KAISER FAMILY FOUNDATION

Program on Medicare Policy

Understanding the Effects of the Medicare Part D Coverage Gap in 2008 and 2009

Costs and Consequences Prior to Improvements in Coverage Established by the 2010 Health Reform Law

SEPTEMBER 2011

THE HENRY J. KAISER FAMILY FOUNDATION

ACKNOWLEDGEMENTS

The authors are grateful to Michel Denarié, Terry Shea, Li-Ling Chang, Joe Duffany, and Julia Feng of IMS Health for assistance with the data analysis, technical explanations, and review of this report. The authors also appreciate the help of Sarah Sattelmeyer, a former intern with the Kaiser Family Foundation, with the review of literature and preparation of exhibits.

KAISER FAMILY FOUNDATION

Program on Medicare Policy

Understanding the Effects of the Medicare Part D Coverage Gap in 2008 and 2009

Costs and Consequences Prior to Improvements in Coverage Established by the 2010 Health Reform Law

SEPTEMBER 2011

Prepared by:

Jack Hoadley
Laura Summer
Health Policy Institute
Georgetown University

Elizabeth Hargrave
NORC at the University of Chicago

Juliette Cubanski
The Henry J. Kaiser Family Foundation

THE HENRY J. KAISER FAMILY FOUNDATION

TABLE OF CONTENTS

EXECUTIVE SUMMARY

As originally designed, the Medicare Part D benefit included a coverage gap (the so-called "doughnut hole") that is starting to phase out, beginning in 2011. This unique feature of the Medicare drug benefit represents a gap in coverage where Part D enrollees, other than those qualifying for the benefit's Low-Income Subsidy (LIS), have been required to pay the full cost of their drugs. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, included a phase-out of this coverage gap that will be complete in 2020. The future of these changes to the Part D benefit remains uncertain, however, as the health reform law is challenged both in the Congress and the courts. Further, some have proposed to maintain the coverage gap, rather than gradually close it, as part of a broader effort to slow the growth in Medicare spending to reduce the federal deficit.[1]

Both the new policy and the fact that a partial gap in coverage will remain in place until 2020 make it an important time to understand the implications of the policy for the 29 million people on Medicare currently enrolled in Part D plans. In a previous report using 2007 data, we found that many people – 26 percent of Part D non-LIS enrollees, or 15 percent of Part D enrollees overall – reached the coverage gap. Those that reached the gap appeared to modify their drug use by stopping or reducing their use of certain medications. Since that report was released, other studies have presented similar findings.

This report updates our previous results and improves on the methodology by following beneficiaries across multiple years and comparing Part D enrollees to other groups that do not face a coverage gap. It represents the first study to look at encounters with the coverage gap in 2009 and experiences with the gap across multiple years.

In 2009, the last year covered by this study, the coverage gap began when a beneficiary incurred $2,700 in total drug spending and ended after that beneficiary had incurred $4,350 in out-of-pocket costs (equivalent to $6,135 in total drug spending under the standard benefit design). Once through the gap, beneficiaries become eligible for catastrophic coverage where about 95 percent of the costs of on-formulary drugs are covered. In 2010, Part D enrollees who reached the gap received a $250 check to help compensate them for their expenses. Starting in 2011, beneficiaries reaching the gap pay 50 percent less for the brand-name drugs they buy while in the gap, and 7 percent less for generics. If current law remains in place, beneficiaries will face average cost sharing of only 25 percent for all drugs in the gap by 2020 – the same as in the initial coverage period – effectively eliminating the coverage gap.

This report looks in detail at the coverage gap, examining who is affected and the nature of its impact. We focus on Part D enrollees taking one or more drugs in nine drug classes to treat several relatively common chronic conditions: Alzheimer's disease, breast cancer, high cholesterol, depression, diabetes, gastroesophageal reflux disease, heart failure, hypertension, and osteoporosis.

DATA AND METHODS

We analyzed nationwide patient-level retail pharmacy claims data for Part D enrollees from IMS Health, a leading pharmaceutical market research organization. IMS Health collects and links data at the person level for nearly two-thirds of all retail prescriptions filled in the United States, excluding prescriptions filled by mail order, institutional pharmacies, and through certain integrated health plans, such as Kaiser Permanente. Their Longitudinal Prescription (LRx) database includes person-level retail pharmacy claims for about 5 million Part D enrollees who filled at least one prescription in 2008 and 2009. We used cumulative total drug spending for each Part D enrollee to estimate whether they reached the coverage gap and catastrophic coverage, and also examined whether they changed their medication regimen when they reached the gap. With research showing that use of specific drugs tends to drop slightly over time in most populations, we compared Part D non-LIS enrollees who reached the coverage gap to people with the same level of spending in two groups that do not experience a gap: Part D LIS enrollees and commercially insured beneficiaries ages 65 and older. Although there are some limitations

in the IMS claims database (discussed further in Appendix B), it is a powerful resource for examining the experience of Part D enrollees with the coverage gap.

FINDINGS

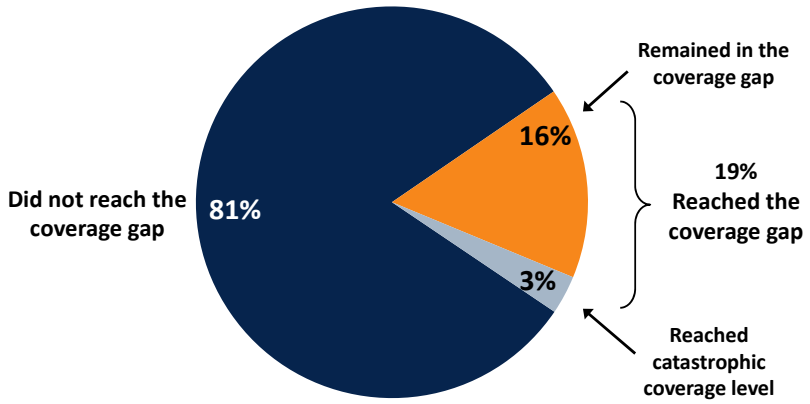
Nearly One of Every Five Part D Non-LIS Enrollees Reached the Coverage Gap in 2009

- Among Part D non-LIS enrollees who filled one or more prescriptions in 2009, about one in five (19 percent) had spending high enough to reach the coverage gap **(Exhibit ES1)**.[2]
- Applying this estimate to the entire population of Part D enrollees, the analysis suggests that more than 3.4 million beneficiaries (12 percent of all Part D enrollees) reached the coverage gap and faced the full cost of their prescriptions in 2009.
- Most people who reached the gap did not have high enough drug spending to receive catastrophic coverage before the end of the year. Only 3 percent of all Part D non-LIS enrollees had enough spending to qualify for catastrophic coverage in 2009, while 16 percent reached the coverage gap and remained in the gap for the rest of the year.
- One-fourth of Part D non-LIS enrollees ages 85 and older reached the coverage gap, a larger share than any other age group.
- Roughly three in 10 Part D non-LIS enrollees who could be tracked across both years reached the gap in either 2008 or 2009 or in both years. Because drug use can change over time, more people are affected by the coverage gap at some point over the course of two years than in any single year.[3]
- Since 2007, the share of Part D non-LIS enrollees reaching the gap has declined modestly, likely due to the increased availability of generic drugs for many chronic conditions and possibly other factors. However, the absolute number of people reaching the gap has declined less than the share because of an increase in the number of Part D enrollees between 2007 and 2009, from 24 million to 27 million.

Exhibit ES1

Share of Medicare Part D Enrollees Who Reached the Coverage Gap and Catastrophic Coverage in 2009

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees in 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

Many Part D Enrollees Reach the Gap Year After Year

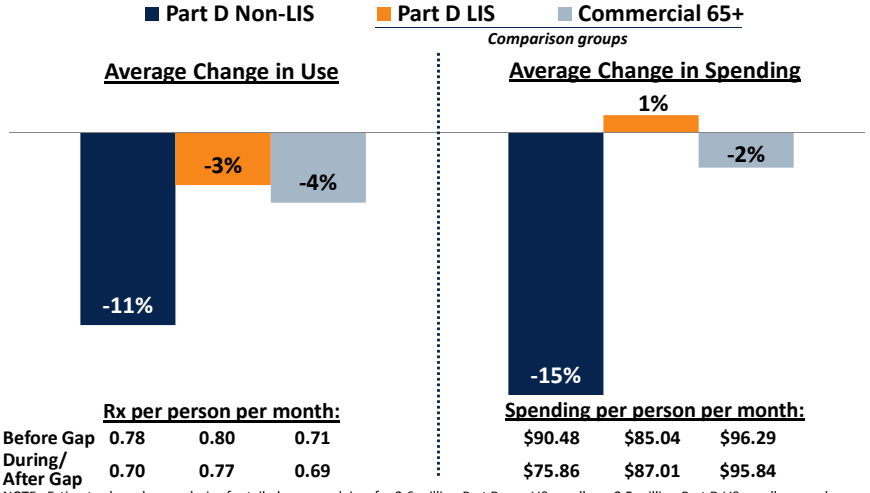
- About 71 percent of Part D non-LIS enrollees who reached the gap in 2008 did so again in 2009. Many of the same people tend to reach the gap year after year because they are taking medications for chronic conditions rather than for acute, short-term medical needs.
- These beneficiaries experience a "rollercoaster" effect, facing dramatically different costs as they move through the different phases of the Part D benefit during the year (deductible, initial coverage, the coverage gap, and possibly catastrophic coverage), and starting over again in January of each year.[4]

Part D Enrollees Reduce Their Medication Use When They Reach the Coverage Gap

- Part D non-LIS enrollees using drugs in one or more of nine selected drug classes in 2009 filled an average of 11 percent fewer prescriptions in the particular drug class after reaching the coverage gap threshold **(Exhibit ES2)**.
- Among beneficiaries in the two comparison groups (Part D LIS enrollees and beneficiaries ages 65 and over in commercially insured plans) who reached the gap spending level, the reduction in the number of prescriptions in the nine drug classes was considerably lower – just 3 to 4 percent, suggesting that much of the drop in use for Part D non-LIS enrollees who reach the coverage gap is due to facing the full cost of their drugs in the gap.
- After reaching the gap, Part D non-LIS enrollees also reduced average total drug spending in the drug class at a greater rate than those in the comparison groups – an average 15 percent reduction. Beneficiaries in the two comparison groups did not reduce their spending in the same way. Beneficiaries in commercially insured plans reduced spending after reaching the gap spending level by only 2 percent, while the Part D LIS enrollees actually increased spending by 1 percent.

Exhibit ES2

Average Change in Use and Spending Among Medicare Beneficiaries After Reaching the Coverage Gap Spending Level in 2009 Across 9 Drug Classes



	Rx per person per month:			Spending per person per month:		
Before Gap	0.78	0.80	0.71	$90.48	$85.04	$96.29
During/ After Gap	0.70	0.77	0.69	$75.86	$87.01	$95.84

NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees, 2.5 million Part D LIS enrollees, and approximately 4 million people age 65+ with private (commercial) drug coverage in 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

Part D Enrollees with Certain Conditions Are More Likely to Be Affected by the Coverage Gap

- More than half of Part D non-LIS enrollees taking drugs for treatment of breast cancer and Alzheimer's disease had spending high enough to reach the coverage gap – much higher than the overall average and higher than the share of enrollees taking drugs in other classes.

- The vast majority of Part D non-LIS enrollees taking medications for treatment of breast cancer who reached the gap in 2008 (82 percent) did so again in 2009. Among other groups of enrollees taking drugs in a particular class, the share of those reaching the gap in both years ranged from 75 percent of those taking an ACE inhibitor for hypertension or a drug for osteoporosis to 79 percent of those taking an oral anti-diabetic drug or an angiotensin receptor blocker.
- Among those who reach the coverage gap, the reduction in drug use varies by drug class, and is particularly high for Part D enrollees with some conditions:
    - Patients taking medications for breast cancer, who have especially high average spending, filled 17 percent fewer prescriptions for their breast cancer drugs in the coverage gap, compared to a 6 percent drop for the two comparison groups.
    - Patients taking medications for diabetes filled 10 percent fewer of these prescriptions after reaching the coverage gap; the comparable reduction for the two comparison groups was 3 percent.

DISCUSSION

Although the Affordable Care Act has initiated the process of phasing out the coverage gap, with a 50 percent discount on brand-name drugs and a 7 percent discount on generics in 2011, Part D non-LIS enrollees with relatively high spending will continue to be exposed to some gap in coverage until it is fully phased out in 2020. However, the discounts mean that enrollees who reach the gap will pay significantly less for their drugs than they would have prior to 2011. Our analysis indicates that 19 percent of Part D non-LIS enrollees reached the gap in 2009 and paid the full cost for all drugs they continued to use. Many of the same beneficiaries likely did so again in 2010 and will continue to do so in subsequent years. In addition, each year, additional Part D enrollees will experience the coverage gap – both new entrants to the program with relatively high drug costs, and other enrollees who experience changes in their medication use and/or spending.

This study shows that when Medicare beneficiaries reach the gap and incur higher out-of-pocket costs for their medications, some take fewer drugs or spend less on drugs in the drug class. The reduction in drug use and spending was much greater among Part D non-LIS enrollees who reached the gap than among beneficiaries in the two comparison groups. This finding is consistent with numerous studies showing the effects of cost sharing on utilization of health services.[5] It is not possible to know how many of these beneficiaries consult with their physicians before making these changes to mitigate potentially adverse health consequences. This study found that the highest rates of reaching the gap, with its subsequent consequences of reduced use, were among Part D non-LIS enrollees taking drugs for breast cancer, diabetes, or Alzheimer's disease. Reduced adherence to drug regimens in these classes can have immediate and potentially serious health consequences. For individuals with other chronic conditions, such as osteoporosis or high cholesterol, the health effects from stopping their medications might not be immediately apparent, but could increase the risk of adverse outcomes over time.

As of 2011, Medicare is phasing in coverage in the gap, which will reduce out-of-pocket costs for Part D non-LIS enrollees who reach the gap. As these enrollees pay a smaller share of total drug costs in the gap over time, it will be important to monitor whether the observed adverse effects on drug adherence – and potentially on health outcomes – are reduced by these changes. It will also be important to assess whether the changes lead to higher drug prices, especially for brand-name drugs, which might mitigate some of the positive effects of closing the gap.

This analysis confirms that the coverage gap results in lower drug utilization among Part D non-LIS enrollees – particularly those with significant health needs and relatively high drug costs. Although the coverage gap is being phased out, understanding the full costs and consequences of the gap for people on Medicare is important, as policymakers consider legislation that would cancel the scheduled phase out of the coverage gap as part of efforts to repeal the 2010 health reform law, reduce the federal deficit, or both.

INTRODUCTION

A unique feature of the Medicare Part D benefit is the so-called "doughnut hole" – the gap in coverage in which Part D enrollees are required to pay the full cost of their drugs until they qualify for catastrophic coverage.[6,7] The Patient Protection and Affordable Care Act (ACA), as amended by the Health Care and Education Reconciliation Act of 2010, initiated a ten-year process of phasing out this coverage gap. Starting in 2011, those reaching the gap are provided a 50 percent discount on the cost of the brand-name drugs they purchase in the gap (while the full cost still counts toward reaching catastrophic coverage).[8] Also in 2011, the phase-in of reduced cost sharing begins for generic drugs, with additional reductions for brand-name drugs beginning in 2013. In 2020, the gap will be completely filled such that Part D enrollees under the standard benefit design will pay just 25 percent of their total drug costs – the same as in the initial coverage period before the gap – until the start of catastrophic coverage.

The decision to start phasing out the coverage gap makes this an important time to understand the implications of reaching the gap for the 29 million people on Medicare currently enrolled in Part D plans. Although the phase-out is under way, many Part D enrollees will continue to be exposed to a partial gap in coverage until 2020. They no longer will be responsible for the full cost of drugs once reaching the spending level associated with the start of the gap, but they will still be required to pay a higher share of drug costs in this period for several years to come.

