chapter five

prescription drug coverage in CKD patients

medicare part D

There's something happening here
What it is ain't exactly clear
There's a man with a gun over there
Telling me I got to beware
I think it's time we stop, children, what's that sound
Everybody look what's going down

Stephen Stills, "For What It's Worth"

As of September 2008, 26 million Medicare-enrolled elderly and disabled people, as well as individuals with ESRD, were enrolled in a Medicare Part D prescription drug plan (PDP).

Before 2006, these patients obtained drug coverage through various insurance plans, state Medicaid programs, or pharmaceutical-assistance programs, received samples from physicians, or paid out-of-pocket. After 2006, however, the majority obtained Part D coverage. Fifty-six to 60 percent of general Medicare patients and patients with CKD, diabetes, or cardiovascular disease were enrolled in Part D in 2008, as were 67 percent of patients with ESRD.

The retiree drug subsidy, designed to encourage employers to supply prescription coverage to Medicare-covered retirees that is at least as valuable as the Medicare Part D standard plan, provides employers with a tax-free rebate for 28 percent of retirees' drug costs. Other patients are enrolled in employer group health plans or government/military plans ("creditable coverage"), which provide coverage that is equivalent to or better than Part D.

The proportion of patients with other creditable coverage is similar among CKD and Medicare patients, at about 12 percent, but a higher proportion of CKD patients have retiree drug subsidy coverage, at 21 compared to 15 percent. Nine percent of CKD patients have no known source of drug coverage — a level lower than in the Medicare population, and similar to that of patients with diabetes or cardiovascular disease.

Prior to the start of the Medicare Part D program in 2006, patients dually-enrolled in Medicare and Medicaid received prescription benefits under state Medicaid programs. The Part D program, however, 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 coverage gap ("donut hole"). Nearly three in four dialysis patients enrolled in Part D have LIS, compared to 51 and 38 percent of their counterparts with CKD and in the general Medicare population. In general, CKD patients thus pay proportionally lower out-of-pocket costs than Medicare patients for their Part D prescriptions.

Part D does not cover every medication prescribed to Medicare enrollees. Several drug categories — including

Definitions of terms used throughout this chapter are provided on page 90.

over-the-counter medications, barbiturates, benzodiazepines, 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 by law. This means that some drugs commonly used in CKD patients (oral iron, ergocalciferol, cholecalciferol) are not currently covered through Medicare Part D. Oral calcitriol, doxercalciferol, and paricalcitol, however, are not considered prescription vitamins, and are thus covered.

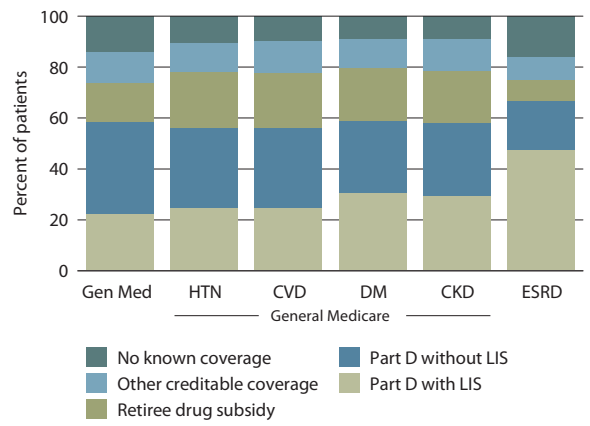
The Medicare Part D program works in concert with Medicare Part B, which covers medications administered in physician offices (e.g. erythropoiesis stimulating agents in CKD patients). Access to certain medications is dependent on whether the drug is included on the PDP formulary. A PDP could, for example, decide to include calcitriol and doxercalciferol on its formulary, but not paricalcitol.

Part D benefits can be managed through a stand-alone PDP or through a Medicare Advantage (MA) plan, which provides medical as well as prescription benefits. CKD patients can chose to enroll in an MA plan; ESRD patients, in contrast, are precluded from entering an MA plan if they are not already enrolled in one when they reach ESRD. Most data presented in this chapter encompass both types of plans.

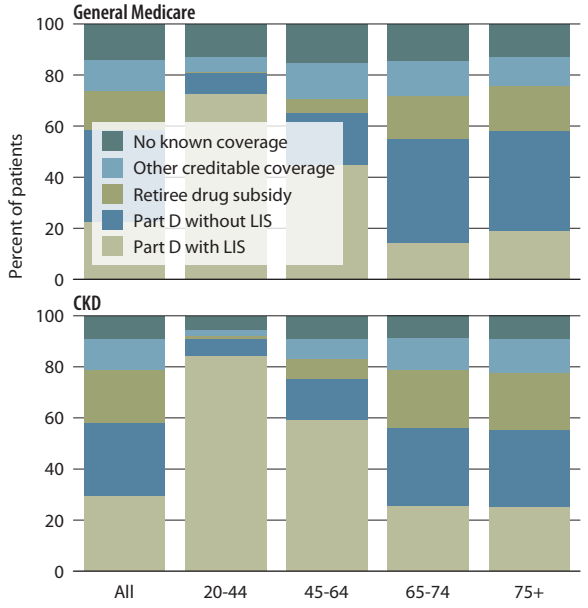
Medicare-enrolled CKD patients obtain outpatient medication benefits through Part B, Part D, retiree drug subsidy plans, or other creditable coverage, including employer group health plans, Veterans Administration benefits, Medicaid wrap-around programs, and state kidney programs. Some also pay out-of-pocket for plan expenses and copayments, over-the-counter medications, and low-cost generic agents at retailers.

>> **Figure 5.1;** see page 126 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, 2008.*

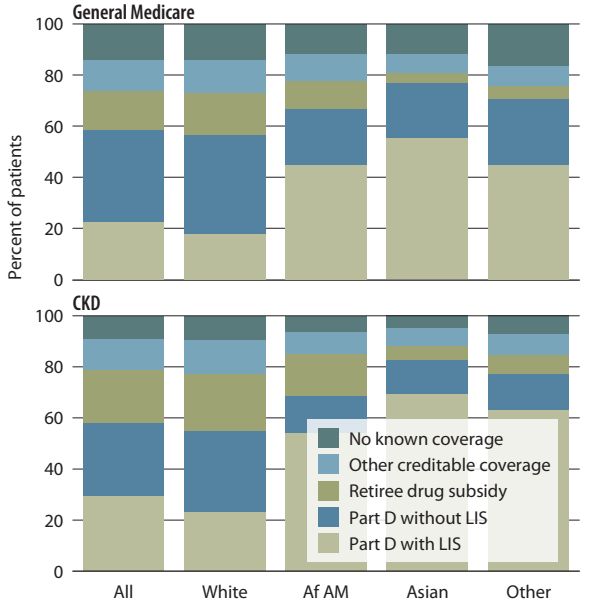
5.1i **Sources of prescription drug coverage in Medicare enrollees, 2008**



