



*Grand Canyon National Park, Arizona*

**PART D PRESCRIPTION DRUG COVERAGE IN ESRD PATIENTS**

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Of the almost 50 million Medicare beneficiaries (eligible because of age, disability, or ESRD) over 28 million were enrolled in a Medicare Part D plan in December, 2010. Before 2006, patients enrolled in Medicare 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. Sixty percent of general Medicare patients, and 69 percent of Medicare-covered ESRD patients, were enrolled in Part D in 2010, with enrollment at 74, 64, and 56 percent in the hemodialysis, peritoneal dialysis, and transplant populations, respectively.

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. ESRD patients 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 ESRD 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.

The proportion of Medicare-covered ESRD patients with no known source of drug coverage is highest in the peritoneal dialysis and transplant populations. Given that many of these patients are employed, it is likely that some have sources of prescription drug coverage not tracked by Medicare.

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”).

Compared to the 37 percent of Part D-enrolled general Medicare patients receiving LIS benefits, higher proportions (73, 63, and 61 percent, respectively) of hemodialysis, peritoneal dialysis, and transplant patients qualify for the LIS. By race, white dialysis patients are the least likely and blacks/African Americans, Hispanics, and patients of other races the most likely to have LIS benefits.

Not surprisingly, cardiovascular agents comprise three of the five most frequently prescribed Part D medication classes in dialysis patients. Phosphate binders are first in terms of both frequency of use and net costs, as sevelamer carbonate and hydrochloride are not available in generic form.

In 2010, Medicare-covered Part D costs for hemodialysis, peritoneal dialysis, and transplant patients ranged from \$4,961 to \$5,537 per person per year. Between 2007 and 2010, total net payments grew 42 and 38 percent, respectively, for hemodialysis and peritoneal dialysis patients, compared to only 25 percent for general Medicare patients; for kidney transplant patients, in contrast, growth was only 16 percent.

In the Grand Canyon, Arizona has a natural wonder which, so far as I know, is in kind absolutely unparalleled throughout the rest of the world. Keep this great wonder of nature as it is. You cannot improve it. The ages have been at work on it, and man can only mar it.

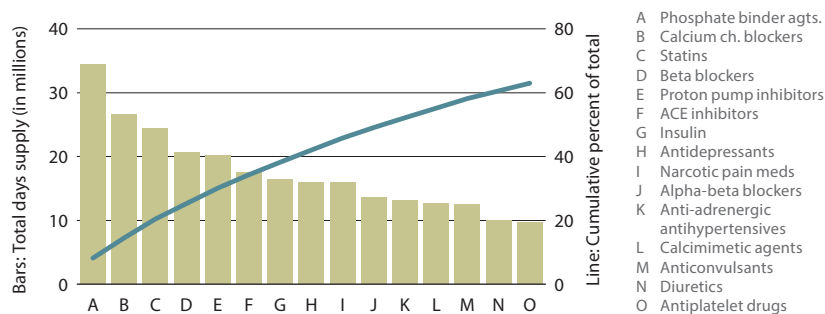
THEODORE ROOSEVELT,  
impromptu speech at the Grand  
Canyon on May 6, 1903

Although the percentage increase in Part D enrollment between 2007 and 2010 was similar between general Medicare and dialysis patients, more dialysis patients receive the LIS, making each patient, on average, more expensive to Medicare. Part D costs for hemodialysis and peritoneal dialysis patients with the LIS were \$7,366 and \$8,651 per patient per year in 2010, respectively, compared to \$3,985 for general Medicare patient with the LIS.

For Medicare-enrolled patients, the Medicare Part D program works in concert with Medicare Part B, which covers medications administered in physician offices (e.g., erythropoiesis stimulating agents (ESAs) in CKD patients), those administered during hemodialysis (e.g., ESAs, intravenous vitamin D and iron products, IV antibiotics, and resuscitative medications), and most immunosuppressant medications required in the three-year period following a Medicare-covered kidney transplant. Medicare-covered transplant patients lose eligibility for Part B benefits after three years, but, if they become Medicare-eligible due to age or disability, they become eligible for lifetime Part B immunosuppressant coverage. Patients with a kidney transplant 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, but coverage depends on whether the drug is included on the plan formulary.

In 2010, per person per year (PPPY) combined Part B and Part D costs reached \$15,300, \$12,700, and \$11,900 for Medicare Part D-covered hemodialysis, peritoneal dialysis, and transplant patients with the LIS, compared to \$7,700, \$5,400, and \$5,400 for their non-LIS counterparts. From 2009 to 2010, PPPY Part B costs fell for all ESRD patients, likely due in part to a decline in ESA use, to the new availability of several generic products for mycophenolate and tacrolimus, and to shifts in tier placement for some Part D medications. Part D PPPY costs continued to increase in both hemodialysis and peritoneal dialysis patients with and without the LIS, but fell in transplant patients with the LIS. » **Figure 6.1;** see page 439 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, 2010. Therapeutic classification based on the Medi-Span's generic product identifier (GPI) therapeutic classification system.*