Notwithstanding the fact that millions of people on Medicare will benefit from this improvement in Part D coverage, the House of Representatives passed a bill in January 2011 to repeal the Affordable Care Act, which, if it became law, would eliminate the phase-out of the coverage gap. Moreover, in his recent budget proposal, Representative Paul Ryan, chairman of the House Budget Committee, proposed to eliminate the phase-out of the coverage gap.[9] These actions further underscore the importance of understanding the impact of the coverage gap on Medicare beneficiaries.

In August 2008, we published a report that looked at the costs and consequences associated with the coverage gap for beneficiaries enrolled in Medicare Part D in 2007.[10] We found that many people (26 percent of Part D non-LIS enrollees, or 15 percent of Part D enrollees overall) reached the coverage gap in a given year, and those that reached the gap modified their drug use by stopping certain medications, switching to an alternative drug in the same drug class, or reducing medication use.[11] Other research, as discussed below, has drawn similar conclusions. The context for analyzing the coverage gap has changed considerably since our 2008 report was released. In addition to the changes to the coverage gap enacted as part of the ACA, everyone – from beneficiaries to physicians to researchers – has gained more experience with and awareness of the coverage gap.

ABOUT THIS STUDY

In this report, we extend our previous analysis of the Part D coverage gap by looking at more recent years and by examining whether the same enrollees reach the gap in multiple years. This report is the first study to look at experience with the coverage gap in 2009 and also gives us the first good opportunity to look at changes over a three-year period in Part D enrollees' behavior when they reach the gap.[12] We also make comparisons to other groups of Medicare beneficiaries: those qualifying for the program's Low-Income Subsidy (LIS) and beneficiaries ages 65 and over with drug coverage through commercial plans. Beneficiaries in these groups typically do not experience a coverage gap.[13] Inclusion of these additional populations allows us to compare their drug spending with that of Part D non-LIS enrollees and to assess whether they are more or less likely to reach the spending levels associated with the coverage gap or with catastrophic coverage, and whether their patterns of drug use and spending differ.

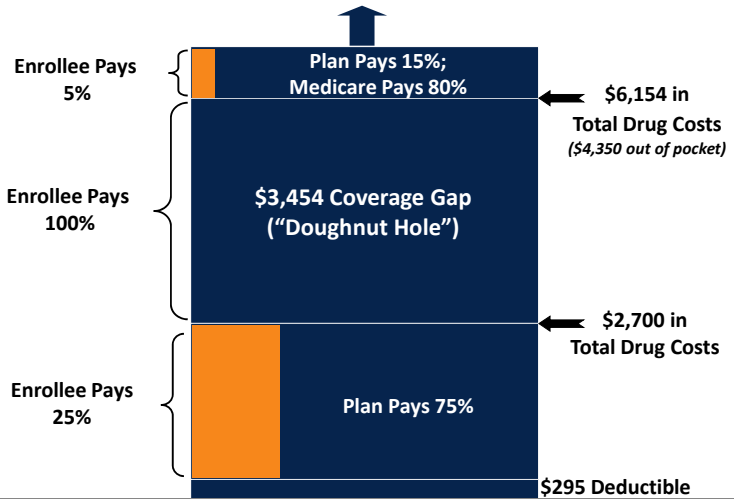
This study uses nationwide patient-level pharmacy claims data for 2008 and 2009 from IMS Health, a leading pharmaceutical market research organization, to estimate the share of Part D enrollees who reached the coverage gap and subsequently qualified for catastrophic coverage during the year. It assesses the extent to which Part D enrollees changed or stopped taking their medications once they reached the coverage gap, focusing on

beneficiaries taking one or more drugs in nine selected drug classes to treat several relatively common chronic conditions. The study also looks at total and out-of-pocket spending among Part D enrollees prior to reaching the coverage gap, during the coverage gap, and during the period of catastrophic coverage.

In 2009, the latest year covered by this study, the coverage gap began when a beneficiary's total drug spending reached $2,700 and ended when a beneficiary had spent a total of $4,350 out of pocket (the equivalent of $6,135 in total drug spending under the standard benefit design).[14] Once these limits were reached, beneficiaries were eligible for catastrophic coverage where most of the costs of on-formulary drugs were covered. During the catastrophic coverage phase, beneficiaries were responsible for the greater of 5 percent coinsurance or modest copayment amounts ($2.40 for generic or preferred multisource drugs or $6.00 for other drugs). Before reaching the catastrophic limit, beneficiaries in 2009 were liable for the full cost of up to $3,454 of drug spending during the gap **(Exhibit 1)**.

Exhibit 1

Medicare Part D Standard Drug Benefit in 2009



NOTE: Amounts rounded to nearest dollar.
SOURCE: Kaiser Family Foundation illustration of 2009 standard Medicare drug benefit parameters.

Although plans offering Part D coverage are permitted to offer an alternative to the standard benefit design, the majority of stand-alone Medicare prescription drug plans (PDPs) and Medicare Advantage Prescription Drug (MA-PD) plans have a coverage gap and most Part D enrollees are in plans with such a gap.[15] Among plans that offer gap coverage, it is mostly limited to generic rather than brand-name drugs, especially among PDPs. In 2009, only 7 percent of PDP enrollees and 50 percent of MA-PD plan enrollees had gap coverage for more than a few drugs – and almost no enrollees had full coverage in the gap.[16]

DATA AND METHODS

For this analysis we analyzed 2008 and 2009 data from IMS Health's Longitudinal Prescription Drug Database (LRx), which includes retail transaction data aggregated to the person level for 64 percent of all retail prescriptions filled in the United States and over 180 million unique de-identified patients. Within LRx, IMS identified 5.1 million Part D enrollees in 2009, estimated to represent approximately 21.6 million of the 26.7 million beneficiaries enrolled in Part D that year (19.7 million of 25.4 million in 2008). Of the 5.1 million Part D enrollees in the database for 2009, 2.5 million were categorized as recipients of the Part D Low-Income Subsidy (LIS), based on copayment information associated with their drug claims (2.4 million LIS enrollees of 5.0 million Part D enrollees in 2008) (Appendix A).[17]

In addition to beneficiaries enrolled in Part D plans, our analysis incorporated a commercially insured population of Medicare beneficiaries ages 65 and older. These individuals did not fill any prescriptions under a Part D plan, but instead filled at least one prescription under another third-party commercial plan, including beneficiaries in employer plans receiving the Medicare Retiree Drug Subsidy, retirees whose employers offer drug coverage but did not participate in the subsidy program, and beneficiaries still insured as active employees. Our sample for commercial beneficiaries consists only of individuals taking drugs in particular drug classes, not the overall population of commercially insured Medicare beneficiaries ages 65 and older. Because many beneficiaries use drugs in more than one of these drug classes, we can provide only a rough estimate of the overall size of the commercial group in our sample: 4 million enrollees, estimated to represent about 14 million people in 2009.[18]

For the Part D non-LIS enrollees in the dataset, we estimated whether they reached the coverage gap and catastrophic coverage based on their cumulative total drug spending, using total drug spending amounts for 2009 of $2,700 ($2,510 in 2008) to determine whether a beneficiary had reached the coverage gap and $6,154 ($5,726 in 2008) to determine whether a beneficiary had reached catastrophic coverage.

For Part D LIS enrollees and commercial beneficiaries age 65+, we used these same thresholds to determine which beneficiaries would have reached the coverage gap and catastrophic coverage had they been enrolled in Part D plans with no gap coverage and not receiving LIS. This approach allows us to examine spending patterns for these other groups and to use them as comparison groups when looking at changes in drug use and spending among Part D non-LIS enrollees, because beneficiaries in these other groups do not face a coverage gap. Neither population is a perfect control group, however. Part D LIS enrollees have higher total spending in all benefit phases, partly because they have more health conditions and take more medications. Furthermore, Part D LIS enrollees are responsible for lower cost sharing than Part D non-LIS enrollees in all benefit phases. Beneficiaries enrolled in commercial plans may also experience different levels of cost sharing when purchasing drugs and may have more generous coverage than Part D non-LIS enrollees. Despite these limitations, use of these groups helps to assess whether changes in behavior that we observe among Part D non-LIS enrollees who reach the coverage gap may be part of a broader pattern of spending for beneficiaries with high levels of spending, or may be more directly attributable to the coverage gap itself. As such, compared to our previous study, these comparison groups allow us to take a more refined look at changes in behavior once Part D non-LIS enrollees reach the gap.

To examine how individuals' medication use and out-of-pocket costs changed once they reached the coverage gap, we focused our analysis on individuals who use one or more drugs in each of nine selected classes to treat several relatively common chronic conditions: (1) angiotensin-converting enzyme (ACE) Inhibitors, generally used to treat hypertension; (2) Alzheimer's disease treatments; (3) anti-depressants; (4) angiotensin receptor blockers (ARBs), generally used to treat hypertension; (5) oral anti-diabetics; (6) osteoporosis treatments; (7) proton pump inhibitors (PPIs) for heartburn, gastroesophageal reflux disease (GERD), and ulcers; (8) HMG-CoA reductase inhibitors (Statins) to treat high cholesterol; and (9) drugs used in the treatment of breast cancer in postmenopausal women, including both aromatase inhibitors and tamoxifen. Our analysis takes into account all drug use for individuals using drugs in these classes, but we focus on changes in medication use only for the selected classes. Additional information on the IMS data, our methodology, and the list of products used to define each drug class is provided in Appendix A.

The IMS Health database used for this analysis has limitations that could affect the precision of our estimate of the share of Part D enrollees with spending in the coverage gap or who reach catastrophic coverage. Factors that may bias our estimates include the exclusion of Part D enrollees who do not fill prescriptions, the possible error in our method of identifying Part D LIS enrollees, the exclusion of prescriptions filled at mail order pharmacies and certain retail pharmacies such as institutional pharmacies, and the possibility that beneficiaries may fill a subset of prescriptions without using their Part D card. We are unable to quantify whether the net bias on our estimate is upward or downward, but as described in Appendix B, our estimates are reasonably close to those calculated by the Centers for Medicare & Medicaid Services (CMS) for 2007 and 2008 based on an analysis of complete Part D prescription drug event data.

Since our first report on the coverage gap was released in 2008, there is a growing body of evidence on how many people reach either the coverage gap or catastrophic coverage (see Appendix C for a review of this literature). At the time of our last report, no calculation based on Medicare claims data was available. Since that time, researchers at CMS have released calculations from Medicare claims data on how many people reached the gap and catastrophic coverage each year from 2006 to 2008.[19] The CMS calculation of the share of beneficiaries reaching the gap is nearly identical to the share we reported in the earlier report and those reported here. More details on this comparison are found in Appendix B.

Unless stated explicitly otherwise, the estimates presented for Part D enrollees in this report exclude LIS enrollees and those who did not use drugs or filled prescriptions only through mail order, institutional pharmacies, or other pharmacies not captured by the IMS Health LRx claims data.

FINDINGS

REACHING THE COVERAGE GAP OR CATASTROPHIC COVERAGE

What Share of Part D Enrollees Reached the Coverage Gap in 2009? What Share Received Catastrophic Coverage?

- Among Part D enrollees who used prescription drugs in 2009 and did not receive a Low-Income Subsidy (LIS), about one in five (19 percent) had spending high enough to reach the coverage gap **(Exhibit 2)**.

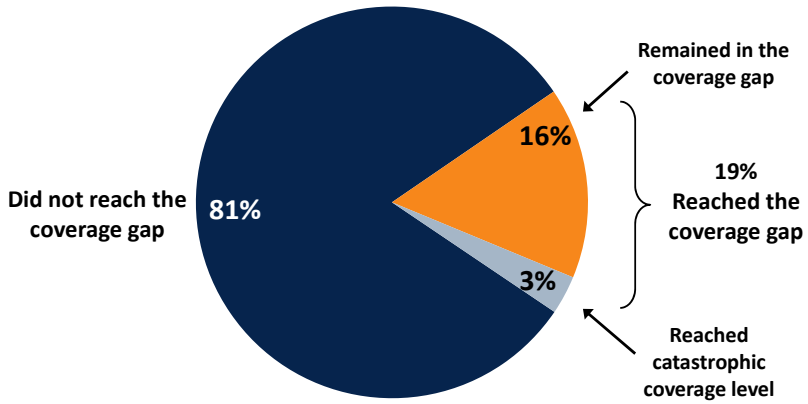
- About 16 percent of Part D enrollees reached the coverage gap but not catastrophic coverage, and 3 percent reached the gap and subsequently qualified for catastrophic coverage. These estimates correspond closely with the CMS estimates for the same population, based on the most recent available data (see Appendix B).

- Overall, about 3.4 million beneficiaries (12 percent of the total population of Part D enrollees) reached the coverage gap and faced the full cost of their prescriptions in 2009. This estimate takes into account the number of beneficiaries who are protected from the gap because they qualify for the LIS.[20]

Exhibit 2

Share of Medicare Part D Enrollees Who Reached the Coverage Gap and Catastrophic Coverage in 2009

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees in 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

Are Part D Enrollees with Certain Health Conditions More Likely to Reach the Coverage Gap?

- The share of Part D enrollees with spending high enough to reach the coverage gap in 2009 varied considerably across the nine drug classes in our study, but for those taking drugs in any of the nine classes, the share reaching the gap is higher than among Part D enrollees overall **(Exhibit 3)**.

- More than half of Part D non-LIS enrollees taking drugs used to treat breast cancer (56 percent) or Alzheimer's disease (54 percent) had spending high enough to reach the coverage gap in 2009. Smaller shares of those taking drugs in other classes – roughly two-fifths of those taking anti-diabetes drugs (40 percent), PPIs (39 percent), and angiotensin receptor blockers (38 percent) – reached the coverage gap in 2009.

- Differences in the share of Part D enrollees reaching the coverage gap by drug class can be attributed to several factors, including the cost of drugs used to treat these conditions, the overall health status of users of drugs in the different classes, and the share of users in each class who took drugs in other classes.[21]
  - The high proportion of enrollees taking breast cancer drugs who reach the coverage gap likely reflects the cost of the drugs as well as the strong incentives for cancer patients to maintain their treatments.
  - Medications for Alzheimer's disease include some of the most expensive drugs in the study, thus contributing to the increased share of these enrollees reaching the coverage gap in 2009. Furthermore, patient compliance is higher than in many other drug classes because caregivers are typically involved in helping ensure the drugs are taken.

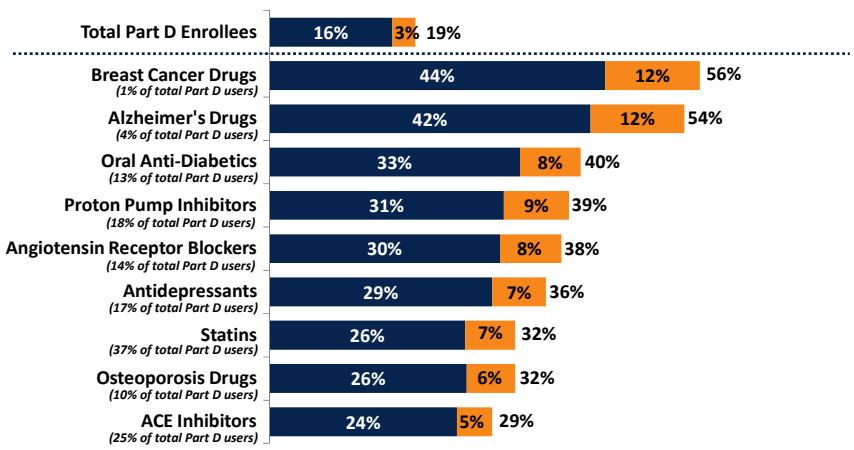
- Among users in the nine drug classes, a greater share of those taking breast cancer drugs reached the coverage gap in 2009, although this group makes up only a small share (1 percent) of all Part D non-LIS enrollees who use at least one drug. Conversely, because statins were more widely used among the Part D non-LIS enrollees in our study, 62 percent of those who reached the coverage gap in 2009 were taking a statin (not shown in exhibit).