5.2i Sources of prescription drug coverage in Medicare enrollees, by age, 2008



5.3i Sources of prescription drug coverage in Medicare enrollees, by race, 2008



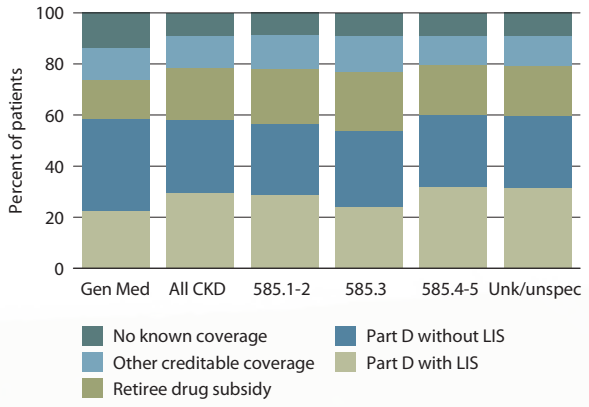
ICD-9-CM CODES

585.1	Chronic kidney disease, Stage 1
585.2	Chronic kidney disease, Stage 2 (mild)
585.3	Chronic kidney disease, Stage 3 (moderate)
585.4	Chronic kidney disease, Stage 4 (severe)
585.5	Chronic kidney disease, Stage 5 (excludes 585.6: Stage 5, requiring chronic dialysis.*)
	Chronic kidney disease, unknown/unspecified

**In USRDS analyses, patients with ICD-9-CM code 585.6 are considered to have code 585.5; see Appendix A for details.*

CKD stage estimates are from a single measurement. For clinical case definition, abnormalities should be present ≥ 3 months.

5.4i Sources of prescription drug coverage in Medicare enrollees, by CKD stage, 2008



Among both general Medicare beneficiaries and those with CKD, the percentage enrolled in Part D declines with age. In the CKD population, however, 91 and 75 percent of those age 20–44 and 45–64, respectively, are enrolled, compared to 81 and 65 percent of their general Medicare counterparts.

Nearly 73 percent of general Medicare patients age 20–44 receive the low income subsidy (LIS). It is important to note that most patients in these younger two age groups are disabled. In the two older age groups, similar proportions of general Medicare and CKD patients age 65 and older are enrolled in Part D, at 55–58 percent. The proportion of patients with LIS declines with age in both populations, but CKD patients in each age category are more likely to receive this subsidy.

Patterns of coverage by race are similar in the general Medicare and CKD populations, with both Part D enrollment overall and Part D coverage with LIS highest in Asian and African American patients, and lowest in whites. LIS coverage is higher across races for CKD patients than among their general Medicare counterparts.

There is less variation in Part D enrollment by CKD stage, with 54 and 60 percent of CKD Stage 3 and Stage 4–5 patients enrolled in Part D, respectively, compared to 59 percent of general Medicare patients. In the CKD population, LIS is least common among those with Stage 3 CKD, at 24 percent. » **Figures 5.2–4;** see page 126 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, 2008.*

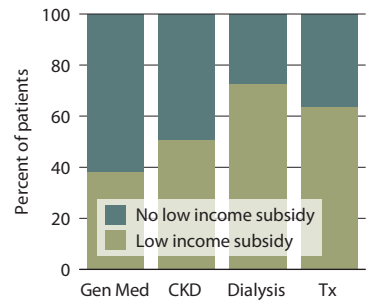
prescription drug coverage in CKD patients

MEDICARE PART D ENROLLMENT PATTERNS IN PATIENTS WITH CKD

Fifty-one percent of Medicare patients with part D coverage had LIS benefits in 2008, compared to 73 percent of dialysis patients and 64 percent of those with a kidney transplant. CKD patients are thus more likely to experience the coverage gap and to have higher premiums, deductibles, and drug copayments, on average, than dialysis and transplant patients. » **Figure 5.5;** see page 126 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, 2008.*

The proportion of patients with LIS varies more by age and race than by CKD stage. In each category, patients with known CKD are more likely to have LIS than their general Medicare counterparts. Among CKD patients, women are far more likely to have LIS than men; in the general Medicare population, in contrast, proportions are similar by gender. In both the general Medicare and CKD populations, Asians are the most likely by race to have LIS, and whites the least. » **Table 5.a;** see page 126 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, 2008.*

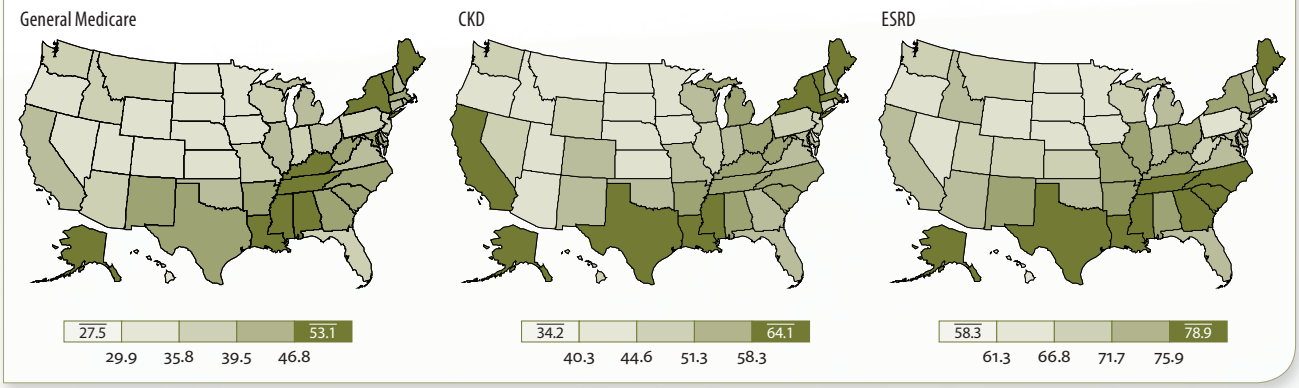
5 5i Medicare Part D enrollees, by low income subsidy (LIS) status & population, 2008



5 ai Medicare Part D enrollees with low income subsidy (LIS), by CKD stage & demographic characteristics, 2008 (percent)

	Medicare	All CKD	585.1–2	585.3	585.4–5	Unk/unspec
All	38.4	50.9	50.6	44.8	53.1	53.2
20-44	90.0	92.7	92.0	94.2	95.5	92.1
45-64	68.3	78.7	79.2	76.7	79.3	79.1
65-74	26.2	45.5	44.5	41.0	50.3	47.0
75+	32.8	45.9	43.6	40.0	48.0	48.5
Male	36.1	44.8	46.5	37.4	44.5	48.0
Female	39.9	55.6	54.0	50.7	59.0	57.2
White	31.6	42.7	40.6	36.3	43.5	45.7
African American	67.2	78.7	76.9	74.8	79.2	80.6
Asian	72.1	84.0	84.6	83.2	82.5	84.6
Other	63.1	81.7	85.8	79.4	81.2	82.1

5 6i Geographic variations in the percent of Medicare Part D enrollees with low income subsidy (LIS), 2008