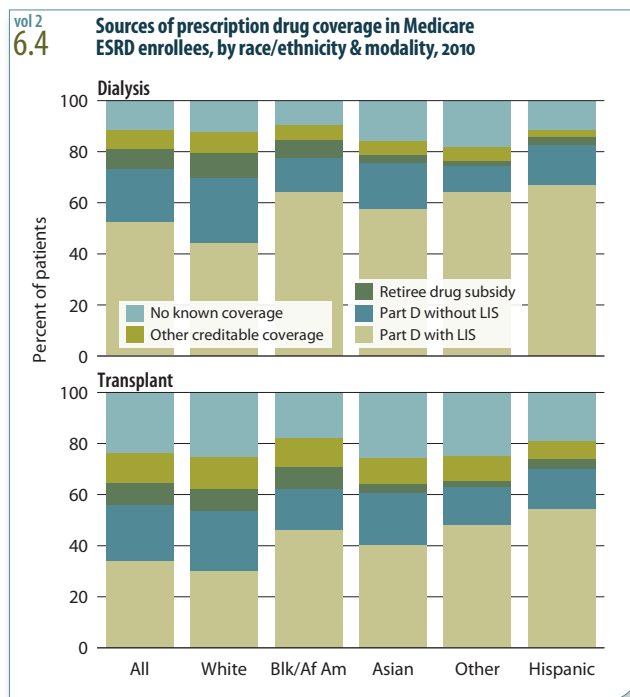
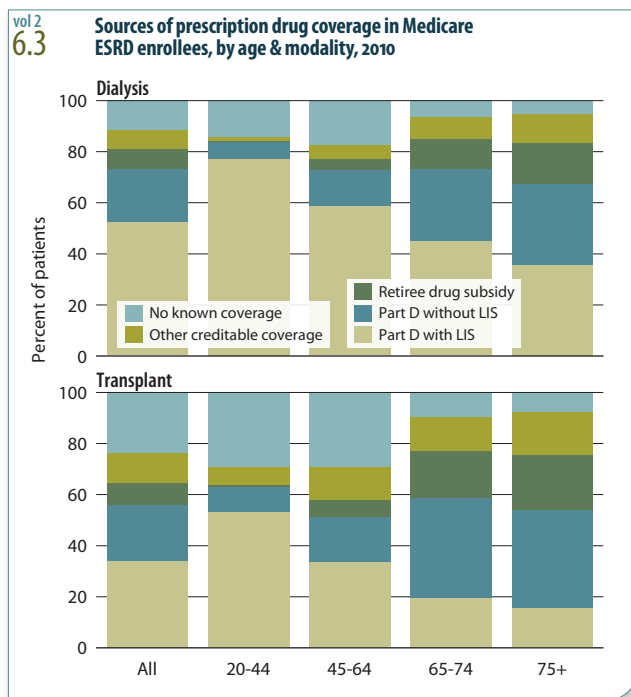
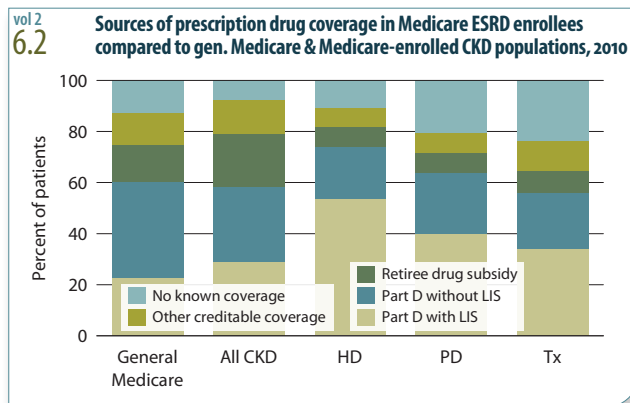
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**6.1** Top 15 drug classes used by Part D-enrolled dialysis patients, by days supply, 2010



Terms used in the Part D analyses are described at the end of this chapter. Comparisons to the overall ESRD population can be found in Volume One, Chapter Five.

Patients with Medicare coverage can enroll in Medicare Part D for prescription drug coverage. Seventy-seven and 64 percent of hemodialysis and peritoneal dialysis patients were enrolled in Part D in 2010, compared to 56–60 percent of general Medicare patients (with or without CKD) and transplant patients.

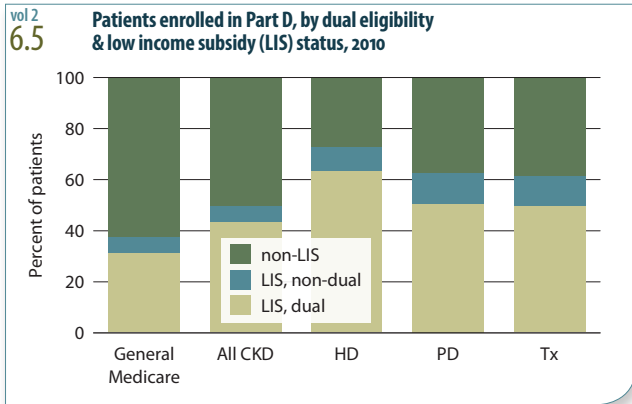
Compared to general Medicare and CKD patients enrolled in Part D, a higher proportion of Part D-enrolled hemodialysis, peritoneal dialysis, and transplant patients (73, 63, and 61 percent compared to 37–50 percent) receive the low-income subsidy (LIS). A higher percentage of patients on peritoneal dialysis or with a transplant have no known prescription drug coverage, but many of these patients are employed and may have coverage that is not tracked by Medicare. » **Figure 6.2**; see page 439 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, 2010.*



Sources of prescription drug coverage in ESRD patients vary widely by age and race. In each age category, for example, transplant patients are markedly less likely than those on dialysis to receive the low income subsidy (LIS). Younger patients on either modality have the highest Part D enrollment, and the monotonic decrease with age in the percentage of patients with the LIS is striking — three in four dialysis patients age 20–44 with Part D receive LIS assistance, in contrast to just 36 percent of patients age 75 and older.

By race, the proportion of dialysis patients enrolled in Part D varies from 70 percent among whites to 78 and 83 percent among blacks/African Americans and Hispanics. Eighty-three

and 81 percent of blacks/African Americans and Hispanics with Part D coverage have the LIS, compared to 63 percent of whites, and blacks/African Americans treated with dialysis are the least likely to have no known prescription drug coverage. Enrollment in Part D is lowest among transplant patients, reaching 62 and 70 percent, for example, among blacks/African Americans and Hispanics compared to 78–83 percent for their counterparts on dialysis. And among transplant patients, blacks/African Americans and Hispanics are more likely to receive the LIS, at 75–77 percent compared to 56 and 67 percent among whites and Asians. » **Figures 6.3–4**; see page 439 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, 2010.*



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6.a Medicare Part D enrollees with or without the low income subsidy (LIS; percent), by age & race, 2010