- The two most widely used drug classes among those studied (statins and ACE inhibitors) are at or near the bottom in terms of the share of users who reach the coverage gap. These drugs are taken by many relatively healthy beneficiaries to treat underlying chronic conditions; this lower overall drug use, along with availability of many generic alternatives in these classes, may help to keep these enrollees from reaching the gap.

Exhibit 3

Share of Part D Enrollees Who Reached the Coverage Gap and Catastrophic Coverage in 2009, By Drug Class

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees in 2009. Groups not mutually exclusive; enrollees may use drugs in more than one of the eight drug classes.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

How Many Part D Enrollees Reached the Gap Across a Two-Year Period?

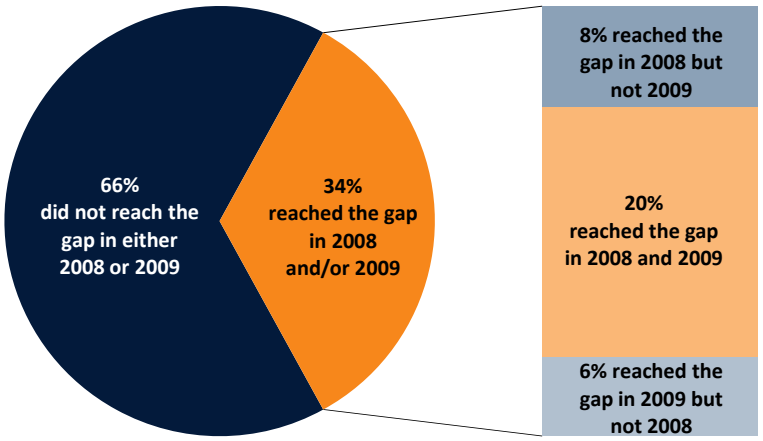
- More Part D non-LIS enrollees reach the coverage gap over longer periods of time than in any one year. Whereas one in five reached the gap in 2009, 34 percent of Part D non-LIS enrollees who could be tracked across two years and who filled a prescription in both years reached the gap in either 2008 or 2009 **(Exhibit 4)**.[22]
    - The two-year sample for this analysis requires that a beneficiary was consistently classified as a Part D non-LIS enrollee and filled a prescription in both years. After adjusting for these sample design issues, the estimate of those reaching the gap in either 2008 or 2009 is 27 percent.

- Nearly 20 percent of Part D enrollees who can be tracked in the two-year sample who used a prescription drug in both years reached the gap in both 2008 and 2009. After adjusting for sample design issues, the estimate of those reaching the gap in both years is 16 percent.
    - The chance of reaching the gap in a particular year is influenced by fluctuating drug prices or availability of generic alternatives, prescribing decisions, and decisions on whether to cut back adherence to prescribed medications.

Exhibit 4

Share of Part D Enrollees Who Reached the Coverage Gap in 2008 and/or 2009

Includes Part D Enrollees Tracked Across Both Years Who Did Not Receive Low-Income Subsidies



NOTE: Estimates based on analysis of retail pharmacy claims for 1.1 million Part D non-LIS enrollees in 2008 and 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

Did Part D Enrollees Who Reached the Gap in 2008 Reach It Again in 2009?

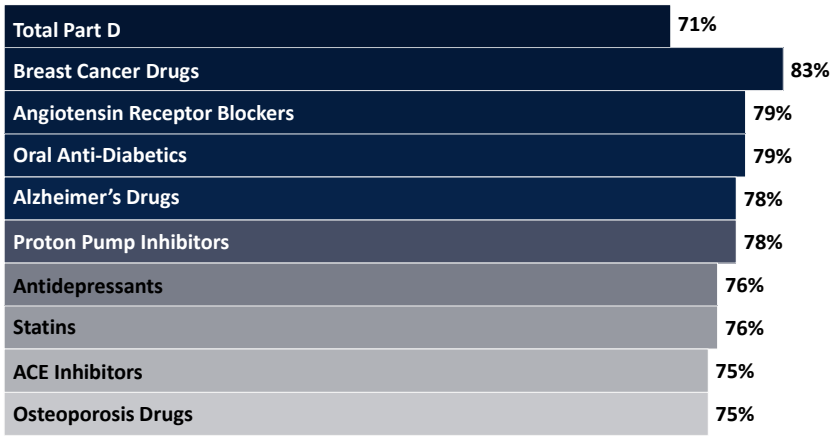
- Part D non-LIS enrollees who reach the gap in one year tend to continue doing so in future years. Among those who reached the gap in 2008, about 71 percent did so again in 2009 **(Exhibit 5)**.

- Just as a greater share of Part D non-LIS enrollees taking a drug for one of the nine selected conditions reach the gap in a given year than the average Part D non-LIS enrollee, a greater share also do so again the following year – ranging from 75 percent for those taking an ACE inhibitor for hypertension or a drug for osteoporosis to about 83 percent for those taking one of the breast cancer treatments.
    - This pattern of reaching the gap in multiple years is consistent with the fact that drug use levels are more predictable from one year to the next than other health expenditures.[23] For many health conditions, the need for medications, once started, continues through the end of life (although specific drugs taken may change).

- When Part D enrollees reach the coverage gap, some are likely to make lasting decisions about what drugs to take that affect their likelihood of reaching the gap in future years. For example, some beneficiaries may switch to a generic alternative in the same drug class, which reduces their out-of-pocket costs. As a means of delaying or avoiding the coverage gap the next year, many enrollees may continue using the generic drug rather than switching back to the brand-name drug. About 29 percent of enrollees who reached the coverage gap in 2008, and whose use is also reported for 2009, did not reach the gap in 2009. For those taking a drug in one of the nine drug classes, the shares not reaching the gap are somewhat lower than for the overall Part D non-LIS population.

Exhibit 5

Share of Part D Enrollees Reaching the Coverage Gap in 2008 Who Reached the Gap Again in 2009, By Drug Class



NOTE: Estimates based on analysis of retail pharmacy claims for 1.1 million Part D non-LIS enrollees in 2008 and 2009. Groups not mutually exclusive; enrollees may use drugs in more than one of the nine drug classes.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

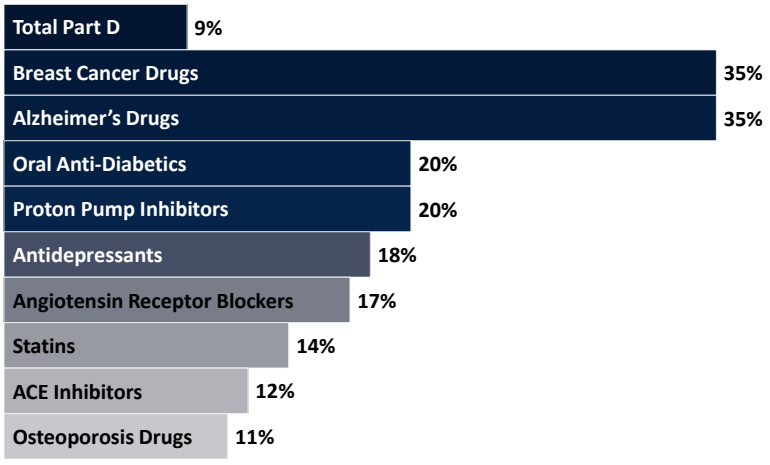
How Many Part D Enrollees Reached the Gap for the First Time in a Given Year?

- Although there is substantial continuity in Part D enrollees reaching the coverage gap from one year to the next, there are some enrollees who are new to reaching the gap each year. Across all of Part D, less than one in ten (9 percent) of those Part D non-LIS enrollees who did not reach the coverage gap in 2008 did reach the gap in 2009 **(Exhibit 6)**.[24]

- The shares of beneficiaries who reached the gap in 2009 after not doing so in 2008 vary by drug class. But they are consistently higher for each group identified based on taking a drug for a particular health condition than for the overall population of Part D non-LIS enrollees. These higher shares would include cases where an enrollee started using a particular class of drugs partway through 2008—not early enough in the year to reach the coverage gap that year—whose use continued during all of the following year, resulting in the enrollee reaching the gap in 2009.
    - About 35 percent of those taking a drug for breast cancer or Alzheimer's disease who did not reach the coverage gap in 2008 subsequently reached the gap in 2009, while only 11 percent of those taking a drug for osteoporosis who did not reach the coverage gap in 2008 went on to reach the gap in 2009.

Exhibit 6

Share of Part D Enrollees Who Reached the Coverage Gap in 2009 but NOT in 2008, By Drug Class



NOTE: Estimates based on analysis of retail pharmacy claims for 1.1 million Part D non-LIS enrollees in 2008 and 2009. Groups not mutually exclusive; enrollees may use drugs in more than one of the nine drug classes.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

Are There Differences by Age and Sex in Reaching the Coverage Gap?

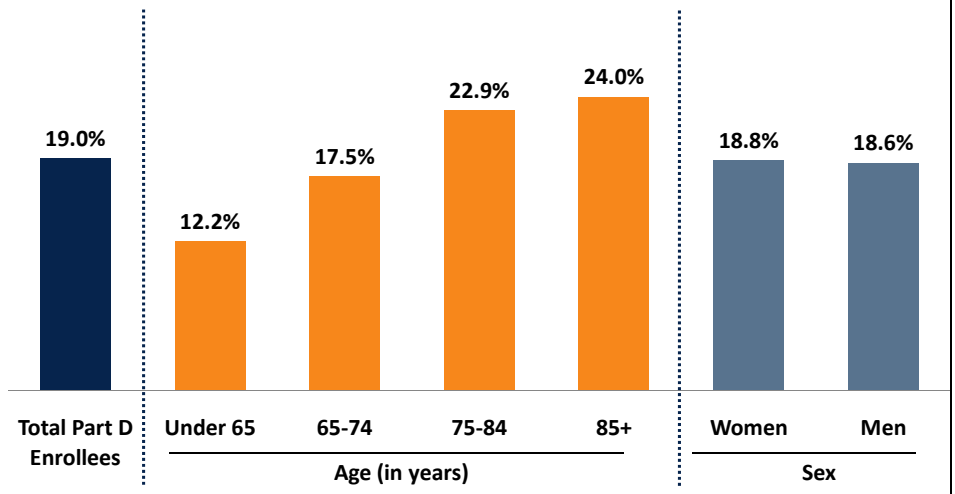
- The share of Part D non-LIS enrollees who reached the coverage gap in 2009 was higher for seniors ages 85 and older (24 percent) than for younger seniors ages 65-74 (18 percent), and lower still among Part D non-LIS enrollees under age 65 with disabilities (12 percent) **(Exhibit 7)**. These patterns are similar to those observed in 2007 and 2008.[25]

- A similar share of women and men enrolled in Part D reached the coverage gap in 2007, 2008, and 2009. The share for women was one percentage point larger in 2007, but this difference was negligible in 2009.

Exhibit 7

Share of Part D Enrollees Who Reached the Coverage Gap in 2009, By Age and Sex

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees in 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

How Have Shares of Part D Enrollees Reaching the Coverage Gap and Catastrophic Coverage Changed Over Time?

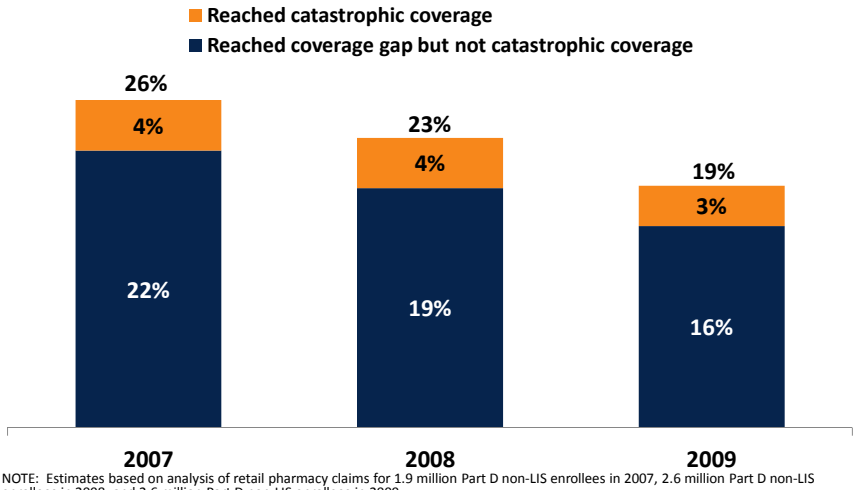
- Among Part D non-LIS enrollees who used prescription drugs, the portion with spending high enough to reach the coverage gap decreased between 2007 and 2009, from 26 percent in 2007 to 23 percent in 2008 and 19 percent in 2009 **(Exhibit 8)**. The pattern of decline follows closely the pattern seen in calculations from Part D claims data.[26]

- The portion of Part D enrollees whose spending qualifies them for catastrophic coverage also declined slightly during the same period from 4 percent in 2007 to 3 percent in 2009.[27]
    - CMS has reported that about 3.8 million people received $250 rebate checks in 2010 based on reaching the coverage gap at some point during the year.[28] This count is higher than our estimate that 3.4 million people reached the gap in 2009. The higher CMS estimate for 2010 may partly reflect the annual 4-5 percent increase in the number of Part D enrollees, but it also suggests that 2010 may reflect a modest reversal of the downward trend in the number of people reaching the gap.

Exhibit 8

Share of Part D Enrollees Who Reached the Coverage Gap and Catastrophic Coverage, 2007-2009

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTE: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D non-LIS enrollees in 2007, 2.6 million Part D non-LIS enrollees in 2008, and 2.6 million Part D non-LIS enrollees in 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

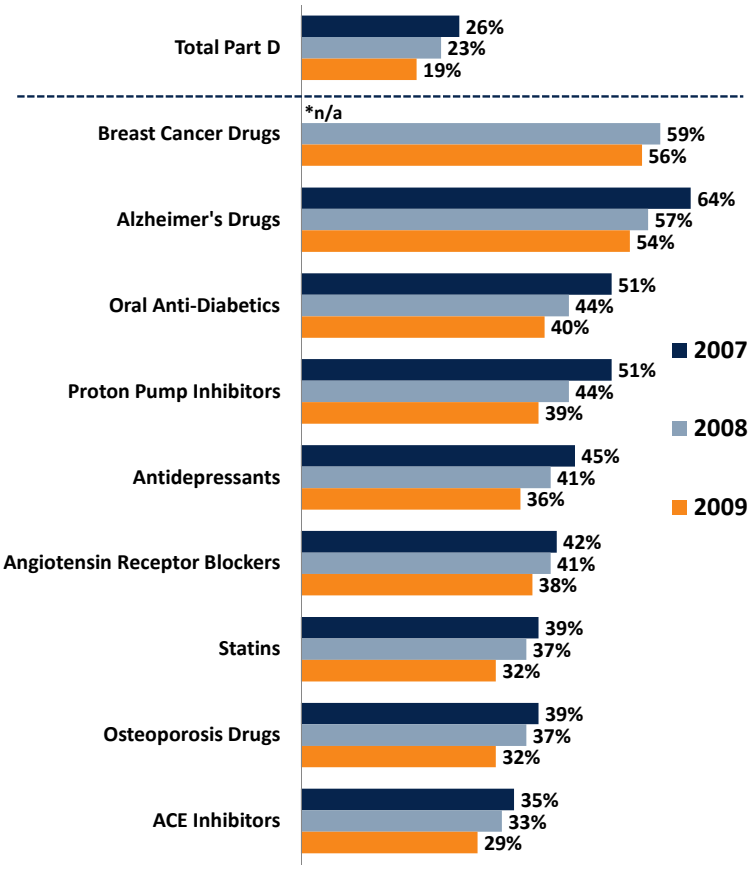
- Similar to the trend for Part D non-LIS enrollees overall, within each of the nine drug classes, the share of beneficiaries reaching the gap has declined each year between 2007 and 2009 **(Exhibit 9)**.