There is substantial state-to-state variability in the percentage of Medicare Part D enrollees with LIS, and the patterns seen in CKD and ESRD patients differ from those of the general Medicare population. In each state there is a monotonic increase in the percentage of patients receiving LIS as populations change from general Medicare to CKD and then to ESRD patients. In Delaware, Minnesota, and Utah, the difference between general Medicare and CKD patients is less than 4 percentage points; in California, in contrast, it is more than 25. » **Figure 5.6;** see page 126 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, 2008.*

CMS provides prescription drug plans (PDPs) with guidance on structuring a "standard" Part D PDP. The upper portion of Figure 5.7 shows the standard benefit design for PDPs in 2006, 2007 and 2008. In 2008, for example, beneficiaries shared costs with the PDP (as coinsurance or copayments) until the combined total reached $2,510 during the initial coverage period. After reaching this level, beneficiaries went into the coverage gap or "donut hole," where they paid 100 percent of costs. Since 2010, the government has been providing those reaching the coverage gap with more assistance each year. In 2008, beneficiaries who obtained a yearly out-of pocket drug cost of $4,050 reached the catastrophic coverage phase, in which they paid only a small copayment for their drugs until the end of the year.

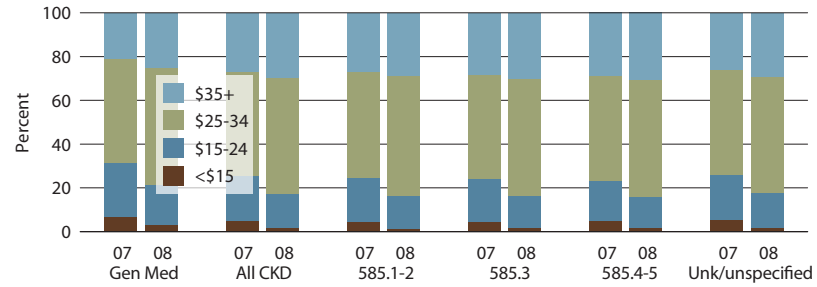
PDPs have the latitude to structure their plans differently from what is presented here; companies offering non-standard plans must show that their coverage is at least actuarially equivalent to the standard plan. Many have developed plans with no deductibles or with drug copayments instead of the 25 percent coinsurance, and some plans provide generic and/or brand name drug coverage during the coverage gap.

The lower portions of the table show drug copayment, coinsurance, and deductible amounts for beneficiaries with full and non-full dual eligibility and with full or partial subsidies. » Figure 5.7 *http://www.q1medicare.com/PartD-The-2008-Medicare-Part-D-Outlook.php.*

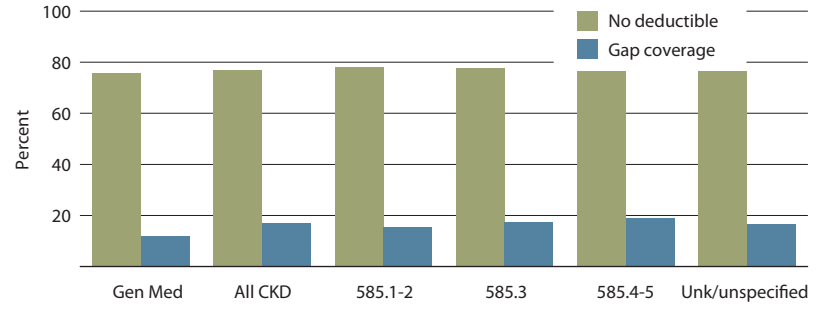
5.7i Medicare Part D benefit parameters, 2006–2008

Part D Standard Benefit Design Parameters:	2006	2007	2008
Deductible - (after the Deductible is met, Beneficiary pays 25% of covered costs up to total prescription costs meeting the Initial Coverage Limit.	$250	$265	$275
Initial Coverage Limit - Coverage Gap (Donut Hole) begins at this point. (The Beneficiary pays 100% of their prescription costs up to the Out-of-Pocket Threshold)	$2,250	$2,400	$2,510
Total Covered Part D Drug Out-of-Pocket Spending including the Coverage Gap - Catastrophic Coverage start after this point.	$5,100.00	$5,451.25	$5,726.25
Out-of-Pocket Threshold - This is the Total Out-of-Pocket Costs including the Donut Hole.	$3,600	$3,850	$4,050
2008 Example:			
$275 (Deductible)	$ 250.00	$ 265.00	$ 275.00
+ (($2,510 - $275) * 25%) (Initial Coverage)	$ 500.00	$ 533.75	$ 558.75
+ (($5,726.25-$2,510) * 100%) (Donut Hole)	$2850.00	$3051.25	$3216.25
= $4,050 (Maximum Out-Of-Pocket Cost prior to Catastrophic Coverage - excluding plan premium)	$3600.00	$3850.00	$4050.00
Catastrophic Coverage Benefit:			
Generic/Preferred Multi-Source Drug	$2.00	$2.15	$2.25
Other Drugs	$5.00	$5.35	$5.60
Part D Full Benefit Dual Eligible Parameters:	**2006**	**2007**	**2008**
Copayments for Institutionalized Beneficiaries	$0.00	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries			
Up to or at 100% FPL:			
Up to Out-of-Pocket Threshold			
Generic/Preferred Multi-Source Drug	$1.00	$1.00	$1.05
Other	$3.00	$3.10	$3.10
Above Out-of-Pocket Threshold	$0.00	$0.00	$0.00
Over 100% FPL:			
Up to Out-of-Pocket Threshold			
Generic/Preferred Multi-Source Drug	$2.00	$2.15	$2.25
Other	$5.00	$5.35	$5.60
Above Out-of-Pocket Threshold	$0.00	$0.00	$0.00
Part D Non-Full Benefit Dual Eligible Full Subsidy Parameters:	**2006**	**2007**	**2008**
Resources ≤ $6,120 (individuals) or ≤ $9,190 (couples)			
Maximum Copayments up to Out-of-Pocket Threshold			
Generic/Preferred Multi-Source Drug	$2.00	$2.15	$2.25
Other	$5.00	$5.35	$5.60
Maximum Copay above Out-of-Pocket Threshold	$0.00	$0.00	$0.00
Resources between $6,120-$20,210 (individuals) or $9,190-$20,410 (couples)			
Deductible	$50.00	$53.00	$56.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%	15%
Maximum Copayments above Out-of-Pocket Threshold			
Generic/Preferred Multi-Source Drug	$2.00	$2.15	$2.25
Other	$5.00	$5.35	$5.60
Part D Non-Full Benefit Dual Eligible Partial Subsidy Parameters:	**2006**	**2007**	**2008**
Deductible	$50.00	$53.00	$56.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%	15%
Maximum Copayments above Out-of-Pocket Threshold			
Generic/Preferred Multi-Source Drug	$2.00	$2.15	$2.25
Other	$5.00	$5.35	$5.60