	General Medicare		CKD		Hemodialysis		Peritoneal dialysis		Transplant	
	Part D w/LIS	Part D w/o LIS	Part D w/LIS	Part D w/o LIS	Part D w/LIS	Part D w/o LIS	Part D w/LIS	Part D w/o LIS	Part D w/LIS	Part D w/o LIS
<b>White</b>										
All ages	30.6	69.4	41.2	58.8	64.0	36.0	55.1	44.9	56.1	43.9
20-44	90.0	10.0	93.5	6.5	91.5	8.5	88.8	11.2	83.8	16.2
45-64	65.3	34.7	78.4	21.7	77.4	22.6	64.9	35.1	61.2	38.9
65-74	18.8	81.3	34.7	65.3	55.3	44.7	27.6	72.4	26.7	73.3
75+	25.4	74.6	36.8	63.2	42.9	57.1	21.6	78.2	21.4	78.6
<b>Black/Af Am</b>										
All ages	66.6	33.4	78.9	21.1	82.7	17.3	78.4	21.6	74.4	25.7
20-44	93.7	6.4	95.5	4.5	93.6	6.4	91.7	8.3	86.8	13.2
45-64	81.6	18.4	87.7	12.3	85.6	14.4	76.8	23.2	74.4	25.6
65-74	51.8	48.2	72.7	27.4	73.5	26.5	51.4	48.6	53.6	46.4
75+	61.4	38.6	77.5	22.5	73.5	26.5	49.0	51.0	56.7	43.3
<b>Asian</b>										
All ages	70.5	29.6	86.5	13.5	77.0	23.0	63.7	36.3	66.5	33.5
20-44	91.6	8.4	93.8	6.3	87.9	12.1	78.4	21.6	83.6	16.4
45-64	74.9	25.1	85.7	14.3	78.5	21.5	64.8	35.2	68.8	31.2
65-74	65.3	34.8	86.7	13.3	72.1	27.9	49.4	50.6	51.4	48.6
75+	73.4	26.6	86.3	13.7	75.6	24.4	58.7	41.3	55.6	44.4
<b>Other race</b>										
All ages	62.4	37.6	79.9	20.1	82.1	17.9	77.1	22.9	77.0	23.0
20-44	87.3	12.7	93.2	6.8	92.7	7.3	88.7	11.3	85.9	14.1
45-64	71.4	28.6	86.0	14.0	85.9	14.1	78.2	21.8	78.4	21.6
65-74	54.7	45.3	75.3	24.7	76.9	23.1	60.5	39.5	63.8	36.2
75+	61.0	39.0	80.0	20.0	72.0	28.0	53.9	46.1	57.3	42.7

Patients dually-enrolled in Medicaid and Medicare qualify for the LIS, and, if they do not choose a plan, are automatically enrolled in a Medicare Part D plan. Sixty-four percent of hemodialysis patients with Part D coverage are dually-eligible LIS beneficiaries, compared to 32 percent of the general Medicare population. An additional but smaller proportion of patients (6–12 percent) receive the LIS after an application documenting low income and resources.

Overall, 73 percent of Part D-enrolled hemodialysis patients received LIS benefits in 2010, compared to 63 percent of peritoneal dialysis and 61 percent

of transplant patients, 50 percent of those with CKD, and 37 percent of general Medicare patients. Within each race, receipt of the LIS generally decreases with age until age 75 and older, when an uptick is seen for general Medicare and CKD patients. In the peritoneal dialysis population, in contrast, with the exception of Asian patients, the decrease in receipt of the LIS continues to the oldest patients. Transplant patients show a reverse trend, with the percentage receiving the LIS generally increasing with age.

» **Figure 6.5 & Table 6.a;** see page 439 for analytical methods.  
*Point prevalent Medicare enrollees alive on January 1.*

CMS provides prescription drug plans (PDPs) with guidance on structuring a “standard” Part D PDP. In 2010, for example, beneficiaries shared costs with the PDP (as co-insurance or copayments) until the combined total reached \$2,830 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. New in 2010, patients reaching the coverage gap also received a \$250 rebate as a first step towards phasing out the coverage gap. In 2010, beneficiaries who obtained a yearly out-of-pocket drug cost of \$4,550 reached the catastrophic coverage phase, in which they paid only a small copayment for their drugs until the end of the year.

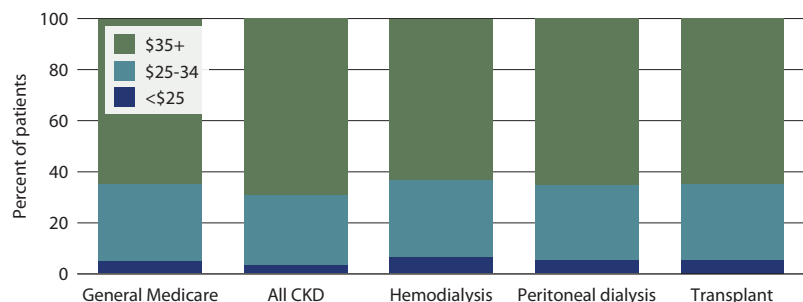
PDPs have the latitude to structure their plans differently from what is presented here; companies offering nonstandard plans must show that their coverage is at least actuarially equivalent to the standard plan. Many have developed plans with no deductibles or with drug copayments instead of the 25 percent co-insurance, and some plans provide generic and/or brand name drug coverage during the coverage gap. The website listed below contains more details on drug copayment, co-insurance, and deductible amounts for beneficiaries with full and non-full dual eligibility and with full or partial subsidies. » **Table 6.b.** *Information from <http://www.q1medicare.com/PartD-The-2010-Medicare-Part-D-Outlook.php>.*

vol 2 6.b Medicare Part D benefit parameters for defined standard benefit, 2006–2010		2006	2007	2008	2009	2010
<b>Deductible</b>	After the deductible is met, beneficiary pays 25% of covered costs up to total prescription costs meeting the initial coverage limit.	\$250	\$265	\$275	\$295	\$310
<b>Initial coverage limit</b>	Coverage gap (donut hole) begins at this point. (The beneficiary pays 100% of prescription costs up to the out-of-pocket threshold.)	\$2,250	\$2,400	\$2,510	\$2,700	\$2,830
<b>Total covered Part D drug out-of-pocket spending including the coverage gap</b>	Catastrophic coverage starts after this point.	\$5,100.00	\$5,451.25	\$5,726.25	\$6,153.75	\$6,440.00 plus a \$250 rebate
<b>Out-of-pocket threshold</b>	This is the total out-of-pocket costs including the donut hole.	\$3,600	\$3,850	\$4,050	\$4,350	\$4,550
2010 example						
	\$310 (deductible)	\$250.00	\$265.00	\$275.00	\$295.00	\$310.00
	+ (((\$2,830 – \$310) * 25%) (initial coverage)	\$500.00	\$533.75	\$558.75	\$601.25	\$630.00
	+ (((\$6,440 – \$2,830) * 100%) (coverage gap)	\$2,850.00	\$3,051.25	\$3,216.25	\$3,453.75	\$3,610.00
	= \$4,550 (maximum out-of-pocket costs prior to catastrophic coverage, excluding plan premium)	\$3,600.00	\$3,850.00	\$4,050.00	\$4,350.00	\$4,550.00
<b>Catastrophic coverage benefit</b>						
	Generic/preferred multi-source drug	\$2.00	\$2.15	\$2.25	\$2.40	\$2.50
	Other drugs	\$5.00	\$5.35	\$5.60	\$6.00	\$6.30