- Although data for this report cannot be used to explain the decline in numbers reaching the coverage gap or catastrophic coverage between 2007 and 2009, several factors may help explain the trend we observed.
    - One likely factor is the increased availability of generic drugs for many chronic conditions. Among the commonly used drugs that became available as generics in 2007 or 2008 are Fosamax, Wellbutrin XL, Risperdal, Imitrex, Topamax, and Prevacid.
    - Another likely factor is learning by beneficiaries. As awareness of the gap has increased for both beneficiaries and their physicians, they are probably taking more steps to modify drug use to avoid reaching the gap as well as coping with costs once they reach the gap. In focus groups conducted for MedPAC in 2009, beneficiaries who had reached the coverage gap in earlier years were well aware of the gap and how it works and reported on a wide array of coping strategies and adjustments to lower their overall costs.[29]

- Another possible explanation is the increased availability of low-cost generics from major retail pharmacy chains, such as the $4 generics available at Walmart, Target, and other retail chains. An IMS analysis of two drug classes found that 10 percent of patients using a diabetes drug and 9 percent of those using an ACE inhibitor filled a prescription without presenting their drug plan card prior to reaching the gap – consistent with anecdotal evidence that some beneficiaries adopt this strategy to postpone reaching the gap. These are low-cost prescriptions, however, and the change between 2008 and 2009 was minimal (less than 1 percentage point), thus suggesting that this is probably not a significant factor in explaining over-time changes in the number reaching the gap.[30]
- The recession of 2008-2009 may offer another possible explanation. As reported by CMS, U.S. health care spending in 2009 grew at the slowest rate in the 50 years the agency has tracked national health expenditures.[31] Although overall national drug spending did not follow this same pattern, economic conditions may have slowed drug spending for Medicare beneficiaries.

Exhibit 9

Share of Part D Enrollees Who Reached the Coverage Gap, By Drug Class, 2007-2009



NOTE: Estimates based on analysis of retail pharmacy claims for 1.9 million Part D non-LIS enrollees in 2007, 2.6 million Part D non-LIS enrollees in 2008, and 2.6 million non-LIS Part D enrollees in 2009. Drug class groups within each year not mutually exclusive; enrollees may use drugs in more than one of the nine drug classes. *Data for breast cancer drugs not collected for 2007.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

What Were the Patterns in Total and Out-of-Pocket Spending Among Part D Enrollees?

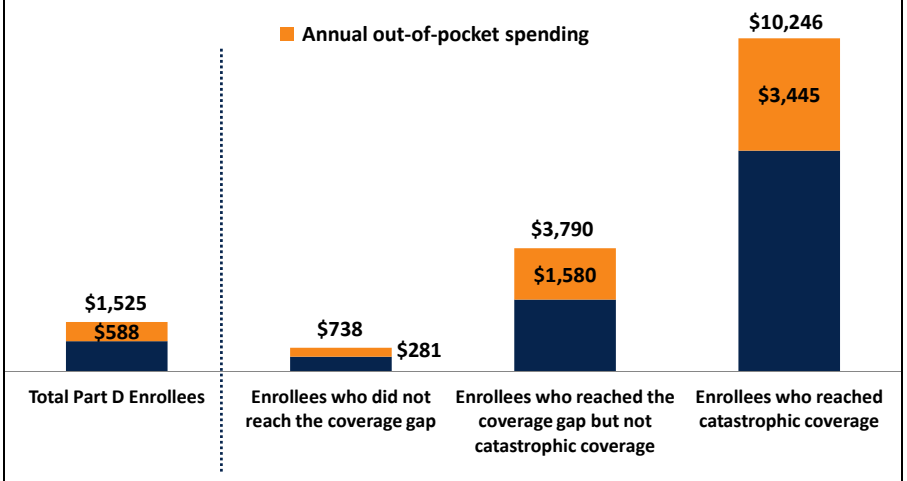
- Average total drug spending among Part D non-LIS enrollees was $1,525 (about $127 per month) in 2009. On average, these enrollees spent 39 percent out of pocket on prescription drugs in 2009 (about $588 per year or $49 per month), excluding whatever amounts enrollees paid in premiums for Part D coverage.

- As would be expected, average annual total spending for Part D non-LIS enrollees who did not reach the coverage gap in 2009 was much lower than for those who reached the coverage gap. On average, those who did not reach the gap spent $738 on prescription drugs in 2009, while those who reached the gap but not catastrophic coverage spent over five times as much ($3,790). Total drug spending among those who reached catastrophic coverage was even higher, averaging $10,246 **(Exhibit 10)**.

Exhibit 10

Average Annual Total and Out-of-Pocket Drug Spending by Part D Enrollees in 2009, By Benefit Phase

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees in 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

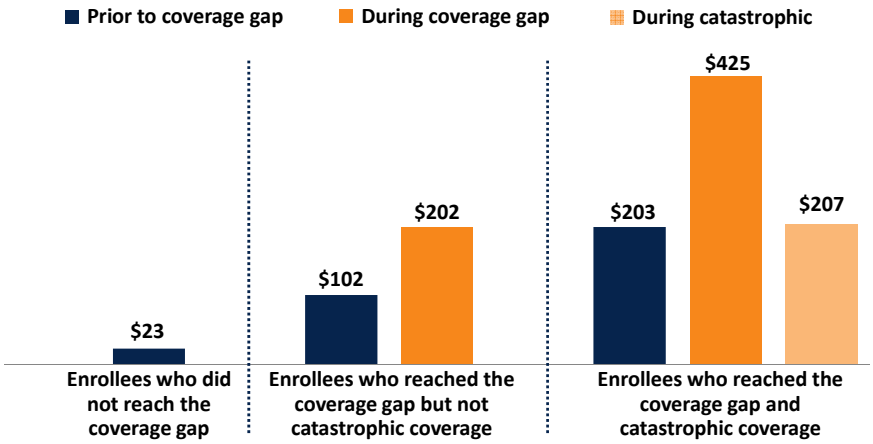
- The design of the Part D benefit means that out-of-pocket spending varies considerably across the year as Part D non-LIS enrollees move through different benefit phases. For those who reached the coverage gap, average monthly out-of-pocket spending on prescription drugs in 2009 roughly doubled after reaching the gap. This increase occurs even though some enrollees stop taking, or reduce their use of, certain medications after reaching the gap **(Exhibit 11)**.
  - Among Part D non-LIS enrollees who did not reach the coverage gap in 2009, out-of-pocket spending averaged $23 per month.
  - Among Part D non-LIS enrollees who reached the gap but not catastrophic coverage in 2009, average out-of-pocket spending increased from $102 per month in the pre-gap period to $202 per month in the gap.
  - Among those with spending high enough to qualify for catastrophic coverage, average out-of-pocket spending increased from $203 per month during the pre-gap period to $425 per month during the gap.
  - These beneficiaries experience the "rollercoaster" effect (first described by Bruce Stuart).[32] Depending on the benefit design for their particular plan, a Part D non-LIS enrollee may start the year paying full drug costs in a plan's deductible phase, followed by a period where they are only responsible for cost sharing, after which they reach the coverage gap and pay full cost again. Those with enough spending to reach catastrophic coverage experience an additional up and down cycle with responsibility only for 5 percent cost sharing once they reach catastrophic. This entire sequence resets and restarts every January.

- For Part D enrollees with spending high enough to qualify for catastrophic coverage in 2009, monthly out-of-pocket spending dropped from $425 per month during the coverage gap, on average, to $207 per month during catastrophic coverage. The finding that out-of-pocket spending in the catastrophic coverage period was similar to the average pre-gap level of $203 per month is somewhat counterintuitive, since Part D plans are required to cover a substantially larger share of drug costs (95 percent) in the catastrophic coverage period than prior to the gap. The relatively high level of out-of-pocket monthly spending we observed during the catastrophic coverage period could be due to several factors:
  - Some Part D enrollees who reach the catastrophic coverage level might have experienced a change in health conditions during the course of the year that resulted in higher total and out-of-pocket costs.
  - Some beneficiaries may be paying the total cost out of pocket for drugs not covered by their Part D plan. These purchases are included in the IMS database, but the expenses do not count towards enrollees' Part D plan costs.
  - The coverage gap status for some beneficiaries might be misclassified based on our methodology. Beneficiaries who were not actually receiving catastrophic coverage would be paying a higher share of their costs than 5 percent.

Exhibit 11

Monthly Out-of-Pocket Drug Spending by Part D Enrollees in 2009, By Benefit Phase

Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees in 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

How Do Part D Non-LIS Enrollees Compare to Other Types of Beneficiaries in Reaching the Level of Spending Associated with Either the Coverage Gap or Catastrophic Coverage?

Part D enrollees who qualify for the Low-Income Subsidy (LIS) and beneficiaries ages 65 and over who are enrolled in commercial plans have no coverage gap in their benefit. In the discussion that follows, they serve as comparison groups for analyzing changes in beneficiaries' drug use and spending after reaching the spending levels associated with the coverage gap and catastrophic coverage.

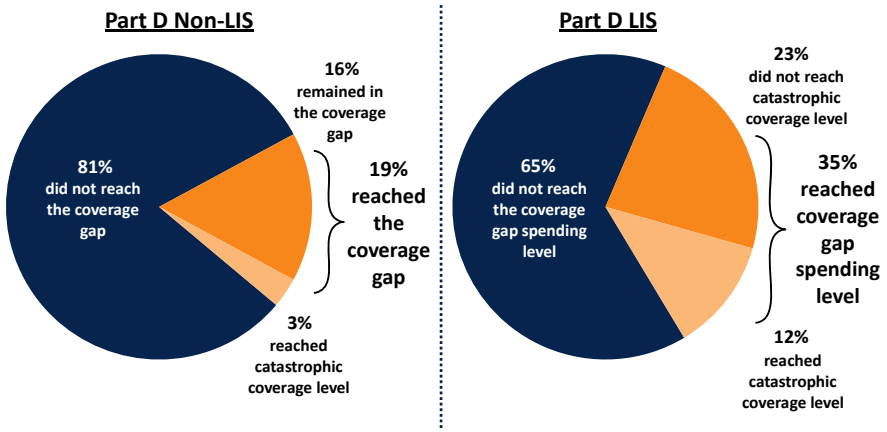
Low-Income Subsidy (LIS) Beneficiaries

- In 2009, 35 percent of Part D LIS enrollees had total drug spending high enough to reach the level associated with the coverage gap. This represents nearly twice the share of Part D non-LIS enrollees who reach the gap. About one-third of Part D LIS enrollees (or 12 percent of all LIS enrollees) had spending high enough to reach the level of catastrophic coverage, four times the share of Part D non-LIS enrollees **(Exhibit 12)**.
  - This finding reflects differences in total drug spending for these two groups. Average annual spending in 2009 was nearly twice as high for LIS enrollees than for non-LIS enrollees ($2,820 vs. $1,525, respectively). Conversely, average out-of-pocket spending as a share of total drug spending was lower for LIS enrollees than non-LIS enrollees (5 percent vs. 39 percent, respectively).[33]

Exhibit 12

Share of Part D Enrollees Who Reached Coverage Gap and Catastrophic Spending Levels in 2009, By LIS Status

Excludes Non-Users



NOTE: LIS is low-income subsidy. Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees and 2.5 million Part D LIS enrollees in 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

- Several factors help explain the differences between the two populations:
  - As a group, Part D LIS enrollees are in poorer health than other beneficiaries. Two-thirds of LIS enrollees are dually eligible for Medicare and Medicaid. Dually eligible beneficiaries are more than twice as likely to report that they are in poor or fair health as others on Medicare. They are also more likely to have three or more chronic medical conditions and much more likely to have cognitive or mental impairments.[34] All these characteristics are associated with a greater need for prescription medications.
  - LIS enrollees face much lower cost sharing because Medicare provides subsidies to help them pay for prescriptions. Thus, they may be more adherent to medication regimens. They also have less incentive to use generics since the cost-sharing difference is modest ($6.00 for brands vs. $2.40 for generics in 2009).
  - LIS enrollees may have less incentive to stop using or reduce use of medications once reaching the spending level associated with the coverage gap, since they are generally not responsible for any additional costs beyond cost sharing in the gap. These different incentives may help explain why LIS enrollees have an especially high rate of reaching spending levels associated with catastrophic coverage.

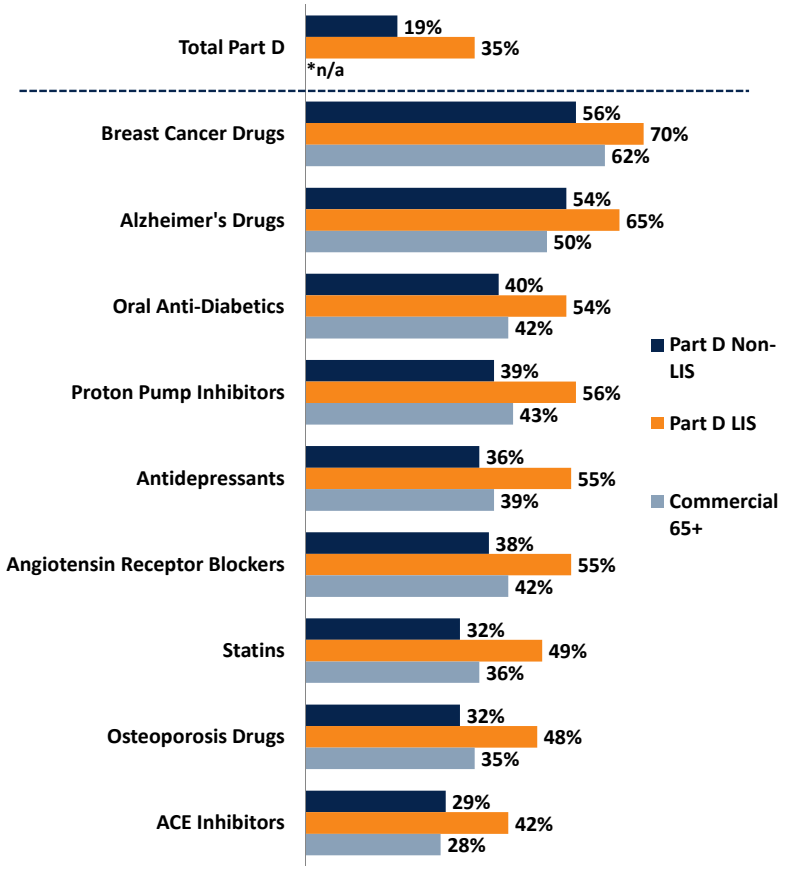
- Substantially higher shares of Part D LIS than non-LIS enrollees had spending that reached the coverage gap level in each of the nine drug classes. For example, among Part D enrollees taking breast cancer drugs, 70 percent of LIS enrollees reached the coverage gap, compared to 56 percent of non-LIS enrollees. The differences were even greater for some more commonly used types of drugs—for example, among those using statin drugs, 49 percent of LIS enrollees reached the gap in 2009 compared to 32 percent of non-LIS enrollees **(Exhibit 13)**.