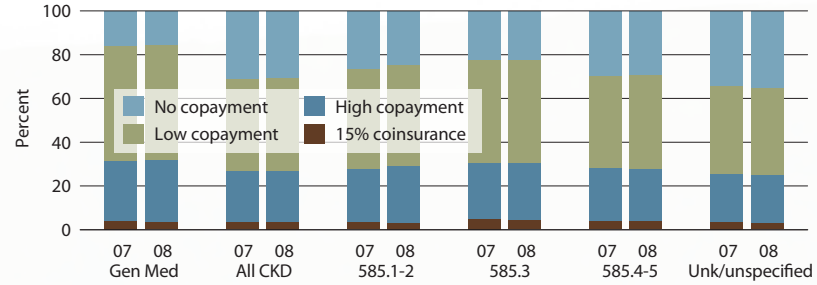
5.8i **Medicare Part D non-LIS enrollees with specified monthly premium, by CKD stage & year**



5.9i **Medicare Part D non-LIS enrollees with gap coverage or no deductible, by CKD stage, 2008**



5.10i **Medicare Part D LIS enrollees with specified coinsurance/copayment, by CKD stage & year**



Copayments, per generic & branded fill, respectively

High 2007: up to $2.15 & $5.35
2008: up to $2.25 & $5.60

Low 2007: up to $1.00 & $3.10
2008: up to $1.05 & $3.10

Patients without LIS pay full monthly premiums. From 2007 to 2008, enrollment increased in plans with higher premiums. In 2008, 28–31 percent of CKD patients enrolled in plans with premiums greater than $35 per month, compared to 25 percent of Medicare patients.

The percentage of Part D non-LIS enrollees with no deductible is similar in the general Medicare and CKD populations, at 76–78 percent. Gap ("donut hole") coverage, in contrast, is more common in CKD patients, at 17 compared to 12 percent. Nineteen percent of CKD Stage 4–5 patients in 2008 were enrolled in plans with gap coverage.

Most Part D LIS enrollees (full-benefit dual-eligible patients) pay no monthly premium, but non-institutionalized LIS patients do pay drug copayments or coinsurance based on income and assets. Sixty-nine to 75 percent of CKD patients with LIS have low or no copayments for their Part D medications, compared to 68 percent of general Medicare patients. Only 3–4 percent pay 15 percent coinsurance for their medications. And even CKD patients with high copayments (23 percent, on average, in 2008) paid a maximum of just $2.25 per generic and $5.60 for branded medication. » Figures 5.8–10; see page 126 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in Medicare Advantage Part D plans.*

ICD-9-CM CODES

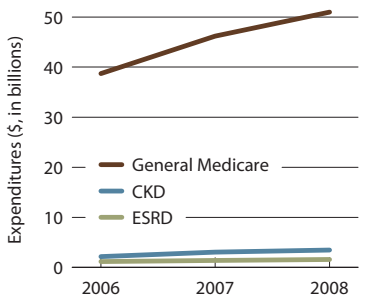
585.1	Chronic kidney disease, Stage 1
585.2	Chronic kidney disease, Stage 2 (mild)
585.3	Chronic kidney disease, Stage 3 (moderate)
585.4	Chronic kidney disease, Stage 4 (severe)
585.5	Chronic kidney disease, Stage 5 (excludes 585.6: Stage 5, requiring chronic dialysis.*)
	Chronic kidney disease, unknown/unspecified

**In USRDS analyses, patients with ICD-9-CM code 585.6 are considered to have code 585.5; see Appendix A for details.*

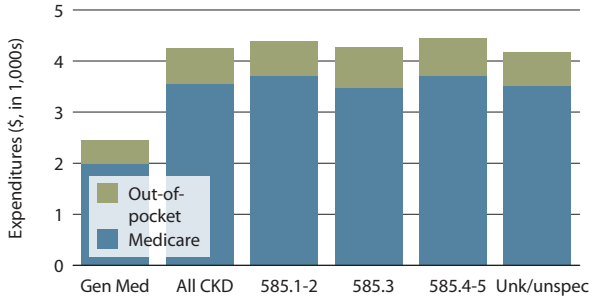
CKD stage estimates are from a single measurement. For clinical case definition, abnormalities should be present ≥ 3 months.

In 2008, total net Part D payment for patients with identified kidney disease (CKD patients not on dialysis, and ESRD patients) was $5 billion — 10 percent of total Part D prescription drug costs. These costs do not include costs of drugs billed to Part B, including intradialytic medications (ESAs, IV vitamin D, iron) and immunosuppressants. » Figure 5.11; see page 126 for analytical methods. *Medicare Part D enrollees.*

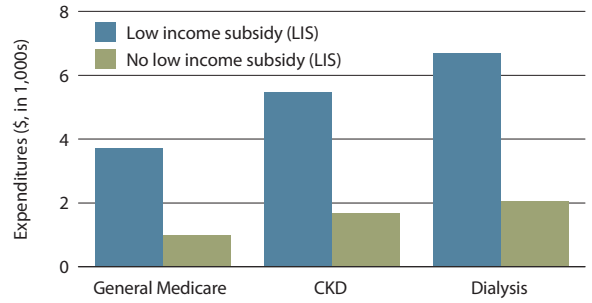
5.11i Net Part D payment for Medicare enrollees



5.12i Per person per year Medicare & out-of-pocket Part D costs for enrollees, 2008



5.13i Per person per year Part D costs for enrollees, by low income subsidy (LIS) status, 2008



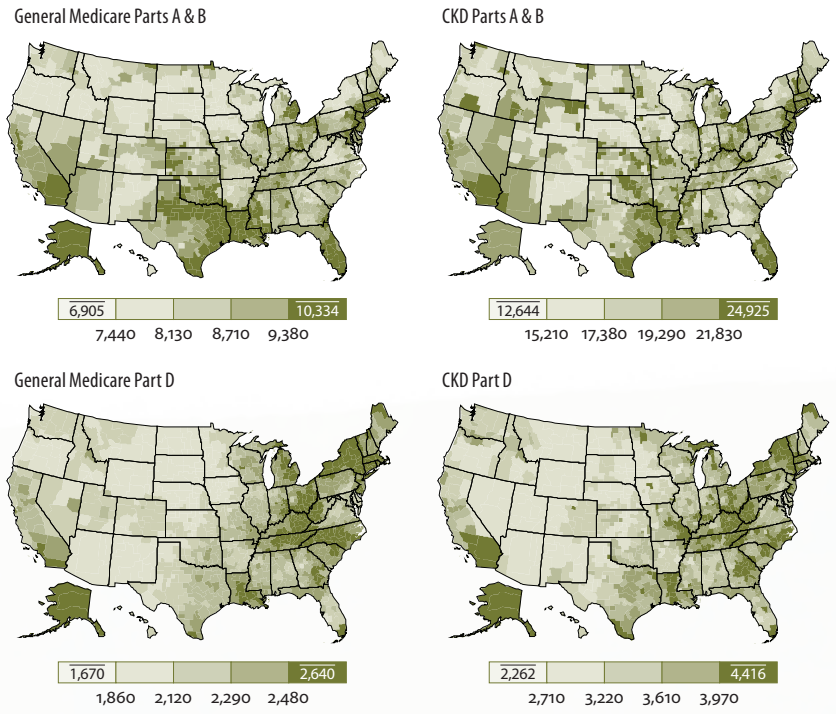
At $4,255, the per person per year (PPPY) total cost of medications covered by Medicare Part D is 1.74 times higher in CKD patients than in the general Medicare population. Proportional to total Part D costs, however, out-of-pocket costs are lower in CKD patients, representing 17 percent of their PPPY costs compared to 19 percent for the general Medicare population. There is little variation in total Medicare Part D or out-of-pocket costs across CKD stages. » Figure 5.12; see page 126 for analytical methods. *Medicare patients surviving 2007 with Medicare as primary payor & enrolled in Part D. Medicare PPPY: sum of Medicare payment & low income subsidy. Out-of-pocket: sum of patient payment & other qualifying amounts.*