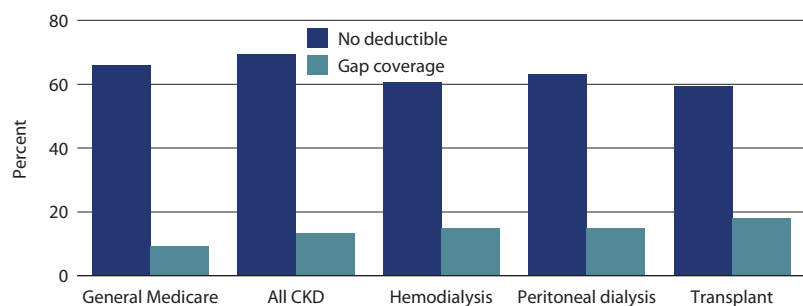
Part D enrollment increased between 2006 and 2010 in the general Medicare population and among Medicare-covered patients with identified CKD, dialysis patients, and kidney transplant patients. Growth was greatest in the peritoneal dialysis and transplant populations, at 4 and 5 percent, and lowest for CKD patients, at 1.2 percent; enrollment increased 2.7 percent for hemodialysis patients. » **Table 6.c.**; see page 439 for analytical methods. *Point prevalent Medicare enrollees alive on January 1 of each year.*

vol 2 6.c General Medicare, CKD, & ESRD patients enrolled in Part D (percent)		General Medicare	All CKD	Hemodialysis	Peritoneal dialysis	Transplant
2006		54.6	55.1	68.4	56.2	47.9
2007		57.0	57.2	71.2	59.6	51.0
2008		58.6	57.7	72.4	61.2	53.2
2009		59.8	58.2	73.2	62.2	54.8
2010		60.4	58.4	73.9	63.7	56.0

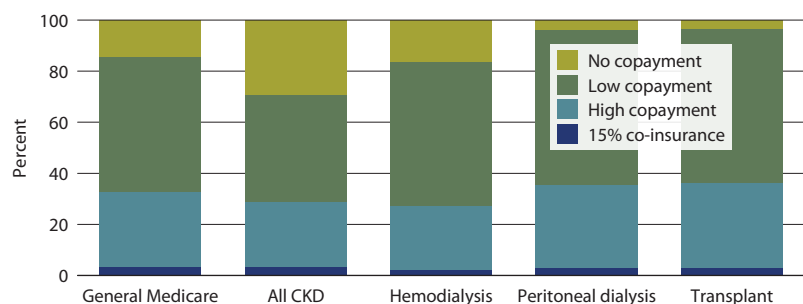
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6.6 Part D non-LIS enrollees with specified monthly premium, 2010



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6.7 Part D non-LIS enrollees with gap coverage or no deductible, 2010



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6.8 Part D LIS enrollees with specified co-insurance/copayment, 2010

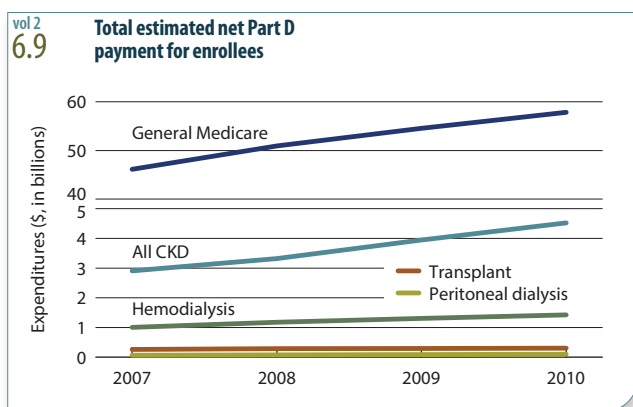


Patients without the low income subsidy (LIS) pay monthly premiums; the weighted average premium for Medicare Part D stand-alone PDPs increased from \$25.93 in 2006 to \$37.25 in 2010 (<http://facts.kff.org/>). In 2010, fewer than 6 percent of general Medicare patient and Medicare-enrolled CKD, dialysis, and transplant patients had a monthly premium below \$25, while 63–69 percent had premiums over \$35.

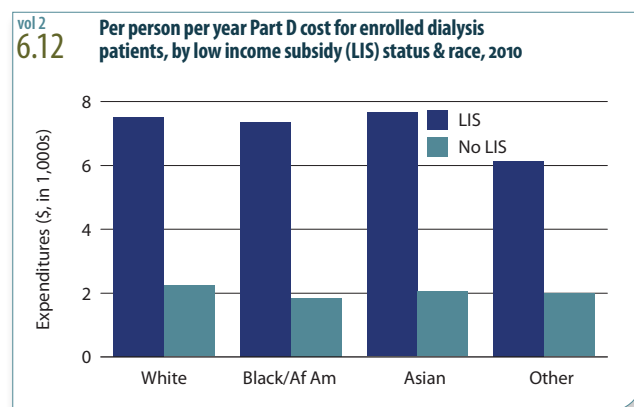
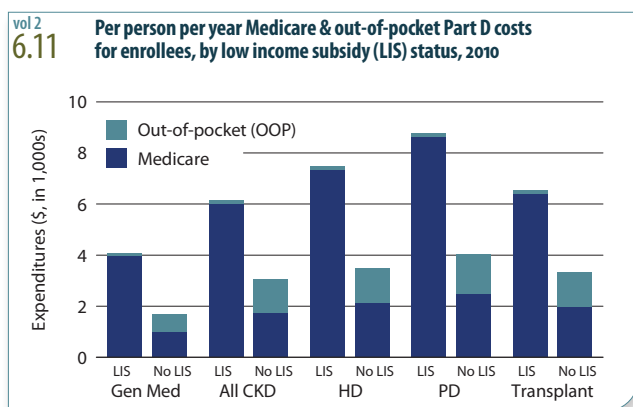
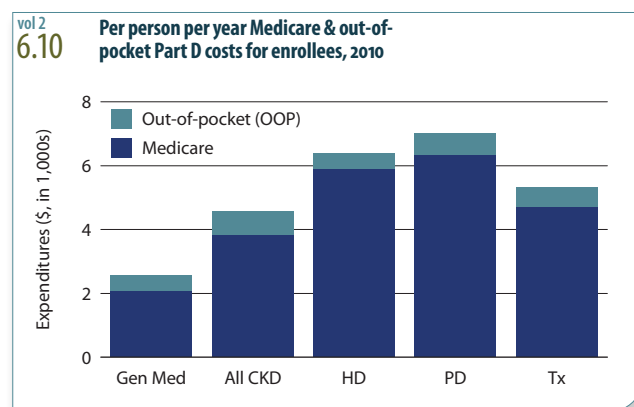
The percentage of Part D non-LIS enrollees with no deductible is higher in the general Medicare and identified CKD populations than among dialysis and transplant patients, at 66–69 compared to 59–63; the percentage of patients with no deductible has declined since 2008 (2011 USRDS ADR). In 2010, most PDPs (80 percent) did not offer gap or “donut hole” coverage (<http://www.kff.org/medicare/8008.cfm>). Gap coverage is more common among dialysis and transplant patients, at 15–18 percent compared to 9 percent in the general Medicare population.