Commercially Insured Beneficiaries Ages 65 and Over

- The share of individuals ages 65 and over with commercial coverage who reached the spending level associated with the coverage gap is similar to that of Part D non-LIS enrollees for the nine drug classes in our study. The commercially insured beneficiaries are somewhat more likely to reach the coverage gap spending level than Part D non-LIS enrollees, although the differences are no more than four percentage points in most drug classes.[35] For example, 36 percent of commercial patients taking a statin reached the gap in 2009, compared to 32 percent of Part D non-LIS enrollees **(Exhibit 13)**.[36]

Exhibit 13

Share of Medicare Beneficiaries Who Reached the Coverage Gap Spending Level in 2009, By Drug Class and Population



NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees, 2.5 million Part D LIS enrollees, and approximately 4 million people age 65+ with private (commercial) drug coverage in 2009. Drug class groups not mutually exclusive; enrollees may use drugs in more than one of the nine drug classes. *n/a: Data for entire population of commercial 65+ enrollees not available.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

CHANGING DRUG USE BEHAVIOR WHEN REACHING THE COVERAGE GAP

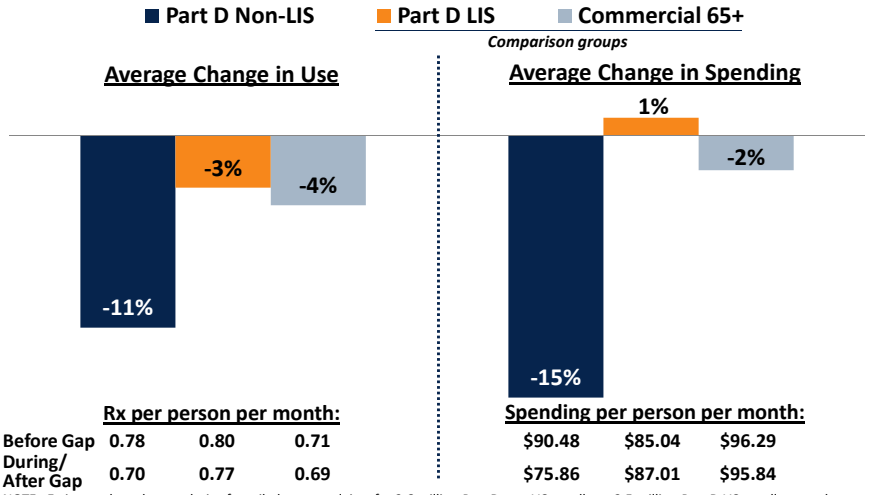
Did Part D Enrollees Change Their Number of Prescriptions or Total Spending When They Reached the Coverage Gap Spending Level?

- In 2009, among those who reached the coverage gap spending level, the number of prescriptions filled per month within a particular drug class declined more among the Part D non-LIS enrollees after reaching the coverage gap spending level (11 percent, averaged across the nine drug classes) than among those in the two comparison groups (3 and 4 percent, respectively) **(Exhibit 14).**[37]

- The difference between the Part D non-LIS group and the two comparison groups is even larger when looking at total spending on medications. Average monthly spending in a given drug class by Part D non-LIS enrollees in the months after they reached the coverage gap decreased by 15 percent (averaged across the nine drug classes) in 2009. By contrast, among Part D LIS enrollees, average monthly spending actually increased by 1 percent after their level of spending was equivalent to the amount needed to reach the coverage gap. Among beneficiaries with commercial insurance, spending fell by just 2 percent.

Exhibit 14

Average Change in Use and Spending Among Medicare Beneficiaries After Reaching the Coverage Gap Spending Level in 2009 Across 9 Drug Classes



	Rx per person per month:			Spending per person per month:		
Before Gap	0.78	0.80	0.71	$90.48	$85.04	$96.29
During/ After Gap	0.70	0.77	0.69	$75.86	$87.01	$95.84

NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees, 2.5 million Part D LIS enrollees, and approximately 4 million people age 65+ with private (commercial) drug coverage in 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

- The decline in drug use for Part D non-LIS enrollees is particularly concentrated in brand-name drugs as opposed to generic drugs. Part D non-LIS enrollees fill fewer brand-name drugs upon reaching the coverage gap, on average, than beneficiaries in the two comparison groups with drug spending equivalent to the level of the coverage gap **(Exhibit 15)**.[38] The two comparison groups average slightly more generic prescriptions after reaching the coverage gap spending level, while Part D non-LIS enrollees decrease their use of generics slightly after reaching the gap.

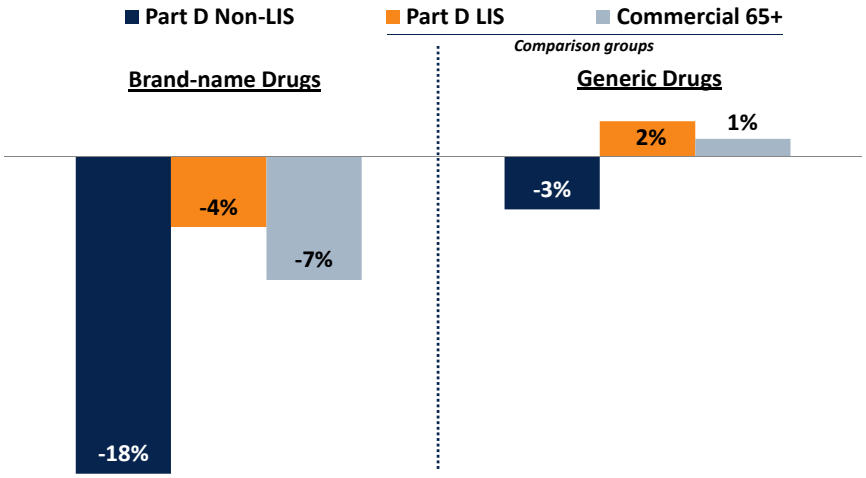
- The reductions in overall drug use and spending once Part D non-LIS enrollees reach the coverage gap is consistent with an intentional change in behavior to reduce high out-of-pocket costs in the gap. It also matches reports from focus groups with beneficiaries who described use of various strategies to reduce their costs.[39] Our finding that these reductions in spending and use are not matched by beneficiaries in the two comparison groups strengthens this conclusion.

- We can also measure behavior change by examining Part D enrollees who stop use of drugs within one of the nine drug classes – the measure we used in our previous report. In that report, we found that 16 percent of enrollees who reached the gap (on average across eight drug classes) either stopped taking a medication in that class or switched to a different medication in the class in 2007.[40] Our findings for the same measure were similar for 2008 and 2009. The share stopping a medication, however, is only modestly greater for the Part D non-LIS enrollees than for the two comparison groups.[41,42] On average across the nine classes, 15 percent of those reaching the coverage gap never filled another prescription for at least one of their medications they were taking in the particular class, compared to 12 percent of those in each of the comparisons groups.

- The consistent finding across the three different measures of behavior – change in use, change in spending, and stopping drug use – is that Part D non-LIS enrollees who reached the coverage gap made adjustments to reduce their use of drugs and thus their drug spending. Because the new measures developed for this study capture this behavior change more fully than the third measure (used in our previous study), we display results from the first two measures.[43]

Exhibit 15

Average Change in Use Among Medicare Beneficiaries After Reaching the Coverage Gap Spending Level in 2009 Across 9 Drug Classes, By Drug Type



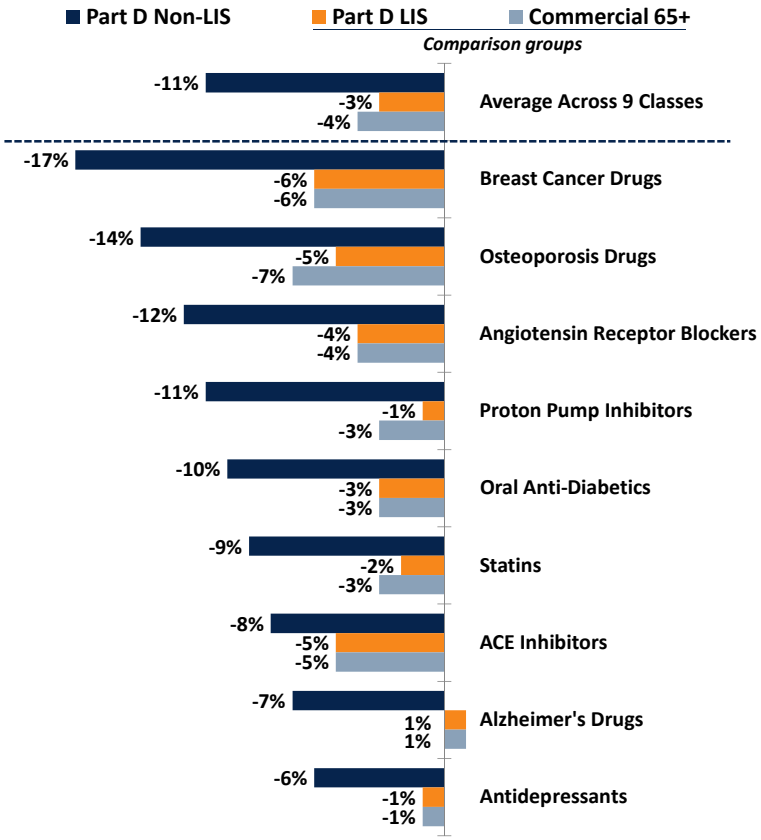
NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees, 2.5 million Part D LIS enrollees, and approximately 4 million people age 65+ with private (commercial) drug coverage in 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

How Did Part D Enrollees Make Changes To Their Drug Use and Spending in Selected Drug Classes When They Reached the Coverage Gap Spending Level?

- Among Part D non-LIS enrollees using one of the nine classes of drugs, there was considerable variation in the share of those who reduced their number of prescriptions filled in that drug class when they reached the coverage gap **(Exhibit 16)**. But the consistent pattern is that, for all of the nine drug classes, a greater share of Part D non-LIS enrollees than beneficiaries in either comparison group reduced drug use when they reached the coverage gap spending threshold in 2009.
    - The largest overall change was for Part D non-LIS enrollees who take drugs for breast cancer or osteoporosis, where enrollees reduced their prescriptions filled by 17 percent and 14 percent, respectively. Drugs for both conditions are typically taken as preventive measures, so reduced use might not result in perceptible short-term health effects, but could increase the risk of a recurrence of breast cancer or of fractures over a longer term. For each drug class, beneficiaries in both comparison groups reduced drug use to a much lesser extent.
    - One of the largest differences between the Part D non-LIS enrollees and the comparison groups was for patients using PPIs for ulcers or acid reflux. In this drug class, drug use was 11 percent lower for Part D non-LIS enrollees, compared to 3 percent of beneficiaries in commercial plans and 1 percent of Part D LIS enrollees. Because there is some concern that PPIs are overused for more routine gastrointestinal conditions, terminating medication use might not pose serious health risks in some cases. Furthermore, some PPI users may have switched either to the over-the-counter version of Prilosec (generic omeprazole) or other gastrointestinal treatments.
    - The difference between the Part D non-LIS enrollees and the comparison groups was smallest for patients using ACE inhibitors, where use was down 8 percent among Part D non-LIS enrollees compared to 5 percent for the comparison groups. Drugs in this class are mostly low-cost generic drugs, so there may be less incentive to make changes.

Exhibit 16

Change in Use Among Medicare Beneficiaries After Reaching the Coverage Gap Spending Level in 2009, By Drug Class and Population

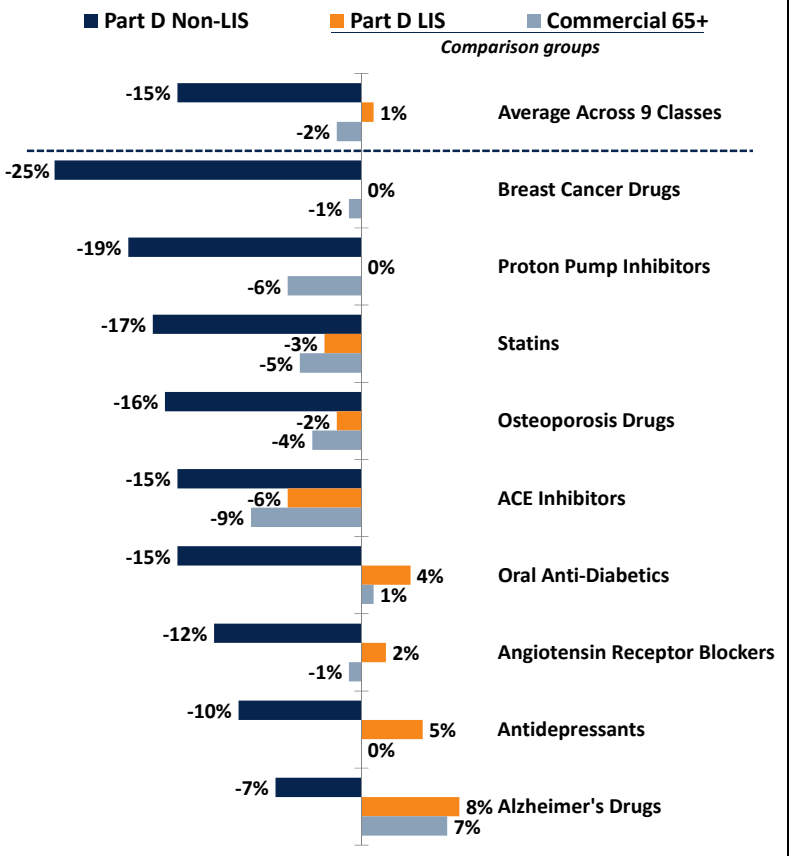


NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees, 2.5 million Part D LIS enrollees, and approximately 4 million people age 65+ with private (commercial) drug coverage in 2009. Drug class groups not mutually exclusive; enrollees may use drugs in more than one of the nine drug classes.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

- We see similar strong patterns for changes in spending levels after reaching the coverage gap. For all of the nine drug classes, a substantially greater share of Part D non-LIS enrollees than beneficiaries in either comparison group reduced drug spending in that drug class when they reached the coverage gap spending threshold in 2009 **(Exhibit 17)**.

Exhibit 17

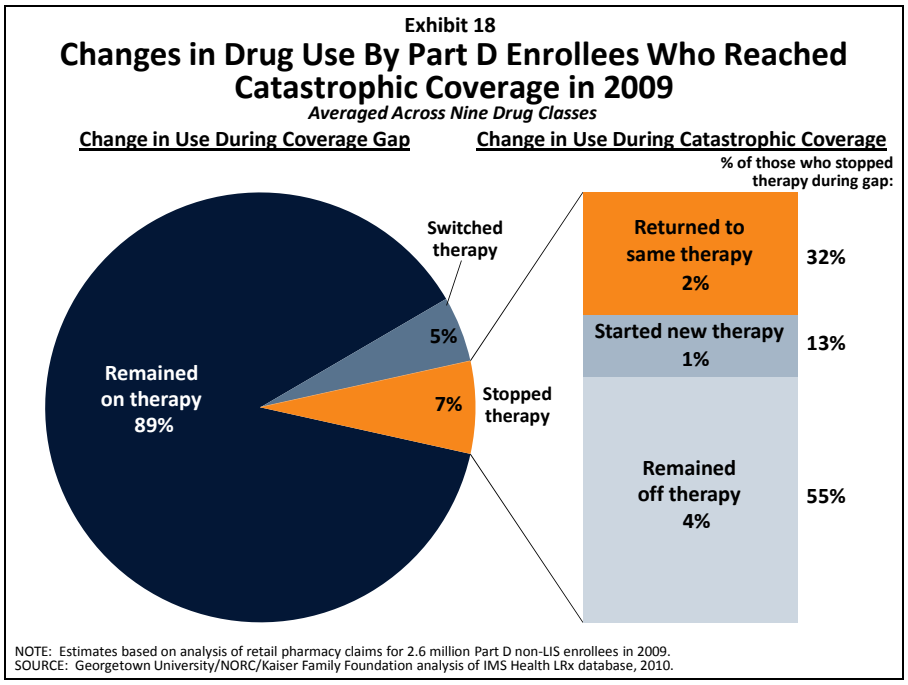
Change in Spending Among Medicare Beneficiaries After Reaching the Coverage Gap Spending Level in 2009, By Drug Class and Population



NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees, 2.5 million Part D LIS enrollees, and approximately 4 million people age 65+ with private (commercial) drug coverage in 2009. Drug class groups not mutually exclusive; enrollees may use drugs in more than one of the nine drug classes.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

Did Part D Enrollees Who Reached the Coverage Gap Change Use When the Gap Ended?