PPPY total costs for Part D-covered medications in 2008 were 3.3–3.8 times greater for LIS patients than for those without LIS. Costs in LIS and non-LIS patients vary from $3,694 and $978 PPPY, respectively, in the general Medicare population to $5,451 and $1,672 among patients with CKD, and to $6,674 and $2,043 among those on dialysis. » Figure 5.13; see page 126 for analytical methods. *Medicare patients surviving 2007 with Medicare as primary payor & enrolled in Part D, & period prevalent dialysis patients, 2008, with Medicare as primary payor. Medicare PPPY: sum of Medicare payment & low income subsidy.*

5.b.i Total per person per year (PPPY) Medicare part D costs (dollars) for enrollees, by CKD stage & low income subsidy (LIS) status, 2008

	Gen Medicare		All CKD		585.1–2		585.3		585.4–5		Unk/unspec	
	LIS	No LIS	LIS	No LIS	LIS	No LIS	LIS	No LIS	LIS	No LIS	LIS	No LIS
All	3,694	978	5,451	1,672	5,680	678	5,734	655	5,479	745	5,287	672
20-44	4,287	1,089	7,629	1,959	8,343	1,999	8,045	2,147	9,833	121	7,031	516
45-64	4,818	1,209	7,377	2,234	7,231	1,050	7,919	763	7,040	975	7,256	924
65-74	3,019	895	5,460	1,776	5,493	628	5,861	740	5,436	824	5,258	726
75+	3,090	1,020	4,553	1,567	4,589	662	4,705	597	4,744	696	4,441	623
Male	3,674	955	5,588	1,682	6,113	601	5,964	600	5,396	685	5,380	606
Female	3,707	995	5,369	1,662	5,367	771	5,601	721	5,522	811	5,230	746
White	3,042	812	5,717	1,693	6,315	700	5,919	678	5,803	775	5,535	691
Af Am	3,969	997	4,927	1,430	4,666	528	5,553	428	4,652	473	4,759	442
Other race	3,263	820	4,979	1,514	4,891	523	5,164	575	5,760	747	4,694	618

5.14.i Geographic variations in Parts A & B & Part D PPPY costs (dollars) in general Medicare & CKD patients, by HSA, 2008



General Medicare and CKD Part A and Part B per person per year costs show similar geographic patterns and are highest in areas of Texas, Mississippi, California, and Florida. CKD Part A and B costs are twice those found in general Medicare patients, averaging $24,925 and $10,334, respectively, in the upper quintile. Similar geographic cost patterns exist as well for Part D patients. CKD Part D costs in the upper quintile average $4,416, compared to $2,640 for general Medicare Part D; costs for both populations tend to be highest in Alaska, parts of California and Appalachia, and areas in New England.
» **Figure 5.14;** see page 126 for analytical methods. *Medicare patients surviving 2007 with Medicare as primary payor & enrolled in Part D. Medicare PPPY: sum of Medicare payment & low income subsidy.*

Total per person per year (PPPY) Medicare Part D costs vary widely between those with and without LIS. Overall, there is less variation by CKD stage and gender (except for patients with Stage 1–2 CKD and LIS, in whom costs are lower for women) and more by age and race. Because they are Medicare-enrolled due to disability, patients younger than 65 have higher Part D costs than older patients of the same CKD stage. By race, and regardless of LIS status, PPPY costs in the Medicare population are highest for African Americans, and in the CKD population are highest for whites.
» **Table 5.b;** see page 126 for analytical methods. *Medicare patients surviving 2007 with Medicare as primary payor & enrolled in Part D. Medicare PPPY: sum of Medicare payment & low income subsidy.*

ICD-9-CM CODES

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**In USRDS analyses, patients with ICD-9-CM code 585.6 are considered to have code 585.5; see Appendix A for details.*

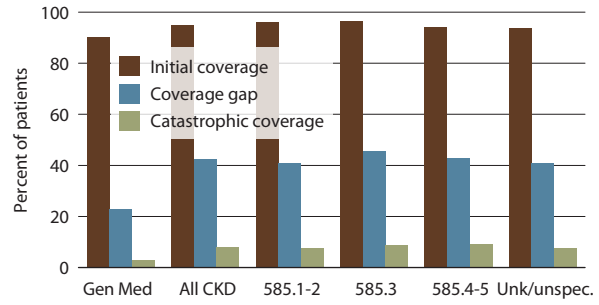
CKD stage estimates are from a single measurement. For clinical case definition, abnormalities should be present ≥ 3 months.

Part D enrollees without the low income subsidy (LIS) may encounter three coverage phases, depending on total and out-of-pocket costs per year. In 2008, patients with total Part D drug costs up to $2,510 fell into the initial coverage phase, while those with costs over that amount entered the coverage gap ("donut hole"), in which they were responsible for 100 percent of drug costs. Patients whose out-of-pocket total reached $4,050 then entered the catastrophic coverage phase, in which they paid only a fraction of overall drug costs.

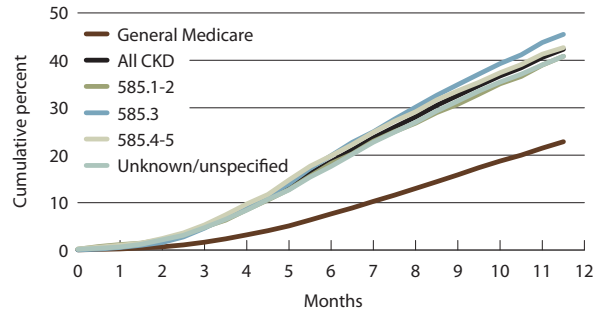
In 2008, 42 percent of all CKD patients (those not on dialysis) reached the coverage gap, compared to 23 percent in the general Medicare population; this varied little by CKD stage. Eight percent reached catastrophic coverage, compared to 3 percent of general Medicare patients.