Most Part D enrollees with the LIS (full-benefit dual-eligible patients) do not pay monthly premiums, but non-institutionalized patients with the LIS do pay drug copayments or co-insurance based on income and assets. Seventy-two percent of hemodialysis patients with the LIS have low or no copayments for their Part D medications, compared to 63–67 percent of peritoneal dialysis, transplant, and general Medicare patients; these rates are all lower than in 2008. Only 2–4 percent pay 15 percent co-insurance for their medications. Even those patients with high copayments (25–33 percent of patients in 2010) paid a maximum of just \$2.50 per generic and \$6.30 for branded medication. » **Figures 6.6–8**; see page 439 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in Medicare Advantage Part D plans.*

Total net Part D payment for patients with identified kidney disease (hemodialysis, peritoneal dialysis, and transplant patients, and CKD patients not on dialysis) was \$6.4 billion in 2010, up from \$4.2 billion in 2007, and accounting for 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. Between 2007 and 2010, Part D costs rose 16, 38, 42, and 56 percent for transplant, peritoneal dialysis, hemodialysis, and CKD patients, respectively, compared to 25 percent in the general Medicare population. » **Figure 6.9**; see page 439 for analytical methods. *All patients enrolled in Part D.*



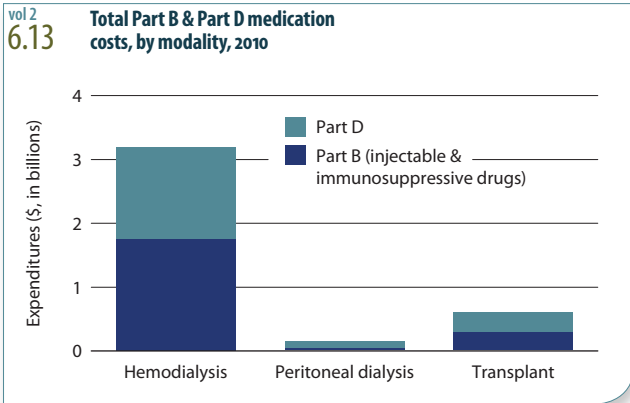
At \$4,580, \$5,326, \$6,379, and \$7,022 per person per year (PPPY) in CKD, kidney transplant, hemodialysis, and peritoneal dialysis patients, respectively, the total cost of medications covered by Medicare Part D is 1.8–2.7 times higher in CKD and ESRD patients than in the general Medicare population. Proportional to total Part D costs, however, out-of-pocket costs are lower in ESRD patients, representing 7 percent of PPPY costs for hemodialysis patients, 10 percent for peritoneal dialysis patients, and 11 percent for those with a transplant, compared to 16 percent for CKD patients and 19 percent in the general Medicare population. » **Figure 6.10**; see page 439 for analytical methods. *All patients enrolled in Part D.*



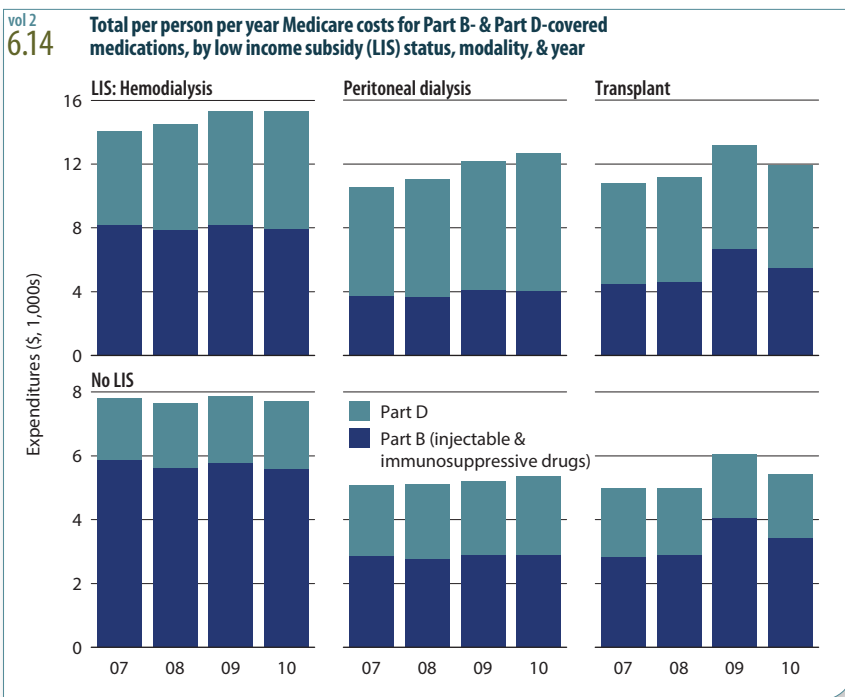
Across populations, total Part D medication costs are approximately twice as high in patients with the LIS benefit than in those without. In the LIS population, however, out-of-pocket costs represent only 2–3 percent of these total expenditures, compared to 39–43 percent in each of the non-LIS populations. Regardless of LIS status, total PPPY Part D costs are 1.8–2.4 times greater for patients with ESRD than for those in the general Medicare population. » **Figure 6.11**; see page 439 for analytical methods. *All patients enrolled in Part D.*

Among dialysis patients with LIS benefits, Part D costs per person per year are \$7,360–\$7,661 for whites, blacks/African Americans, and Asians, compared to \$6,142 for patients of other races. There is no wide variation in costs for non-LIS populations. » **Figure 6.12**; see page 439 for analytical methods. *Period prevalent dialysis patients enrolled in Part D.*





Medicare Part D covers most medications taken by ESRD patients at home, while Medicare Part B covers those administered during dialysis (e.g., erythropoiesis stimulating agents and IV vitamin D) as well as immunosuppressive medications for patients with Medicare-covered transplants. In 2010, Part D costs for ESRD patients reached \$1.83 billion, while Part B costs were \$2.12 billion. » **Figure 6.13**; see page 439 for analytical methods. *Period prevalent ESRD patients.*