- In 2009, about 17 percent of those Part D non-LIS enrollees who reached the coverage gap also reached catastrophic coverage. Those who reached catastrophic coverage were less likely to reduce their use of drugs in a particular drug class than others who reached the gap, perhaps because they knew their drug spending would be high enough to exceed the catastrophic coverage level. Among the 7 percent of those who received catastrophic coverage who did stop or reduce therapy when they reached the coverage gap, just over half did not fill another prescription in that class (averaged across the nine drug classes studied), even after reaching catastrophic coverage **(Exhibit 18)**. The others either returned to taking the medication they had stopped or started a new medication in the class once they reached catastrophic coverage.

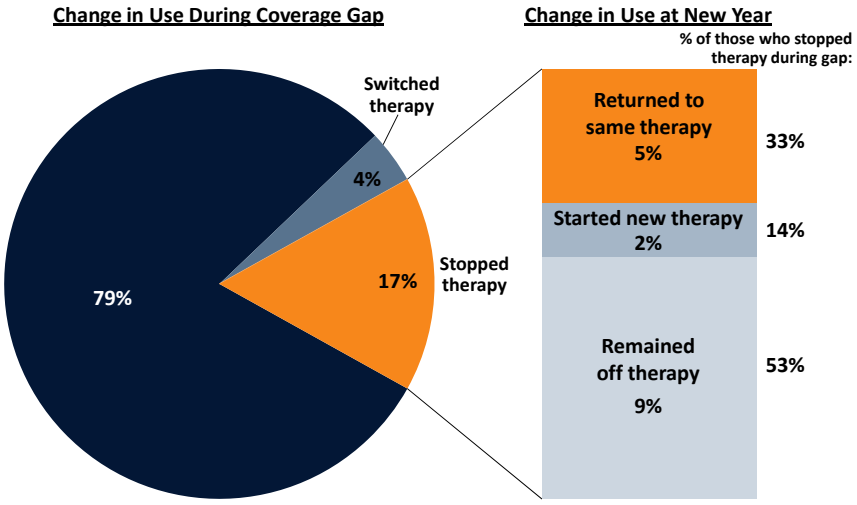


- As mentioned previously, the Part D benefit resets at the beginning of each year. Among Part D non-LIS enrollees who reached the coverage gap in 2008 but did not reach catastrophic coverage, 17 percent stopped or reduced therapy in the particular drug class when they reached the gap (averaged across the nine drug classes) **(Exhibit 19)**. In 2009, when coverage resumed (and after meeting a deductible if applicable), about half of these enrollees remained off therapy in the classes we studied. Another one-third returned to taking the same medication in 2009 that they had stopped taking when they reached the coverage gap in 2008, and the others started taking a new medication in the class.

Exhibit 19

Changes in Drug Use By Part D Enrollees Who Did Not Reach Catastrophic Coverage, 2008 to 2009

Averaged Across Nine Drug Classes



NOTE: Estimates based on analysis of retail pharmacy claims for 1.1 million Part D non-LIS enrollees in 2008 and 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

TIMING OF THE COVERAGE GAP

When Did Part D Non-LIS Enrollees Reach the Coverage Gap?

- Few Part D enrollees had enough spending to reach the coverage gap in the early months of 2009. Only 1 percent of all Part D non-LIS enrollees had reached the gap in the first quarter of 2009 **(Exhibit 20)**.

- Not surprisingly, as drug spending accumulated, the share of enrollees with spending high enough to reach the gap increased as the year progressed. Just over half of all Part D non-LIS enrollees who reached the coverage gap at some point in 2009 did so by the end of August.
  - Of Part D non-LIS enrollees who reached the gap in 2009, about one in four (27 percent) did so in the first half of the year **(Exhibit 21)**.
    - 5 percent reached the gap in the first quarter (January-March); of this group, 85 percent went on to receive catastrophic coverage before the end of the year **(Exhibit 22)**.
    - 22 percent reached the gap in the second quarter (April-May); of this group, 51 percent went on to receive catastrophic coverage before the end of the year.
  - The remaining 73 percent of Part D non-LIS enrollees who reached the gap in 2009 did so in the second half of the year.
    - 36 percent reached the gap in the third quarter (July-September); of this group, only 3 percent went on to receive catastrophic coverage before the end of the year.
    - 37 percent reached the gap in the fourth quarter (October-December); of this group, less than 1 percent went on to receive catastrophic coverage before the end of the year.
- Just over half (1 percent) of Part D non-LIS enrollees who reached catastrophic coverage at some point during 2009 did so in the last quarter of the year. Fewer than 20 percent of those reaching catastrophic coverage did so in the first six months of 2009.
- The share of enrollees who reached the coverage gap in each quarter was essentially the same in 2007, 2008, and 2009, though in each year fewer enrollees reached the coverage gap than the year before.

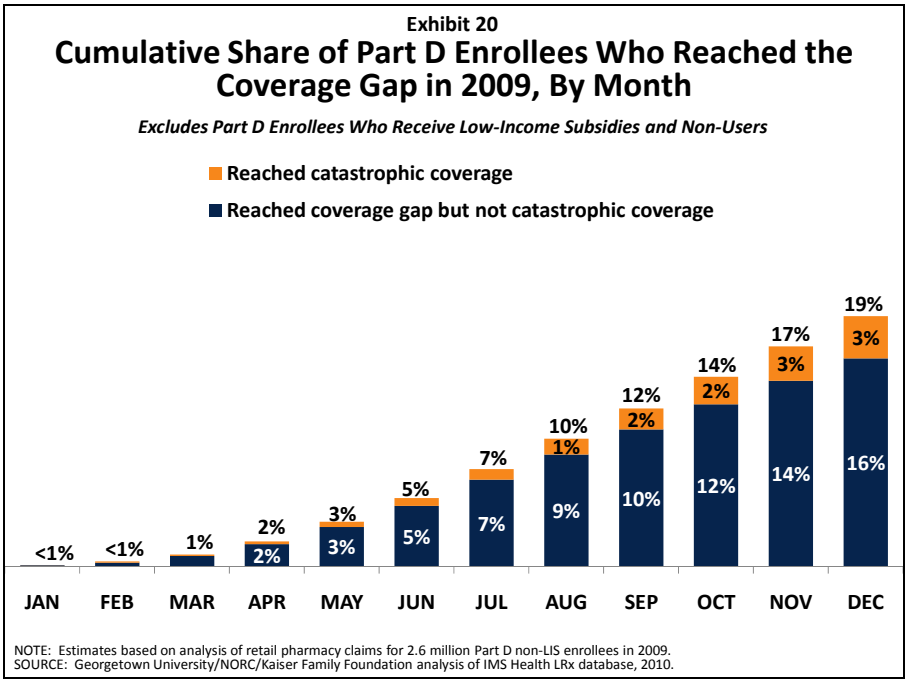
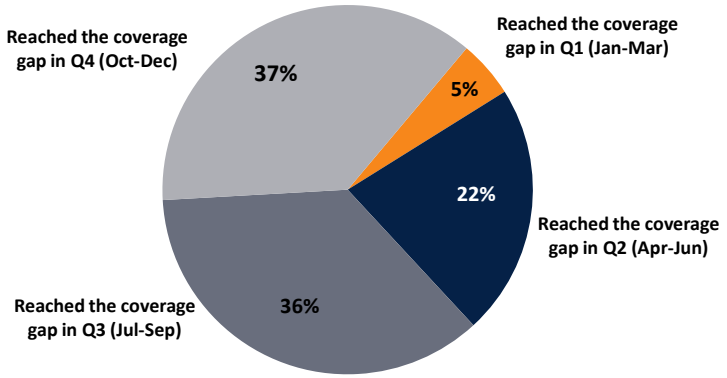


Exhibit 21

Distribution of Part D Enrollees Who Reached the Coverage Gap in 2009, By Quarter

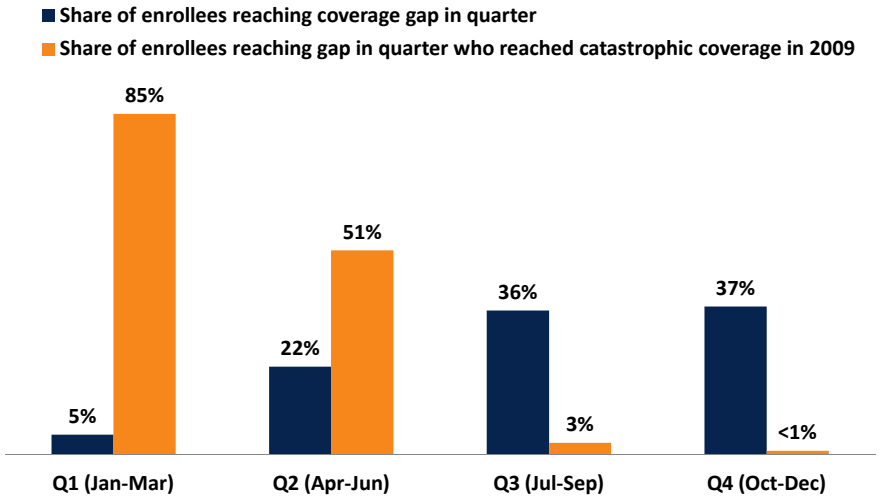
Excludes Part D Enrollees Who Receive Low-Income Subsidies and Non-Users



NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees in 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

Exhibit 22

Share of Part D Enrollees Reaching the Coverage Gap and Catastrophic Coverage, By Quarter



NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees in 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

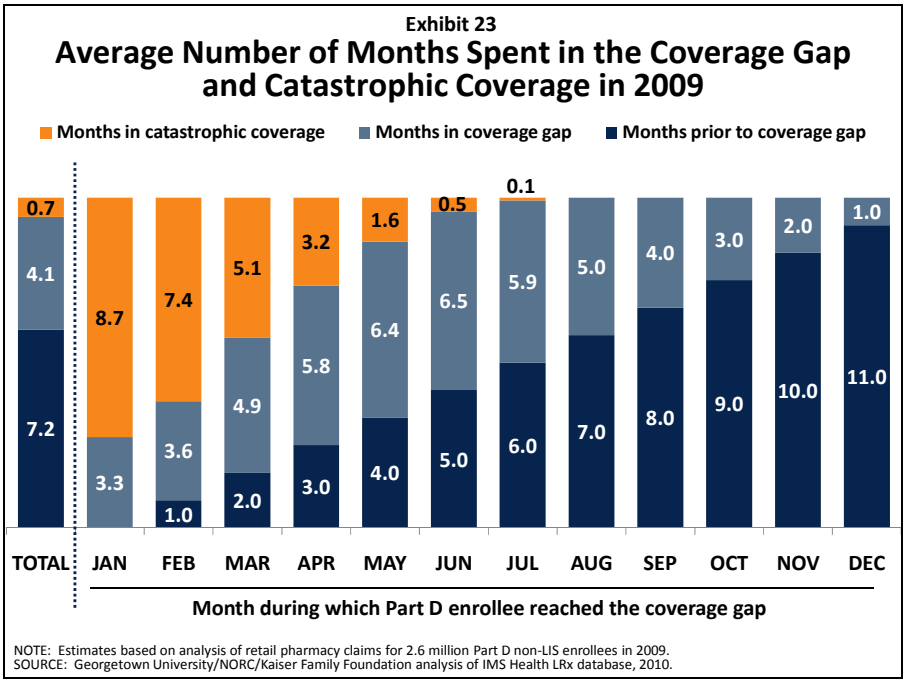
How Long Did Part D Enrollees Who Reached The Coverage Gap Stay in the Gap?

- Overall, Part D enrollees who reached the coverage gap in 2009 did so after spending 7.2 months in the initial benefit period and then remained in the coverage gap for an average of 4.1 months **(Exhibit 23)**. On average, Part D non-LIS enrollees who reached the coverage gap in 2009 received less than one month of catastrophic coverage.[44]

- Among Part D non-LIS enrollees whose spending exceeded the catastrophic coverage threshold in 2009, the average beneficiary spent 4.0 months with catastrophic coverage in 2009.[45]
    - On average, those with spending high enough to reach the coverage gap in the first three months of 2009 spent fewer months in the gap than in the catastrophic coverage period. For example, Part D non-LIS enrollees who first reached the coverage gap in January were in the gap for an average of 3.3 months until they reached catastrophic coverage (thus reaching catastrophic coverage during April), and then had catastrophic coverage for the remaining 8.7 months of the year.
    - Enrollees who reached the gap in the second quarter (April-June) spent about half the year in the gap, on average.
    - Those who reached the coverage gap in July or later were unlikely to reach catastrophic coverage at any time during the year. Therefore these enrollees spent little time, if any, in the catastrophic coverage period.

- The length of stay in the coverage gap was nearly identical in 2007, 2008, and 2009.

Exhibit 23



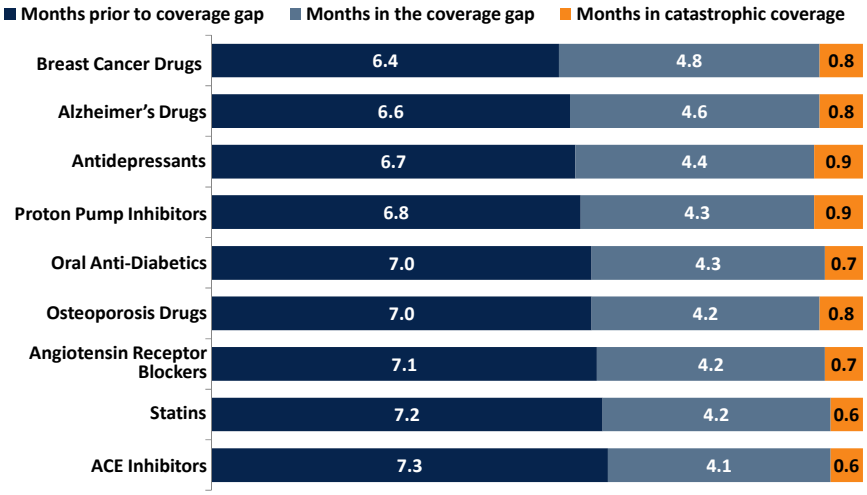
NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees in 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

Did Time Spent in the Coverage Gap and Catastrophic Coverage Vary by Drug Class?

- Our analysis shows only modest variation across the nine drug classes in the average number of months spent by Part D non-LIS enrollees in the coverage gap and in catastrophic coverage. Across all classes, the time spent in the gap varied by less than one month. The duration of time in the gap has been unchanged across the three years studied **(Exhibit 24)**.[46]
    - Part D enrollees using drugs for Alzheimer's disease or breast cancer reached the coverage gap somewhat sooner than enrollees using other types of drugs and spent slightly more time in the gap than those with other conditions.
    - Among Part D non-LIS enrollees taking breast cancer drugs who reached the gap, the average number of months in the initial benefit period (prior to reaching the coverage gap) was 6.4 months, slightly less time than among users of other types of drugs. Users of breast cancer drugs who reached the coverage gap spent 4.8 months in the gap and just under one month in the catastrophic coverage period.
    - Part D enrollees using ACE inhibitors, statins, and ARBs looked more like average users, reaching the coverage gap slightly later in the year than users of other types of drugs in our analysis, and spending a shorter average amount of time in the gap. The people using drugs in these three classes appear to be relatively healthy beneficiaries taking drugs to treat a single chronic condition.