Patients with Stage 3 CKD reach the coverage gap slightly sooner, on average, than those with CKD of other stages, while general Medicare patients take the longest. And 18–21 percent of CKD patients who reach the coverage gap subsequently attain catastrophic coverage, compared to 12.5 percent of general Medicare patients. Patients with Stage 4–5 CKD reach catastrophic coverage slightly faster than do patients in the earlier stages of CKD, and patients with CKD of any stage reach this coverage considerably faster than general Medicare patients. » Figures 5.15–17; see page 126 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in employer-sponsored & national PACE Part D plans.*

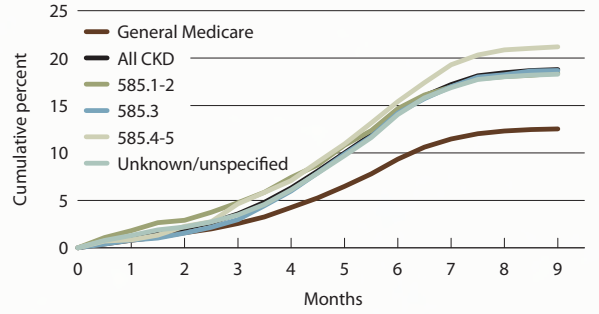
5.15i Part D non-LIS enrollees who reach each coverage phase, by CKD stage, 2008



5.16i Cumulative percent of Part D non-LIS enrollees who reach the coverage gap, by CKD stage, 2008



5.17i Cumulative percent of Part D non-LIS enrollees who reach catastrophic coverage after reaching the coverage gap, by CKD stage, 2008



prescription drug coverage in CKD patients
COVERAGE PHASE ANALYSES FOR PART D ENROLLEES

5 Ci Twelve-month probability of reaching the coverage gap in Part D non-LIS enrollees, by CKD stage, 2008

	Gen Med	All CKD	585.1–2	585.3	585.4–5	Unk/unspec
All	22.9	42.4	40.9	45.5	42.7	40.9
45-64	28.4	43.8	46.9	46.1	44.4	42.1
65-74	19.8	43.8	40.9	48.9	45.6	41.0
75+	25.3	41.6	40.5	43.6	41.4	40.7
Male	21.6	40.8	40.5	43.6	40.4	39.5
Female	23.8	43.8	41.2	47.4	44.7	42.1
White	23.5	43.3	41.8	46.3	43.6	41.8
African American	16.5	30.7	34.4	35.3	30.8	27.2
Asian	14.5	39.0	23.1	50.0	57.9	31.5
Other	17.8	37.4	27.3	38.8	40.7	37.5
Hypertension	33.0	43.8	41.7	46.6	43.2	42.8
CVD	37.4	45.0	45.2	48.3	43.9	43.6
Diabetes	42.1	50.3	49.1	54.8	48.4	48.5
Cancer	33.1	39.4	47.6	42.7	42.1	36.6
Fills per month in 2007						
<2 per month	7.2	15.7	14.4	18.3	18.4	14.4
2-<4	26.4	33.7	30.1	34.9	33.0	33.8
4-<6	45.3	49.5	53.2	52.5	43.9	48.8
6+	68.0	69.5	73.7	71.5	63.9	69.4

Across CKD stages, 40–46 percent of non-LIS Part D enrollees reach the coverage gap within 12 months; this varies little by age or gender. In the general Medicare population, white patients are more likely to reach the gap. This is true in the overall CKD population as well, but for Stage 3–5 CKD patients the probability is highest among Asians, and lowest in African Americans. By comorbidity, patients with diabetes reach the gap at a higher rate than do those with other diagnoses. Not surprisingly, the likelihood of reaching the gap rises with the number of prescription fills per month in the previous year. » **Table 5.c;** see page 126 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in employer-sponsored & national PACE Part D plans.*

5 di Rate of Part D-covered prescription fills per person per month in Part D non-LIS enrollees, by CKD stage, 2008

	Gen Med	All CKD	585.1–2	585.3	585.4–5	Unk/unspec
Patients who do not reach the coverage gap	1.96	3.09	2.89	3.19	3.54	2.98
Patients who reach coverage gap, but not catastrophic coverage						
During initial coverage period	4.55	5.45	5.19	5.42	5.68	5.46
During coverage gap	4.49	5.35	5.17	5.25	5.53	5.40
Patients who reach catastrophic coverage						
During initial coverage period	6.83	7.97	8.00	7.92	7.60	8.10
During coverage gap	7.27	8.30	8.46	8.20	7.83	8.48
During catastrophic coverage	7.50	8.77	8.94	8.88	8.72	8.69

Number, fill rate, and prescription cost influence whether patients stay in the initial coverage phase or progress to the coverage gap and then to catastrophic coverage. Among CKD patients who reach the initial coverage phase or coverage gap, the fill rate rises monotonically from Stages 1–2 to Stages 4–5. In patients reaching catastrophic coverage, however, the rate decreases monotonically with CKD stage.

Among patients who reach the coverage gap, the fill rate consistently declines from that of the initial coverage period. This could be due either to a reduction in medication adherence or to a decision to obtain medications outside the Part D plan, and it is a pattern not seen in patients who reach catastrophic coverage. In these patients, the fill rate rises as patients move from initial coverage to the gap, and then again as they reach catastrophic coverage. Patients with a higher number of Part D medications could be incentivized to fill prescriptions in order to reach this phase more quickly, as their out-of-pocket expenses then decrease dramatically. » **Table 5.d;** see page 126 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in employer-sponsored & national PACE Part D plans.*

ICD-9-CM CODES

585.1	Chronic kidney disease, Stage 1
585.2	Chronic kidney disease, Stage 2 (mild)
585.3	Chronic kidney disease, Stage 3 (moderate)
585.4	Chronic kidney disease, Stage 4 (severe)
585.5	Chronic kidney disease, Stage 5 (excludes 585.6: Stage 5, requiring chronic dialysis.*)
	Chronic kidney disease, unknown/unspecified

**In USRDS analyses, patients with ICD-9-CM code 585.6 are considered to have code 585.5; see Appendix A for details.*

CKD stage estimates are from a single measurement. For clinical case definition, abnormalities should be present ≥ 3 months.

In terms of frequency of use, the top 15 drugs covered by Medicare Part D are similar in the general Medicare and CKD populations. Furosemide, for example, is the most frequently used drug in the CKD population, and fifth on the list for general Medicare patients. Two drugs — hydrochlorothiazide and metformin — appear in the top 15 for general Medicare patients, but not for CKD patients, in whom furosemide (a loop diuretic) has a more potent diuretic effect, and metformin is contraindicated secondary to the increased risk of lactic acidosis. Carvedilol, allopurinol, and atenolol, in contrast, make the list only for CKD patients. Interestingly, potassium chloride is one of the most frequently used medications in the CKD population, which may indicate a more aggressive use of diuretics in these patients.