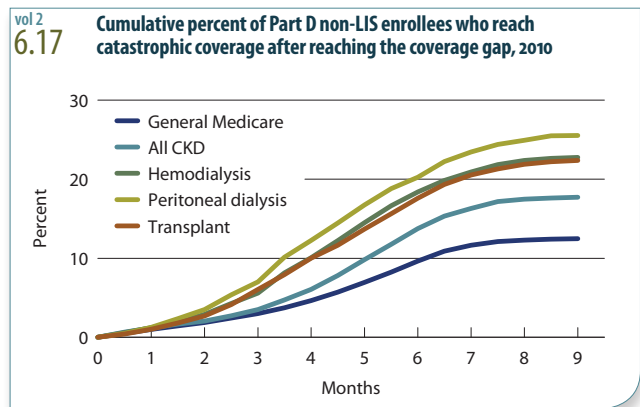
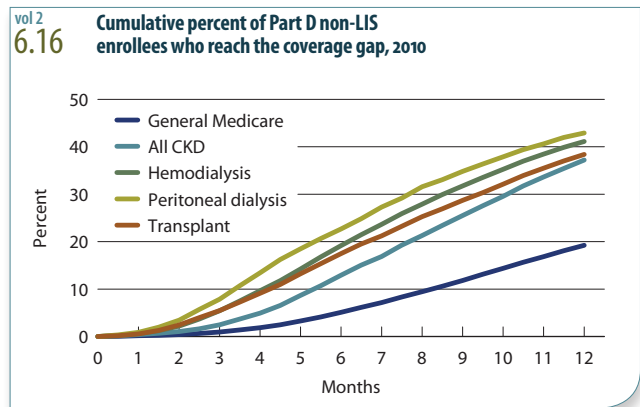
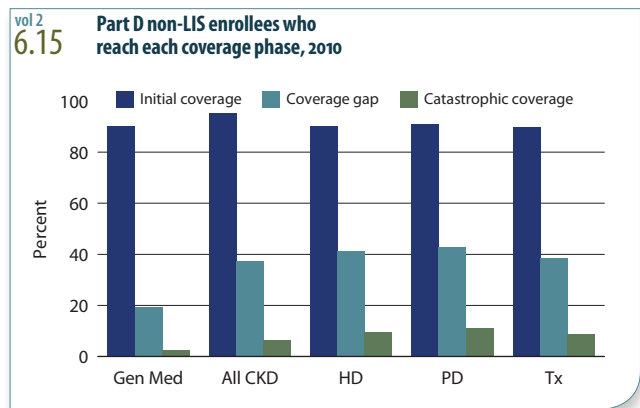
In 2010, hemodialysis, peritoneal dialysis, and kidney transplant patients with LIS benefits had combined Part B and Part D medication costs of \$15,311, \$12,724, and \$11,904 per person per year (PPPY), respectively. Regardless of LIS status, combined costs were greatest in hemodialysis patients.

Part B PPPY costs declined from 2009 to 2010 for all ESRD patients, likely due in part to a decline in the use of erythropoiesis stimulating agents, to the availability of several generic products for mycophenolate and tacrolimus that entered the market from mid-2008 through 2010, and to possible shifts in tier placement for some Part D medications. » **Figure 6.14**; see page 439 for analytical methods. *Period prevalent ESRD patients.*

Part D enrollees who do not have the low income subsidy (LIS) may encounter three coverage phases, depending on total and out-of-pocket (OOP) costs per year. In 2010, patients with total Part D drug costs up to \$2,830 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 minus a \$250 rebate given in 2010. Patients whose total OOP costs reached \$4,550 then entered the catastrophic coverage phase, in which they paid only a fraction of overall drug costs.

In 2010, 37–43 percent of non-LIS CKD, hemodialysis, peritoneal dialysis, and transplant patients reached the coverage gap, and 7–11 percent reached catastrophic coverage, compared to 19 and 2 percent, respectively, in the general Medicare population. In all populations, the percentage reaching the coverage gap and catastrophic coverage was lower in 2010 than in 2008.

On average, peritoneal dialysis patients reach the coverage gap sooner than CKD or other ESRD patients, while general Medicare patients take the longest. Twenty-two to 26 percent of ESRD patients who reach the coverage gap will subsequently attain catastrophic coverage, compared to 18 percent in the CKD population and 12.5 percent of general Medicare patients. ESRD and CKD patients thus reach catastrophic coverage much faster than do general Medicare patients. » **Figures 6.15–17;** see page 439 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in employer-sponsored & national PACE Part D plans.*



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**Twelve-month probability (percent) of reaching the coverage gap in Part D non-LIS enrollees, by modality, 2010**

	General Medicare	Hemodialysis	Peritoneal dialysis	Transplant
All	19.2	41.2	42.9	38.4
20-44	16.8	27.9	31.1	18.4
45-64	23.7	40.4	41.1	37.0
65-74	16.7	45.3	48.0	46.1
75+	21.6	39.7	42.0	38.3
Male	18.6	38.2	41.7	37.5
Female	19.7	45.7	44.6	39.8
White	19.8	43.2	44.2	39.8
Black/African American	14.2	35.3	35.9	32.4
Asian	12.9	42.3	46.4	34.5
Other	14.8	39.5	27.9	34.6
Hispanic	15.4	34.2	38.2	31.7
Hypertension	27.9	41.3	43.3	39.4
CVD	32.1	41.4	42.5	47.5
Diabetes	36.3	43.4	46.9	50.6
Cancer	28.1	41.7	49.2	47.0

The twelve-month probability of non-LIS Part D enrollees reaching the coverage gap is 38–43 percent across ESRD modalities, but varies by demographic characteristic. Patients age 20–44, males, and blacks/African Americans are the least likely to reach the gap; by comorbidity, patients with diabetes reach it at a higher rate than do those with other diagnoses. » **Table 6.d;** see page 439 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in employer-sponsored & national PACE Part D plans.*

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**Part D-covered prescription fills per person per month in Part D non-LIS enrollees, by modality, 2010**

	Hemodialysis	Peritoneal dialysis	Transplant
Patients who do not reach the coverage gap	2.60	2.74	2.76
Patients who reach coverage gap, but not catastrophic coverage			
During initial coverage period	4.82	4.74	5.39
During coverage gap	4.47	4.37	5.11
Patients who reach catastrophic coverage			
During initial coverage period	6.22	5.98	7.02
During coverage gap	6.51	6.07	7.43
During catastrophic coverage	7.02	6.78	7.97