Exhibit 24

Average Number of Months Prior to the Coverage Gap and in the Coverage Gap in 2009, By Drug Class



NOTE: Estimates based on analysis of retail pharmacy claims for 2.6 million Part D non-LIS enrollees in 2009.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

The Effect of the Coverage Gap on Use of Drugs for Treating Diabetes

- This study included 45 oral products used to treat diabetes, including branded, generic, and combination forms of 17 drugs. It did not include insulin, which is injected. Because the various drugs use different mechanisms, they may be used in combination to improve blood glucose control. While some individuals are able to stop taking anti-diabetes medications with changes in their diet and exercise regime, many who start taking an anti-diabetes medication continue to need a drug in this class for the rest of their lives.

- About 13 percent of Part D non-LIS enrollees used anti-diabetes medications in 2009, of whom 40 percent had spending high enough to reach the coverage gap. Among enrollees taking these drugs who can be tracked for both 2008 and 2009, about three-fifths reached the gap in at least one of the two years.

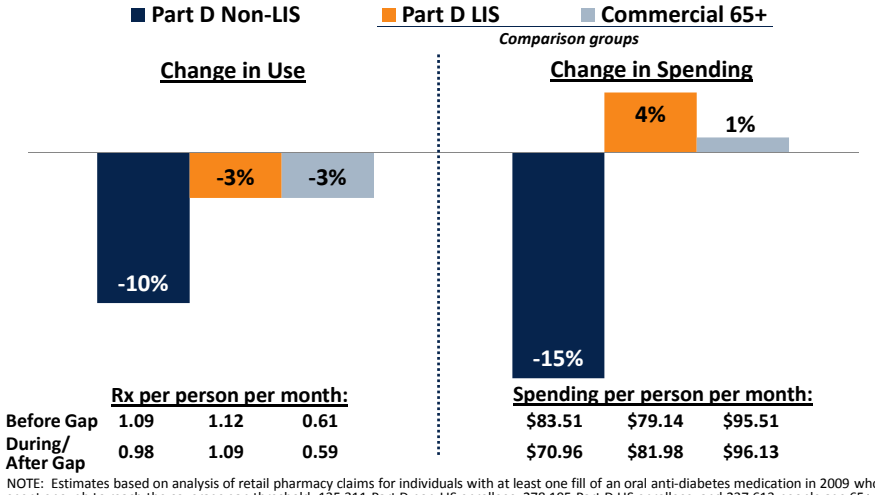
- Among Part D non-LIS enrollees using anti-diabetes drugs, those who reached the gap had average spending of $960 per year on these drugs. They reached the coverage gap because of their total spending on a larger number of drugs – an average of $4,969 in 2009. On average, these enrollees reached the coverage gap in August.

- Among Part D non-LIS enrollees using anti-diabetes medications who reached the gap, the number of prescriptions filled within this class per person per month was 10 percent lower in the gap than before the gap **(Exhibit 25)**. By way of comparison, beneficiaries enrolled in commercial insurance and Part D LIS enrollees reduced their use by just 3 percent. Terminating use of drugs used to manage diabetes could pose serious and immediate health concerns.

- Part D non-LIS enrollees who reached the coverage gap in 2009 reduced their monthly spending within this class by 15 percent after reaching the gap. Beneficiaries enrolled in commercial insurance and Part D LIS enrollees actually increased their average spending on anti-diabetics after reaching the coverage gap spending level by 1 percent and 4 percent, respectively.

Exhibit 25

Change in Use and Spending Among Medicare Beneficiaries Using Diabetes Drugs After Reaching the Coverage Gap Spending Level in 2009



	Rx per person per month:			Spending per person per month:		
Before Gap	1.09	1.12	0.61	$83.51	$79.14	$95.51
During/ After Gap	0.98	1.09	0.59	$70.96	$81.98	$96.13

NOTE: Estimates based on analysis of retail pharmacy claims for individuals with at least one fill of an oral anti-diabetes medication in 2009 who spent enough to reach the coverage gap threshold: 135,311 Part D non-LIS enrollees, 278,195 Part D LIS enrollees, and 237,613 people age 65+ with private (commercial) drug coverage.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

The Effect of the Coverage Gap on Use of Drugs for Treating Breast Cancer

- Our study included four drugs used to treat breast cancer: three on-patent aromatase inhibitors (Arimidex, Aromasin, and Femara), and the selective estrogen receptor modulator tamoxifen, which is off-patent. These drugs are regularly taken for at least five years after the onset of breast cancer; typically, only one is taken at a time.

- About 1 percent of Part D non-LIS enrollees used these medications in 2009. Of those, 56 percent had spending high enough to reach the coverage gap. Among users of these drugs who can be tracked for two years, four out of five reached the gap in either 2008 or 2009 and many did so in both years.

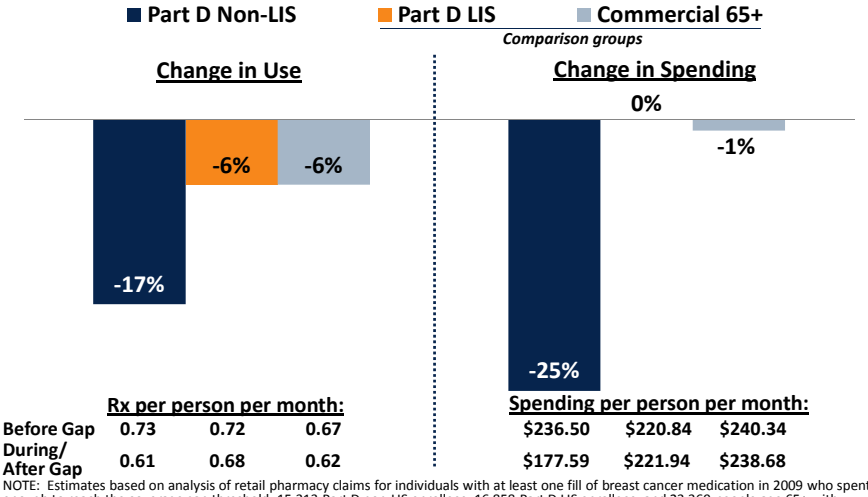
- Breast cancer drugs are expensive. In 2009, among beneficiaries who reached the coverage gap, average total spending on these drugs alone was $2,592 per year, just under the coverage gap threshold. However, many beneficiaries taking these drugs also take other medications. Among beneficiaries using breast cancer drugs who reach the coverage gap, average total spending was $6,567 per year, and the average user who reached the gap did so in July.[47]

- Among Part D non-LIS enrollees using breast cancer drugs who reached the gap, the number of prescriptions filled within this class per person per month was 17 percent lower in the gap than before the gap **(Exhibit 26)**. Beneficiaries enrolled in commercial insurance or LIS had a much smaller drop of just 6 percent. Making changes to medication regimens in this class could have a significant impact on the patients' chances of surviving the disease.

- Part D non-LIS enrollees reduced their monthly spending on breast cancer drugs by 25 percent after reaching the gap. After reaching the same total spending level, beneficiaries enrolled in commercial insurance reduced spending on these drugs by just 1 percent; those enrolled in LIS did not decrease their spending.

Exhibit 26

Change in Use and Spending Among Medicare Beneficiaries Using Breast Cancer Drugs After Reaching the Coverage Gap Spending Level in 2009



	Rx per person per month:			Spending per person per month:		
Before Gap	0.73	0.72	0.67	$236.50	$220.84	$240.34
During/ After Gap	0.61	0.68	0.62	$177.59	$221.94	$238.68

NOTE: Estimates based on analysis of retail pharmacy claims for individuals with at least one fill of breast cancer medication in 2009 who spent enough to reach the coverage gap threshold: 15,313 Part D non-LIS enrollees, 16,858 Part D LIS enrollees, and 23,369 people age 65+ with private (commercial) drug coverage.
SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

DISCUSSION

The provision in the 2010 health reform law to phase out the Medicare prescription drug benefit's coverage gap, or "doughnut hole," makes this an important time to understand the implications of eliminating the gap for the 29 million people on Medicare currently enrolled in Part D plans. Although the Affordable Care Act has initiated the process of phasing out the coverage gap, with a 50 percent discount on brand-name drugs and a 7 percent discount on generics in 2011, Part D non-LIS enrollees with relatively high spending will continue to be exposed to some gap in coverage until it is fully phased out in 2020. However, the discounts mean that enrollees who reach the gap will pay significantly less for their drugs than they would have prior to 2011. The ongoing political debate over whether to repeal or amend the health reform law makes it important to examine the impact of the coverage gap and the implications of proposals to cancel the scheduled phase-out.

This study focused on estimating how many enrollees reached the coverage gap and catastrophic coverage in 2008 and 2009 and assessing the extent to which the gap affected enrollees' use of medications and out-of-pocket spending. Our findings suggest that a large share of Medicare Part D enrollees who take prescription drugs and are not receiving Low-Income Subsidies can expect to have spending in the coverage gap, while only a small share of these enrollees pass through the gap and qualify for catastrophic coverage. The numbers have diminished modestly between 2007 and 2009, as beneficiaries' awareness of and exposure to this feature of the drug benefit's design has grown. Some enrollees may have made changes to their drug regimens that prevent them from reaching the coverage gap, including switching from brand-name to generic drugs that have entered the market in recent years. The evidence suggests, however, that most Part D enrollees who reach the gap in one year continue to do so in future years, most likely because their health circumstances dictate drug use and spending that cannot be modified enough to help these enrollees avoid reaching the gap.

Out-of-pocket spending increases substantially when enrollees reach the coverage gap, which could help to explain our finding that some enrollees make changes to their drug use regimen when they reach the gap, including reducing their level of drug use and spending for the medications they take in the particular drug classes examined in this study. A greater share of Part D non-LIS enrollees change their behavior than the two comparison groups examined in this study. The latter groups face no gap in coverage when reaching the level of spending where the gap begins for Part D non-LIS enrollees. Differences between the Part D non-LIS group and the comparison groups are consistent across several different measures. Furthermore, they are generally consistent with findings of several other studies.

From a health outcomes perspective, our finding that some enrollees reduced use of their medications when they reached the coverage gap is a serious concern. Individuals with diabetes, for example, risk immediate and potentially serious health consequences if they stop taking their medications. For individuals with other chronic conditions, such as osteoporosis, the health effects from stopping their medications might not be immediately apparent but it could increase their risk of hip fractures and other adverse outcomes. On the other hand, some reductions or medication switches to save money might be a clinically acceptable response to the coverage gap. Our study is unable to find direct evidence for increased use of generics, although we do find that the drop in drug spending once in the gap was concentrated in brand-name drugs. Anecdotal evidence also suggests that beneficiaries may take fewer pills to stretch out a prescription over more days – consistent with our finding that beneficiaries fill fewer prescriptions after reaching the gap.

Ultimately, both stopping and switching medications could result in higher costs for other parts of the Medicare program if beneficiaries have health issues that are not being controlled by medication, or if they simply require more physician visits to prescribe and monitor changes in medications. Studies on the impact of cost sharing for drugs have offered evidence that, for people with chronic illnesses, higher cost sharing leads to more use of hospital inpatient and emergency department services.[48] This seems to occur at least in part because people cut back on their use of essential drugs. But no studies as yet have tested this hypothesis on the Medicare Part D coverage gap.

As the phase-out of the coverage gap moves forward over this decade – assuming the provision in the 2010 health reform law is implemented fully – it will be important to monitor the impact of the change on Part D enrollees' adherence to their medications and their propensity to use generic drugs. It has been noted that the drug-use patterns of Part D enrollees who experience the coverage gap are similar to those of seniors who lacked prescription drug coverage prior to the implementation of Part D in 2006.[49] Better adherence, if it occurs, should be associated with improved health outcomes – as long as patients are taking an optimal set of drugs and avoiding the overuse of drugs. On the other hand, if the reduced size of the coverage gap leads Part D enrollees to give less attention to seeking appropriate generic alternatives, then overall program costs could rise, which could have significant spillover effects on both system costs and the premiums paid by beneficiaries.

Collectively, our findings and those of other studies lend support to the policy decision to phase out the coverage gap. Understanding the full effects of this major change in the design of the Part D benefit, as well as the ongoing costs and consequences faced by Part D enrollees who reach the coverage gap between now and 2020 when the gap is fully phased out, will be essential as policymakers consider proposals that would reverse this change and once again expose current and future Part D enrollees to the full cost of their drugs in the gap.

APPENDIX A: DATA AND METHODOLOGY

IMS Health Longitudinal Prescription (LRx) Database

The IMS Health Longitudinal prescription database (LRx) used for this analysis consists of patient de-identified longitudinal prescription data from a sample of IMS' retail prescription universe. Data is collected for the LRx database via direct data feeds from retail pharmacies (pharmacy chains, food stores, independent pharmacies, mass merchandisers) and from pharmacy benefit managers (PBMs). This database currently captures over 64 percent of all retail prescriptions filled in the United States and over 180 million unique patients.[50] To ensure completeness of the data, IMS requires that the pharmacies used by eligible patients consistently supply data (including reliable data on costs) to the LRx database throughout the study year.

Each prescription in the IMS LRx database includes information about the name, form, strength, and units dispensed, the date the prescription was dispensed, and the specific amount and source of payment (e.g., beneficiary, Medicare drug plan, other payer).

The database maintains longitudinal, person-level records, tracking beneficiaries as they use multiple pharmacies as long as their pharmacy or PBM is part of the IMS panel. All data loaded into the LRx database are encrypted by an independent third party to ensure HIPAA compliance while allowing the database to maintain person-level records. The database includes only basic demographic information such as age and sex.

Identifying Part D Enrollees

In the LRx database, IMS identified Part D enrollees based on information about the third-party payers covering part of their transactions. Individuals were labeled by IMS as Part D enrollees only if there was information that clearly identified them as being in a Part D plan. Within the database, some plans are more clearly labeled than others. For about 16.5 percent of Part D plans, IMS has information indicating only the PBM or the organization, not the specific Part D plan. In these cases, IMS does not assign individuals to a Part D plan, because it is possible that they are enrolled in an employer-sponsored plan using the same insurance company as a Part D plan.

Within LRx, IMS identified 5.1 million Part D enrollees in 2009 and 5.0 million in 2008. Comparing the patient and prescription metrics from the LRx data relative to total prescriptions from its *National Prescription Audit* (NPA), IMS estimates that these 5.1 million individuals represent approximately 21.6 million of the 26.7 million beneficiaries enrolled in Part D in 2009 (81 percent of total Part D enrollees). For 2008, the 5.0 million represent about 19.7 million of 25.4 million beneficiaries (78 percent). The remaining 5.1 million Part D enrollees not represented by this database (5.7 million in 2008) include: Part D enrollees for whom plan type could not be clearly identified; Part D enrollees who did not fill at least one prescription during the year; Part D enrollees residing in institutions such as long-term care or assisted living facilities that fill prescriptions through institutional pharmacies; and Part D enrollees who use mail order exclusively to fill prescriptions.

Unless stated explicitly otherwise, the estimates presented for Part D enrollees in this report exclude LIS enrollees and those who did not use drugs or filled prescriptions only through mail order, institutional pharmacies, or other pharmacies not captured by the IMS Health LRx claims data.

Identifying Part D Low-Income Subsidy Enrollees

Dual eligibles and other beneficiaries receiving the Part D Low-Income Subsidy (LIS) are not subject to the coverage gap, so we treated them separately in this report. However, IMS data do not identify whether Part D enrollees participate in LIS or if they are enrolled in Medicaid. As a proxy, we identified patients whose cost-sharing amount was $6.00 or less per prescription ($5.60 or less in 2008) and 15 percent or less of the total cost for an individual prescription. Part D non-LIS enrollees were those who filled any prescriptions in the year and had at least one

copayment that exceeded $6.00 ($5.60 for 2008). Some beneficiaries (e.g., those with low copays that are more than 15 percent of the total cost for that drug), do not fall clearly in either group so are dropped from the analysis file.[51] Applying this methodology to the 5.1 million total Part D enrollees in our sample, 2.5 million individuals were categorized as LIS recipients (2.4 million of 5.0 million in 2008).