When ranked by net cost, the list of medications used in the general Medicare population contains more psychiatric drugs than do the lists for CKD patients. Epoetin alfa, in contrast, appears only in the CKD lists. Regardless of CKD stage, the highest net costs in the CKD population are for insulin, reflecting both the high prevalence of diabetes in these patients and the fact that many new insulin therapies are still under patent and not available as generics. » **Tables 5.e–g;** see page 126 for analytical methods. *Part D claims for all patients in the Medicare 5 percent sample (claims & costs scaled up by a factor of 20 to estimate totals). Costs are the sum of Medicare payment & low income subsidy. All patients in the Medicare 5 percent sample (5.e). CKD Stage 1–2 (5.f) & CKD Stage 3–5 (5.g) Medicare patients, with Medicare as primary payor for calendar year 2007; all Part D claims for calendar year 2008 are included.*

5ei Top 15 drugs used in general Medicare Part D enrollees, by frequency & net cost, 2008

By frequency Generic name	Number of claims (total days supply)	By net cost Generic name	Number of claims (total days supply)	Total cost (dollars)
Levothyroxine	1,225,172,540	Atorvastatin	715,616,280	1,689,949,868
Metoprolol	1,185,946,920	Clopidogrel bisulfate	503,434,240	1,623,624,733
Simvastatin	1,110,441,360	Insulin	430,389,280	1,462,130,302
Lisinopril	1,109,528,540	Quetiapine	173,723,800	1,313,634,585
Furosemide	834,425,200	Olanzapine	86,212,560	1,226,233,408
Amlodipine	751,541,500	Esomeprazole	272,699,040	1,155,414,751
Atorvastatin	715,616,280	Donepezil	222,360,480	960,019,158
Atenolol	697,444,000	Fluticasone/salmeterol	184,390,060	934,809,565
Hydrochlorothiazide	690,887,100	Risperidone	123,939,200	893,321,411
Metformin	681,207,820	Pioglitazone	188,373,800	801,123,887
Potassium chloride	632,254,340	Aripiprazole	52,034,300	758,493,924
Omeprazole	604,076,240	Lansoprazole	172,437,720	757,764,448
Warfarin	521,725,860	Oxycodone Hcl	92,118,120	665,977,548
Clopidogrel bisulfate	503,434,240	Pantoprazole	215,815,240	597,458,072
Insulin	430,389,280	Divalproex	117,348,180	595,811,168

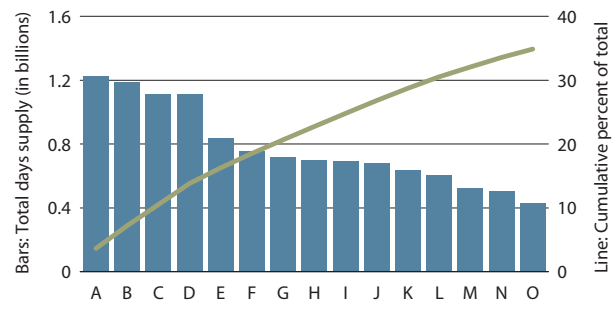
5fi Top 15 drugs used in general Medicare Part D enrollees with Stage 1–2 CKD, by frequency & net cost, 2008

By frequency Generic name	Number of claims (total days supply)	By net cost Generic name	Number of claims (total days supply)	Total cost (dollars)
Furosemide	2,817,380	Insulin	1,581,320	6,368,182
Metoprolol	2,518,320	Clopidogrel bisulfate	1,211,480	4,295,143
Levothyroxine	1,918,480	Atorvastatin	1,226,340	3,295,077
Simvastatin	1,810,660	Epoetin alfa	94,680	3,218,843
Amlodipine	1,802,720	Olanzapine	208,580	3,047,066
Lisinopril	1,703,520	Pioglitazone	564,400	2,751,017
Insulin	1,581,320	Esomeprazole	480,360	2,301,388
Potassium chloride	1,520,580	Oxycodone	183,600	2,293,847
Atorvastatin	1,226,340	Quetiapine	373,980	2,267,263
Clopidogrel bisulfate	1,211,480	Donepezil	440,780	2,264,634
Omeprazole	1,187,340	Lenalidomide	11,840	2,180,317
Warfarin	1,047,620	Bosentan	15,000	1,889,414
Carvedilol	790,840	Fluticasone/salmeterol	293,740	1,712,539
Allopurinol	781,500	Lansoprazole	338,880	1,596,808
Atenolol	755,980	Pantoprazole	479,320	1,574,168

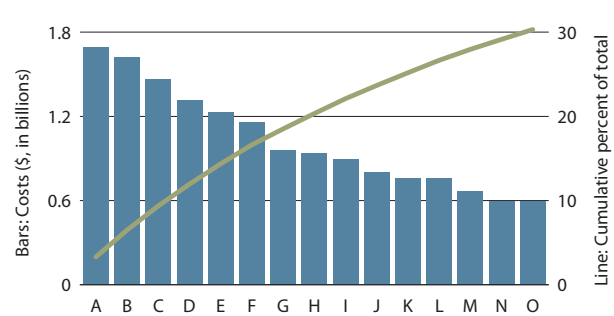
5gi Top 15 drugs used in general Medicare Part D enrollees with Stage 3–5 CKD, by frequency & net cost, 2008

By frequency Generic name	Number of claims (total days supply)	By net cost Generic name	Number of claims (total days supply)	Total cost (dollars)
Furosemide	27,289,280	Insulin	16,384,020	61,164,340
Metoprolol	22,685,680	Clopidogrel bisulfate	11,821,660	39,430,800
Levothyroxine	18,963,740	Atorvastatin	11,813,340	30,251,640
Amlodipine	16,757,980	Epoetin alfa	696,000	21,252,860
Insulin	16,384,020	Pioglitazone	4,619,960	20,300,120
Lisinopril	15,731,220	Esomeprazole	4,437,660	19,314,500
Simvastatin	15,666,800	Fluticasone/salmeterol	2,802,100	15,066,980
Potassium chloride	12,087,080	Donepezil	3,113,740	14,227,260
Clopidogrel bisulfate	11,821,660	Pantoprazole	4,542,080	13,250,320
Atorvastatin	11,813,340	Quetiapine	1,992,100	13,135,020
Warfarin	10,743,680	Lansoprazole	2,753,300	12,599,460
Allopurinol	10,006,460	Olanzapine	891,580	12,129,340
Omeprazole	9,686,280	Valsartan	6,263,760	11,353,040
Carvedilol	9,179,120	Tamsulosin	4,596,400	10,236,720
Atenolol	7,522,160	Omeprazole	9,686,280	9,584,160

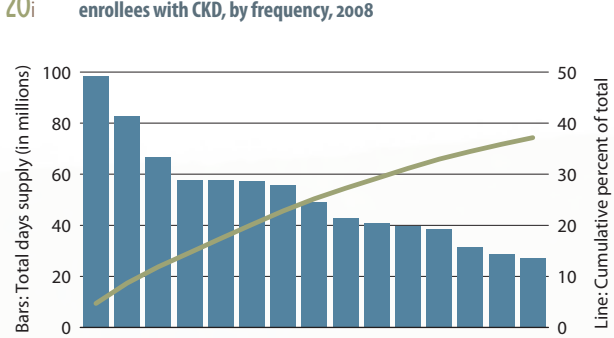
5.18i **Top 15 drugs in general Medicare Part D enrollees, by frequency, 2008**