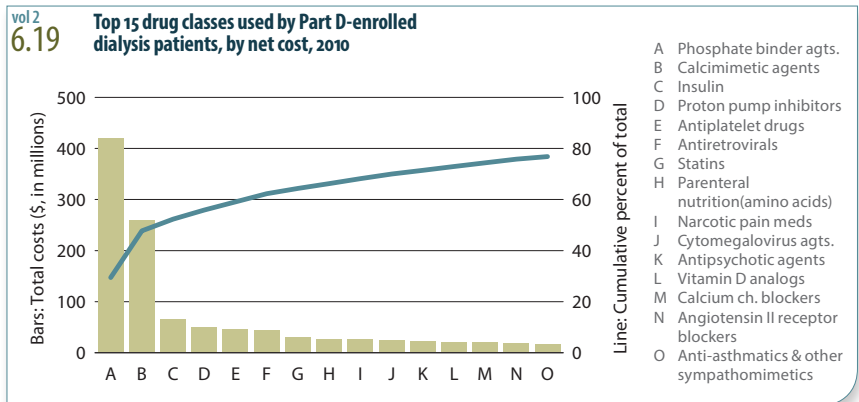
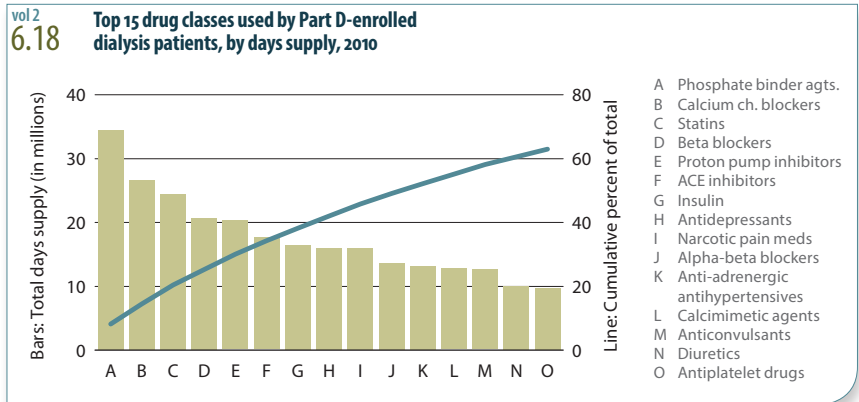
Number, fill rate, and prescription cost influence whether patients stay in the initial coverage phase or progress to the coverage gap and then to catastrophic coverage. Among those who reach one of the latter two phases, transplant patients have the highest fill rate. Among those who reach the gap but do not get to catastrophic coverage, the fill rate declines once the gap is reached. 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 each phase is reached. 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 6.e;** see page 439 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in employer-sponsored & national PACE Part D plans.*

Positioning of the top Part D medications used by dialysis patients changed between 2008 (shown in the 2011 ADR) and 2010. Amlodipine has become the most frequently used drug, after being at fourth place in 2008. Sevelamer hydrochloride has dropped off the list as use has transitioned to sevelamer carbonate, now in fourth place. Use of calcium acetate and cinacalcet increased somewhat from 2008 to 2010, while use of lanthanum carbonate has declined. Together, sevelamer carbonate and hydrochloride maintain their status as the top medications, by cost, used by dialysis patients in 2010, with cinacalcet keeping second place. Use of carvedilol has grown since 2008. As illustrated by days supply, medication use is a combination of use in the individual patient multiplied by the number of patients in the prevalent dialysis population, which continues to increase. » **Table 6.f**; see page 439 for analytical methods. *Part D claims for all dialysis patients, 2010.*

**vol 2 6.f Top 15 drugs used by Part D-enrolled dialysis patients, by days supply & net cost, 2010**

By days supply Generic name	Total days supply	By net cost Generic name	Total days supply	Total cost (dollars)
Amlodipine	19,476,423	Cinacalcet	12,948,729	260,023,205
Insulin	19,185,188	Sevelamer carbonate	15,723,597	235,623,936
Metoprolol	18,897,578	Sevelamer HCL	5,580,405	96,695,276
Sevelamer carbonate	15,723,597	Insulin	19,185,188	76,032,463
Simvastatin	15,547,902	Lanthanum carbonate	2,790,692	63,996,592
Calcium acetate	14,777,969	Calcium acetate	14,777,969	51,855,070
Lisinopril	14,425,980	Clopidogrel bisulfate	10,529,417	48,746,816
Cinacalcet	12,948,729	Esomeprazole	4,916,511	27,757,642
Omeprazole	12,265,329	Atorvastatin	6,102,510	20,658,562
Carvedilol	11,904,875	Pantoprazole	3,992,742	14,284,534
Clonidine	11,349,738	Doxercalciferol	855,446	14,108,077
Levothyroxine	10,570,307	Valsartan	4,562,564	12,885,699
Clopidogrel bisulfate	10,529,417	Pioglitazone	2,130,208	12,426,793
Furosemide	9,888,422	Nifedipine	6,588,609	11,260,004
Warfarin	8,170,035	Clonidine	11,349,738	10,202,044

Phosphate binders are the most frequently prescribed Part D medication class in dialysis patients, and are also first in terms of net cost, as sevelamer carbonate and hydrochloride are not available as generics. Calcimimetic agents are ranked twelfth for frequency of use, but second in terms of total net cost, as cinacalcet is not generically available. Insulin comprised 3.9 percent of overall Part D drug use and 3.5 percent of Part D drug costs in dialysis patients in 2010. And not surprisingly, cardiovascular agents comprised three of the five most frequently used Part D medication classes in dialysis patients in 2010. » **Figures 6.18–19**; see page 439 for analytical methods. *Part D claims for all dialysis patients, 2010. Therapeutic classification based on Medi-Span's generic product identifier (GPI) therapeutic classification system.*



Among transplant patients, prednisone (a generic immunosuppressant) was the most frequently used medication in 2010, followed by metoprolol and insulin; these ranks are unchanged since 2008.

Trimethoprim-sulfamethoxazole, used for prophylaxis against *pneumocystis carinii* pneumonia, dropped from sixth to seventh place. No trade name immunosuppressant made the top 15 list in terms of

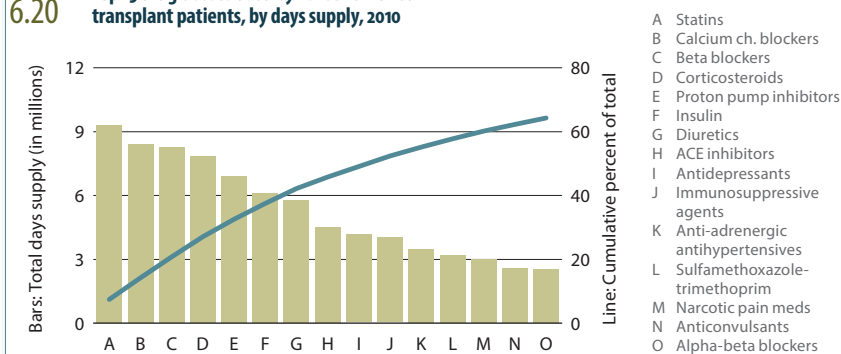
frequency, not surprising given that most are covered under Medicare Part B.

