesics and antipyretics \$5.8 1.3 14

\$1.1

0.6

Antithrombotic agents

β-adrenergic blocking agents

Table 10.7 continued on next page.

Antithrombotic agents

15

1.0

\$4.7

vol 2 Table 10.7 Top 15 drug classes received by different ESRD cohorts, by modality and insurance spending, 2015 (continued)

(b) Medicare Advantage

Dialysis Transplant

Rank	Drug class	Costs	%	Drug class	Costs	%
1	Ion-removing agents	\$13.9	27.4	Immunosuppressive agents	\$5.2	34.8
2	Cinacalcet	\$7.3	14.3	Antivirals	\$2.8	19.0
3	Antidiabetic agents	\$5.2	10.3	Antidiabetic agents	\$1.3	8.8
4	Antineoplastic agents	\$2.2	4.3	Cinacalcet	\$1.3	8.4
5	Diabetic consumables	\$1.9	3.7	Diabetic consumables	\$0.5	3.5
6	Antivirals	\$1.7	3.4	Ion-removing agents	\$0.4	2.8
7	Lipid-lowering agents	\$1.6	3.2	Lipid-lowering agents	\$0.3	2.2
8	Vasodilating agents	\$1.2	2.3	Antithrombotic agents	\$0.2	1.3
9	Analgesics and antipyretics	\$1.0	1.9	Antiulcer agents and acid	\$0.2	1.3
10	Antiulcer agents and acid	\$0.8	1.6	Antibacterials	\$0.2	1.3
11	Calcium-channel Blocking agents	\$0.7	1.5	Psychotherapeutic agents	\$0.2	1.1
12	Psychotherapeutic agents	\$0.7	1.5	Analgesics and antipyretics	\$0.2	1.0
13	Anti-inflammatory agents	\$0.7	1.4	Calcium-channel Blocking agents	\$0.1	0.9
14	Antibacterials	\$0.7	1.4	Serums	\$0.1	0.9
15	Hypotensive agents	\$0.7	1.4	β-adrenergic blocking agents	\$0.1	0.8

(c) Managed care

Dialysis Transplant

Rank	C Drug class	Costs	%	Drug class	Costs	%
1	Ion-removing agents	\$8.4	35.6	Immunosuppressive agents	\$9.4	43.2
2	Cinacalcet	\$3.2	13.7	Antivirals	\$3.4	15.9
3	Antidiabetic agents	\$2.4	10.3	Cinacalcet	\$1.5	6.7
4	Antineoplastic agents	\$1.2	5.0	Antidiabetic agents	\$1.4	6.4
5	Antivirals	\$1.1	4.8	Ion-removing agents	\$1.0	4.4
6	Immunosuppressive agents	\$0.7	3.0	Lipid-lowering agents	\$0.4	2.1
7	Diabetic consumables	\$0.5	2.2	Hematopoietic agents	\$0.4	1.8
8	Lipid-lowering agents	\$0.5	2.2	Antibacterials	\$0.4	1.6
9	Antibacterials	\$0.3	1.3	Diabetic consumables	\$0.3	1.6
10	Vasodilating agents	\$0.3	1.3	Antithrombotic agents	\$0.2	1.0
11	Calcium-channel Blocking agents	\$0.3	1.3	Pituitary	\$0.2	1.0
12	Hypotensive agents	\$0.3	1.2	β-adrenergic blocking agents	\$0.2	0.8
13	Hematopoietic agents	\$0.3	1.1	Calcium-channel Blocking agents	\$0.2	0.7
14	Analgesics and antipyretics	\$0.3	1.1	Antifungals	\$0.2	0.7
15	β-adrenergic blocking agents	\$0.3	1.1	Psychotherapeutic agents	\$0.2	0.7

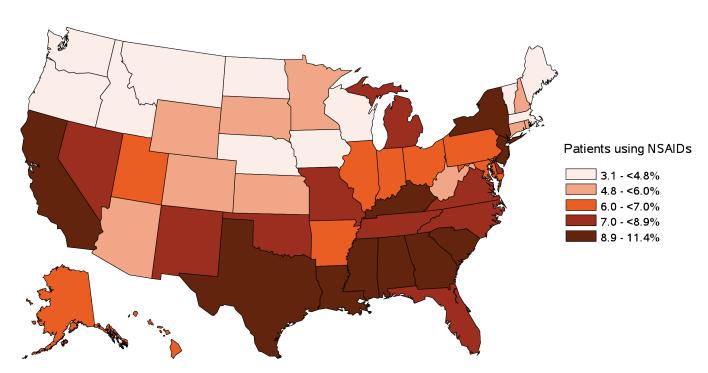
Data source: Medicare Part D claims and Optum Clinformatics™ claims. Part D spending represents the sum of the Medicare covered amount and the Low-income Subsidy amount. Ion-removing agents include phosphate-binding agents, potassium-binding agents, etc. Hypotension agents include alpha-2-agonists and vasodilators. Diabetic consumables refer to blood glucose test strips, blood glucose meters/sensors, lancets, needles, pen needles, etc.

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 higher frequency among ESRD patients (e.g., gastrointestinal bleeding, respiratory depression; Pham et al., 2009). Figure 10.6 and Figure 10.7 display the state-specific proportions of ESRD Medicare Part D patients prescribed NSAIDs and opioid analgesics in 2015.

The overall national proportion of prescription NSAID use was 8.3%. California, the District of Columbia, and southern states 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.

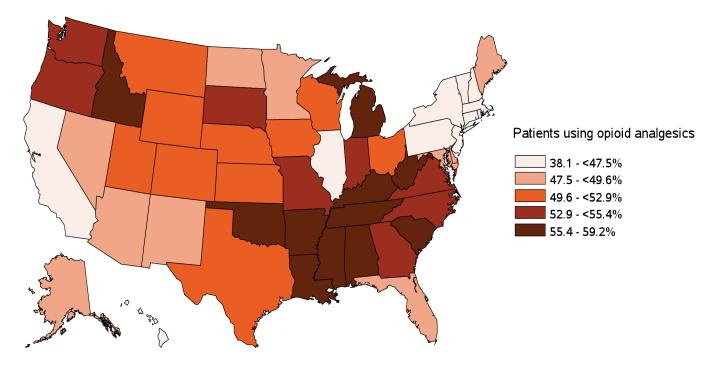
The proportion of patients using opioid analysics was very high, at 50.3%. Use was greatest in the south central region (Alabama, Oklahoma, Louisiana, and Mississippi). These state differences could reflect varying prevalence of coexisting conditions, pain management practices, and preferences by state.

vol 2 Figure 10.6 Estimated utilization rate of prescription NSAIDs by state, Medicare ESRD Patients, 2015



Data source: Medicare Part D claims. ESRD patients with Medicare Part D stand-alone prescription drug plans. Abbreviations: 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, 2015



Data source: Medicare Part D claims. ESRD patients with Medicare Part D stand-alone prescription drug plans.

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