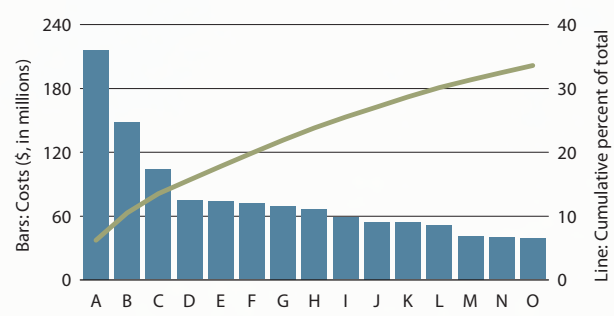
5.19i **Top 15 drugs in general Medicare Part D enrollees, by cost, 2008**



5.20i **Top 15 drugs in Medicare Part D enrollees with CKD, by frequency, 2008**



5.21i **Top 15 drugs in Medicare Part D enrollees with CKD, by cost, 2008**



As measured by total days supply, insulin therapies represented 2.8 percent of Part D drug use among CKD patients in 2008, but 6.2 percent of their Part D costs — the same relative proportion seen in general Medicare patients, where insulin therapies represented 1.3 percent of Part D drug use and 2.9 percent of costs. This suggests that CKD patients are being prescribed branded insulin therapies at about the same rate as their general Medicare counterparts. The same is true of clopidogrel, accounting for 2.1 percent of Part D use in the CKD population, and 1.5 percent among general Medicare patients.

Epoetin alfa, used for anemia treatment in CKD patients, accounted for 2.1 percent of their total Part D costs in 2008. This may represent CKD patients who are self-administering epoetin alfa at home, rather than having it administered in a doctor's office, where billing would be covered under Medicare Part B rather than Part D.

Furosemide, metoprolol, and levothyroxine were the top three drugs, as measured by total days supply, in the identified CKD population in 2008; they accounted for nearly 12 percent of total Part D drug use in this population. The top 15 drugs represented 37 and 34 percent of Part D use and costs in these patients, similar to the 35 and 30 percent seen in general Medicare patients. » Figures 5.18–21; see page 126 for analytical methods. *Part D claims for all patients in the Medicare 5 percent sample (5.18–19). Medicare CKD patients with Medicare as primary payor for calendar year 2007; includes Part D claims for calendar year 2008 (5.20–21). Cumulative percentage is the percentage of all Part D, & costs are the sum of Medicare payment & low income subsidy. Claims & costs scaled up by a factor of 20 to estimate totals.*

Sources of prescription drug coverage among Medicare enrollees, 2008

Part D with low income subsidy » General Medicare 22% » CKD 30% » ESRD 48% (Fig 5.1)

Part D without low income subsidy » General Medicare 36% » CKD 28% » ESRD 19% (Fig 5.1)

Retiree drug subsidy » General Medicare 15% » CKD 21% » ESRD 8% (Fig 5.1)

Medicare Part D enrollees with low income subsidy, 2008

» General Medicare 38% » CKD 51% » Dialysis 73% » Transplant 64% (Fig 5.5)

Total estimated Medicare Part D net payment for enrollees, 2008

» General Medicare $51 billion » CKD $3.5 billion » ESRD $1.6 billion (Fig 5.11)

Per person per year Part D costs for enrollees, 2008

Medicare costs » General Medicare $1,985 » CKD $3,547 (Fig 5.12)

Out-of-pocket costs » General Medicare $459 » CKD $708 (Fig 5.12)

Per person per year Medicare Part D costs for enrollees, 2008

Patients with low income subsidy » General Medicare $3,694 » CKD $5,451 » Dialysis $6,674 (Fig 5.13)

Patients with no low income subsidy » General Medicare $978 » CKD $1,672 » Dialysis $2,043 (Fig 5.13)

Part D non-LIS enrollees who reach the coverage gap, 2008

At 11.5 months » General Medicare 23% » All CKD 42% » Stage 3 CKD 45% (Fig 5.16)

Part D non-LIS enrollees who reach catastrophic coverage after reaching the coverage gap, 2008

At 9 months » General Medicare 13% » All CKD 19% » Stage 3 CKD 19% (Fig 5.17)

Terms used in the Part D analyses

Low income subsidy (LIS) For Medicare beneficiaries with limited income and/or assets, the costs of participation in Medicare Part D may be reduced by the LIS. Beneficiaries who are dually eligible for Medicare and Medicaid are automatically granted the LIS, while beneficiaries who are not dually eligible may apply for it. While the LIS may take eight different levels, with monthly premiums and copayments either eliminated or reduced, all dually eligible beneficiaries pay no monthly premiums.

Creditable coverage Prescription drug coverage that is actuarially equivalent to the standard Part D benefit, as defined annually by CMS. Beneficiaries with creditable coverage may forgo participation in Medicare Part D without having to pay increased monthly premiums upon future enrollment. Examples of creditable coverage include the Federal Employee Health Benefits Program, TRICARE, VA Health Care Benefits, State Pharmacy Assistance Programs (SPAPs), and private insurance that is eligible for the retiree drug subsidy. Private insurance for the working aged may or may not be creditable.

Retiree drug subsidy (RDS) A program designed to encourage employers to continue to provide prescription drug coverage to retirees eligible for Medicare Part D. Under the program, employers receive a tax-free rebate equal to 28 percent of covered prescription drug costs incurred by their retirees. The program is relatively simple to administer, but may ultimately be more costly than providing employees a type of Part D plan known as an "employer group waiver plan." Following passage of the Patient Protection and Affordable Care Act, the tax-free status of the subsidy is due to expire on December 31, 2012.

Fills per person Each prescription drug purchase constitutes a fill. Fills per person are calculated from the quotient of cumulative fills in a population and the number of people in that population.

Total days supply Each prescription drug is disbursed with sufficient quantity to administer for a set number of days, so long as instructions are followed (i.e., so long as adherence is perfect). Total days supplied equals the cumulative number of days supplied through all fills of a particular medication in a population.

Deductible At the beginning of each calendar year, each non-LIS Part D enrollee is responsible for 100 percent of gross drug costs up to a set amount (i.e., the deductible), at which point cost sharing begins. In the standard benefit, the deductible was $250, $265, and $275 in 2006, 2007, and 2008, respectively.

Initial coverage period The interval following the deductible phase, but preceding the coverage gap. During this time, the Part D enrollee without the LIS is normally responsible for 25 percent of gross drug costs (in the standard benefit).

Coverage gap The interval following the initial coverage period, but preceding catastrophic coverage. During this time, non-LIS Part D enrollees are normally responsible for 100 percent of gross drug costs (in the standard benefit). In 2010, the Affordabl e Health Care Act made several changes to Medicare Part D to reduce the effect of the coverage gap, so that it phases out by 2020. In 2010, non-LIS enrollees received a $250 rebate from Medicare to partially cover costs during the coverage gap. In 2011, non-LIS enrollees were given a 50 percent discount on the total price of brand name drugs and a 7 percent reduction in cost of generic medications while in the gap.

Catastrophic coverage The interval following the coverage gap. During this time, the Part D enrollee without the LIS is normally responsible for 5 percent of gross drug costs (in the standard benefit).

Medicare Advantage Part D plans (MA-PDs) Medicare Part D plans that are offered only to participants in Medicare Part C.