In terms of costs, insulin therapies moved from fourth place to second. The use of valganciclovir, employed for prophylaxis against cytomegalovirus, rose slightly, and maintained its first position by cost — not surprising, as it has no available generic. The immunosuppressants mycophenolate mofetil, sirolimus, cyclosporine, and mycophenolate sodium appear on the list by cost, implying that their costs are relatively higher than the frequency of their use. Although generic products became available starting in 2009, tacrolimus remained on the top cost list in 2010. Epoetin alfa and darbepoetin alfa, trade name products not among the most frequently used medications, were among those with the greatest cost, though their use has declined substantially since 2008. » **Table 6.g;** see page 439 for analytical methods. *Part D claims for all kidney transplant patients, 2010.*

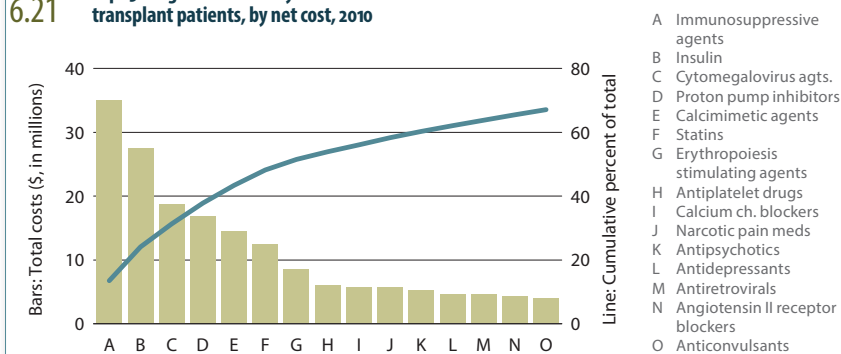
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6.g Top 15 drugs used by Part D-enrolled transplant patients, by days supply & net cost, 2010

By days supply Generic name	Total days supply	By net cost Generic name	Total days supply	Total cost (dollars)
Prednisone	7,547,599	Valganciclovir	982,135	45,474,908
Metoprolol	6,690,222	Insulin	6,497,226	28,914,728
Insulin	6,497,226	Tacrolimus	1,192,352	15,799,835
Amlodipine	5,202,017	Cinacalcet	862,809	15,790,929
Furosemide	4,184,856	Esomeprazole	1,666,478	9,430,347
Omeprazole	4,079,765	Mycophenolate mofetil	1,184,242	8,940,645
Trimethoprim/ sulfamethoxazole	4,040,453	Atorvastatin	2,830,453	8,685,651
Simvastatin	4,006,447	Epoetin alfa	197,966	6,086,743
Lisinopril	2,944,375	Clopidogrel bisulfate	1,376,772	5,917,211
Atorvastatin	2,830,453	Pantoprazole	1,190,918	4,307,687
Clonidine hydrochloride	2,405,996	Sirolimus	191,171	3,933,897
Levothyroxine	2,309,616	Mycophenolate sodium	229,983	3,432,389
Nifedipine	2,050,584	Darbepoetin alfa	71,610	3,226,774
Allopurinol	1,721,115	Pioglitazone	576,497	3,227,370
Calcitriol	1,694,629	Cyclosporine	686,376	3,092,528

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6.20 Top 15 drug classes used by Part D-enrolled transplant patients, by days supply, 2010



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6.21 Top 15 drug classes used by Part D-enrolled transplant patients, by net cost, 2010



By class, immunosuppressants were tenth on the list in terms of Part D medication use among kidney transplant patients during 2010, but second in terms of cost, even though generic products for tacrolimus and mycophenolate mofetil became available during 2008–2010. Statins were first, representing 7.4 percent of Part D medication use (by days supply) in transplant patients, but only 4.8 percent of cost. Cardiovascular medication classes comprised seven of the top fifteen categories in terms of use. Insulin was fifth on the list based on days supply, but second on the list in terms of cost, most likely reflecting use of trade name products. » **Figures 6.20–21;** see page 439 for analytical methods. *Part D claims for all kidney transplant patients, 2010. Therapeutic classification based on Medi-Span's generic product identifier (GPI) therapeutic classification system.*

## MEDICARE PART D ENROLLMENT PATTERNS

*sources of prescription drug coverage among Medicare enrollees, 2010 (Figure 6.2)*

Part D with low income subsidy	» general Medicare · 23%	» all CKD · 29%	» HD · 54%	» PD · 40%	» TX · 34%
Part D without low income subsidy	· 38%	· 29%	· 20%	· 24%	· 22%
retiree drug subsidy	· 14%	· 21%	· 8.2%	· 8.1%	· 8.5%

*Patients enrolled in Part D, 2010 (Figure 6.5)*

LIS (dual)	» general Medicare · 32%	» all CKD · 44%	» HD · 64%	» PD · 51%	» transplant · 50%
LIS (non-dual)	· 5.9%	· 5.9%	· 9%	· 12%	· 11.5%
non-LIS	· 63%	· 50%	· 27%	· 37%	· 39%

## OVERALL COSTS OF PART D ENROLLMENT

*total estimated Part D net payment for enrollees, 2010 (Figure 6.9)*

» hemodialysis · \$1.43 billion » peritoneal dialysis · \$98 million » transplant · \$306 million

*per person per year Part D costs for enrollees, 2008 (Figure 6.10)*

Medicare costs	» hemodialysis · \$5,910	» peritoneal dialysis · \$6,344	» transplant · \$4,725
out-of-pocket costs	· \$468	· \$678	· \$602

*total per person per year Medicare & out-of-pocket Part D costs for enrollees, 2008 (Figure 6.11)*

patients with low income subsidy (LIS)	» hemodialysis · \$7,488	» peritoneal dialysis · \$8,795	» transplant · \$6,547
patients with no LIS	· \$3,500	· \$4,042	· \$3,342

## COVERAGE PHASE ANALYSES FOR PART D ENROLLEES

*Part D non-LIS enrollees who reach the coverage gap, 2010 (Figure 6.16)*

at 12 months » general Medicare 19% » all CKD · 37% » HD · 41% » PD · 43% » transplant · 38%

*Part D non-LIS enrollees who reach catastrophic coverage after reaching the coverage gap, 2010 (Figure 6.17)*

at 9 months » general Medicare 12.5% » all CKD · 18% » HD · 23% » PD · 26% » transplant · 22%

## 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 Affordable 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.