Our methodology may inaccurately classify some low-spending non-LIS enrollees as LIS enrollees. The misclassification of some non-LIS enrollees as LIS enrollees could result from several factors, such as when they pay full price to use off-formulary drugs or use inexpensive drugs for which their small copayment is a relatively high percentage of the total cost. As a test of how well our specifications classified beneficiaries, we examined out-of-pocket costs for both groups. Beneficiaries classified as LIS enrollees paid an average of 5 percent of total drug costs out of pocket in 2009, while beneficiaries classified as non-LIS enrollees paid an average of 39 percent of total drugs costs out of pocket, results which seem to be in the expected range.

We also tested the accuracy of our classifications by comparing spending levels for the two populations with calculations from 2008 Medicare claims, as published by MedPAC.[52] This test provides considerable support for the contention that the IMS data offer an accurate portrayal of Part D drug spending.

Table A1: Comparison of Spending Using IMS Claims Data and Medicare PDE Data, 2008

	2008 LIS Spending		2008 Non-LIS Spending	
	PDE data	IMS data	PDE data	IMS data
Total Spending	$3,888	$2,781	$1,908	$1,655
Out-of-Pocket Spending	$84	$148	$684	$658
Percent Out-of-Pocket	2.2%	5.3%	35.8%	39.8%

SOURCE: IMS estimates are from the analysis conducted for this report. PDE estimates are calculated by MedPAC from prescription drug event (PDE) data as reported in Chart 11-17 of *Healthcare Spending and the Medicare Program: A Data Book*, June 2010.

Our total spending numbers are lower than those calculated from claims data. This is a likely result of some of the limitations of the IMS data (described elsewhere in this Appendix), such as prescriptions filled by mail order or through pharmacies not included in the data. The underestimate is proportionally larger for the LIS population, suggesting that it could also be affected by some misclassifications of low-spending Part D non-LIS enrollees as LIS enrollees. The estimated out-of-pocket shares of spending are remarkably similar, however. Our data show modestly higher shares for each population group.

Commercially Insured Beneficiaries Ages 65 and Older

In addition to beneficiaries enrolled in Part D plans, our analysis included a commercially insured population of Medicare beneficiaries ages 65 and older. This group includes individuals who are 65 or older and did not fill any prescriptions under a Part D plan, but instead filled at least one prescription under another third-party commercial plan. This group includes beneficiaries participating in Part D through the Medicare retiree drug subsidy available to employers who provide their retirees drug coverage at least as generous as Part D. It also includes retirees whose employers did not participate in the subsidy program and beneficiaries still working as active employees and receiving drug benefits through their current employers. Our sample of commercial plan enrollees includes only individuals taking drugs in the nine drug classes used in parts of the analysis, not the overall population of commercial enrollees. Because of overlaps of those in these groups, we can provide only a rough estimate of the overall size of this population as summarized in Table A2.

Table A2: Number of Medicare Beneficiaries (Raw and Projected) in Study Database, 2008-2009

Year	Part D LIS Enrollees	Part D Non-LIS Enrollees	Total Part D Enrollees	Commercial 65+ Beneficiaries
2008 Raw	2,388,924	2,621,587	5,010,511	4 million
2009 Raw	2,543,950	2,588,681	5,132,631	4 million
2008 Proj.	9,394,428	10,347,023	19,741,451	13 million
2009 Proj.	10,670,702	10,974,734	21,645,436	14 million

SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

Classification of Part D Enrollees Using Drugs in Nine Drug Classes

In order to analyze adherence among Part D enrollees who reached the coverage gap, we selected nine groups comprised of users of drugs in nine drug classes: (1) ACE inhibitors; (2) Alzheimer's disease treatments; (3) anti-depressants; (4) angiotensin receptor blockers (ARBs); (5) oral anti-diabetics; (6) osteoporosis treatments; (7) proton pump inhibitors (PPIs); (8) HMG-CoA reductase inhibitors (statins); and (9) drugs used to treat breast cancer, including both aromatase inhibitors and tamoxifen. Each group consists of individuals who filled at least one prescription during the period from January 1, 2009 through December 31, 2009 in the class (or market) of interest (and similarly for 2008). An enrollee may be included in more than one group, if that enrollee filled prescriptions in more than one class during the year. Table A5 includes the full listing of products used to define each drug class. For the plan enrollees identified based on at least one prescription in the select drug classes, information was retained on drugs used in all drug classes. As described below, information on changes in medication use was studied for only the select drug classes.

Table A3: Number of Medicare Beneficiaries (Projected) in Study Database, by Drug Class, 2009

Drug Class	Part D LIS Enrollees	Part D Non-LIS Enrollees	Total Part D Enrollees	Commercial 65+ Beneficiaries
Breast Cancer Treatments	89,255	102,397	191,651	115,160
Alzheimer's Treatments	418,636	408,412	827,048	499,700
Oral Anti-Diabetics	2,044,706	1,347,109	3,391,814	1,757,521
Proton Pump Inhibitors	3,002,875	1,835,322	4,838,197	2,442,042
Angiotensin Receptor Blockers	1,492,563	1,416,861	2,909,424	1,813,710
Antidepressants	2,720,064	1,786,679	4,506,743	1,913,967
Statins	4,112,104	3,826,690	7,938,794	4,486,038
Osteoporosis Treatments	1,088,418	1,076,890	2,165,308	1,197,073
ACE Inhibitors	3,370,773	2,776,615	6,147,388	3,925,569

SOURCE: Georgetown University/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

Defining the Coverage Gap and Catastrophic Coverage

To determine when a Part D non-LIS enrollee reached the coverage gap and catastrophic coverage, total spending per enrollee on all prescriptions across all drug classes in the year was aggregated and divided into spending by month. If an enrollee's cumulative total drug spending for 2009 reached $2,700 in a particular month ($2,510 for 2008), the upper limit of the initial benefit period, the enrollee was classified as having reached the coverage gap that month. If an enrollee's total drug spending reached $6,154 in a particular month ($5,726 for 2008), the upper limit of the coverage gap, the enrollee was classified as having reached catastrophic coverage in that month. Some reached both limits in the same month.

For Part D LIS enrollees and commercial 65+ beneficiaries, we used these same thresholds to determine which enrollees would have reached the coverage gap and catastrophic coverage had they been enrolled in Part D plans and had they not received LIS status. This approach allowed us to examine spending patterns for these other groups and to use them as comparison groups when looking at drug use and spending after reaching the spending level associated with the gap and catastrophic coverage.

As a test of how well these rules classified enrollees, we examined the percent of total spending that enrollees paid out of pocket in 2009. According to the standard benefit design, we would expect beneficiaries to pay 33 percent of costs before entering the coverage gap, on average (a deductible plus 25 percent of the costs in the initial coverage period), 100 percent of costs during the coverage gap, and at least 5 percent of costs after reaching catastrophic coverage. Our results generally follow this pattern but are not equal to the expected rates of out-of-pocket spending, as shown in Table A4.

Table A4: Out-of-Pocket Spending as Share of Total Spending for Part D Non-LIS Enrollees, by Gap Status, 2009

	Before the Coverage Gap	Month Coverage Gap is Reached	During Gap	Month Catastrophic is Reached	During Catastrophic
All Part D non-LIS drug users	35%	48%	66%	40%	14%

SOURCE: Georgetown/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010.

The fact that Part D enrollees did not appear to pay 100 percent of costs in the gap could be due to several reasons:

- Some beneficiaries have partial coverage for drug costs in the gap, either from a drug plan offering enhanced coverage or from a state pharmaceutical assistance program (SPAP).

- Because of the inclusion of uncovered drugs and the exclusion of prescriptions filled outside of pharmacies in the IMS sample, we may have inaccurately estimated when some individual beneficiaries reach the gap.

Similarly, the fact that enrollees paid considerably more than 5 percent of costs during catastrophic coverage has several potential explanations:

- Some beneficiaries pay out of pocket for the full cost of off-formulary drugs.

- Because enrollees in 2009 paid the greater of $2.40 (for generic or preferred multisource drugs), $6.00 (for other brand drugs), or 5 percent of the cost of a drug during catastrophic coverage ($2.25 and $5.60 in 2008), those using a significant number of inexpensive drugs could pay considerably more than 5 percent of the cost for those drugs.

- For various reasons, we may have inaccurately estimated when some beneficiaries reach catastrophic coverage.

We tested an alternate definition of catastrophic coverage as part of this analysis. As described here (and in our previous study), we defined the catastrophic threshold based on total spending for the year, whereas the actual threshold defined in the law is total out-of-pocket spending – $4,350 in 2009 and $4,050 in 2008. Analysis with this alternate definition for the Part D standard non-LIS population yielded somewhat smaller numbers of Part D enrollees reaching the catastrophic threshold. For 2008, using our original method, we find that 3.9 percent of Part D non-LIS enrollees who filled at least one prescription reached catastrophic coverage. The comparable share using the alternate method is 2.0 percent. As described further in Appendix B, the share in catastrophic coverage, as calculated by CMS from claims data, was 2.6 percent. In the report, we used the total spending threshold (our original method) for two reasons. First, although the alternate approach yields results somewhat closer to that from the claims data, the original method provided continuity with results from our previous report. Second, the alternate definition does not work for the two comparison populations – Part D LIS enrollees and the commercially insured population ages 65 and over – since beneficiaries in these groups do not pay out of pocket for the full cost of drugs in the gap.

Defining Changes in Drug Use for Those Who Reach the Coverage Gap

For Part D enrollees with total spending high enough to reach the coverage gap, we examined whether they made any changes in drug use while in the gap. As a benchmark for comparison for each enrollee, we determined the drug or set of drugs (within the class) that the enrollee filled most recently prior to the month in which they reached the coverage gap.[53] We then compared this regimen to prescriptions filled within the drug class during the gap. Each enrollee was categorized into one of the following groups:

- **No change (remained on medication):** For these enrollees, their drug regimen during the coverage gap was the same as the drug use prior to the gap, based on the second prescription filled within the class during the coverage gap (and all other prescriptions within the class with days supply overlapping the second

prescription). We used the second prescription based on the assumption that beneficiaries might have only realized they reached the coverage gap upon filling an initial prescription. However, if an enrollee did not have a second prescription within the coverage gap, the first prescription filled within the class of interest in the coverage gap was compared to the pre-gap regimen.

- **Stopped taking medication**: These enrollees filled at least one prescription for a drug in the class of interest prior to reaching the coverage gap and filled no more than one initial prescription for any drug in the same market while in the coverage gap.

- **Switched medications:** For these enrollees, their drug regimen during the coverage gap was different from their pre-coverage gap use, as defined above. Those who switched drugs in the coverage gap were further categorized as switching to generic therapy or switching to another brand.

- **Reduced medication use:** For these enrollees, their drug regimen during the coverage gap was a subset of the regimen they were taking prior to the coverage gap, indicating that the enrollee continued some products within the class of interest in the gap but not the entire regimen. This behavior was tested for enrollees taking drugs in the anti-depressants, oral anti-diabetics, Alzheimer's disease and osteoporosis classes, in which it is common for patients to take multiple drugs within the class. For the other drug classes in this study, patients generally take just one drug in the class at any given time.

Enrollees who subsequently reached catastrophic coverage were similarly categorized into these four categories while in the period of catastrophic coverage. Using this information, we were able to identify such patterns as stopping medications during the gap and then resuming them during catastrophic or remaining off the medications during catastrophic coverage.

Our analysis considers only medication changes within the classes selected for study. We are unable to tell if enrollees who reached the gap stopped taking or reduced medications in another drug class in order to continue taking medication within the classes in our study, nor are we able to tell if enrollees were receiving free samples from their physicians. Some individuals shown as discontinuing, reducing, or switching medications might have done so for clinical reasons coincidental with the time of reaching the gap.

Defining the Two-Year Population for 2008 and 2009

A new feature of the analysis for this report is to look at two-year patterns for 2008 and 2009. This allows us to determine, for example, whether beneficiaries who reached the coverage gap in 2008 also did so in 2009. The population base for the two-year analysis is smaller than that used for either the 2008 or 2009 analysis. Individuals included in the two-year analysis must be enrolled in Part D as a non-LIS enrollee both years and must have filled a prescription in both years. Furthermore, they must have filled prescriptions in pharmacies that are tracked in the IMS database and report reliable data for both years. The resulting group of beneficiaries has higher average drug spending and is somewhat more likely to reach the coverage gap. For example, whereas our estimate for 2009 is that 19 percent of Part D enrollees reached the gap, 26 percent of the two-year sample reached the gap in 2009.

We also used this population to look at the therapy decisions in 2009 for patients who reached the gap in 2008. For this analysis, we compare the earlier prescription or drug regimen in 2009 to the same patient's status during the coverage gap and catastrophic coverage (if applicable) in 2008.

Patients who "remained on therapy" or "returned to therapy" during the coverage gap or catastrophic coverage in 2008 were classified into any of three categories based on their initial 2009 prescription or regimen within a particular drug class compared with the final 2008 prescription or regimen filled within the drug class prior to the coverage gap and catastrophic coverage: (1) remained on therapy, (2) switched therapies, or (3) stopped therapy. Patients who discontinued or switched therapy in a particular drug class while in the coverage gap or catastrophic

coverage in 2008 were classified as either returning to therapy or not, based on the presence of a prescription for that same drug class during the year of 2009.

Data Limitations

The IMS Health database used for this analysis has omissions and limitations that could affect the precision of our estimate of the share of Part D enrollees with spending in the coverage gap or reach catastrophic coverage. These limitations may result in either over- or under-estimation of the share that can be calculated using claims data from all Part D plans.[54] However, we are not able to quantify the impact of these sources of bias, and it is not entirely clear whether the limitations would result in a net bias that produces higher or lower estimates of the share of enrollees who reached the coverage gap. There are factors that operate in both directions in terms of inflating and deflating the estimate.

Our estimate could be biased upward due to several factors:

- The IMS database includes only Part D enrollees who use prescriptions.[55] Including non-users enrolled in Part D in the denominator would produce a lower estimate of the share of Part D enrollees who reach the coverage gap.

- The IMS database does not allow for identification of LIS status other than by using low cost-sharing amounts. The designation of LIS status based on cost-sharing amounts could inadvertently exclude valid cases from the study sample by misidentifying some Part D non-LIS enrollees with low drug spending (e.g., those who use a limited number of generic drugs only) as LIS enrollees and thus excluding them from the count of those not reaching the gap. This factor might be somewhat mitigated by the exclusion of some enrollees with coverage through state pharmaceutical assistance programs (SPAPs) that brings out-of-pocket costs down to LIS levels, but who might have costs sufficient to reach the gap without the protection provided by the SPAP.

- The IMS database does not provide sufficient information about Part D plans (in particular, it does not distinguish among the multiple plan offerings of a single sponsor) to allow for identification of the small share of enrollees in plans with full gap coverage, which prevents us from excluding them from the analysis. In 2008 and 2009, no beneficiaries in stand-alone PDPs and fewer than 2 percent of those in Medicare Advantage drug plans were in plans that eliminated the gap completely.

- The IMS database does not identify which pharmacy claims are for the purchase of off-formulary drugs, which do not count toward the spending totals that trigger either the coverage gap or catastrophic coverage. Because we cannot exclude these spending amounts from our analysis, this would inflate expenses for at least a subset of Part D enrollees, placing them in the gap and catastrophic coverage sooner than they otherwise might be.

In addition, our estimate could be biased downward due to several factors:

- For those Part D enrollees in the IMS sample who also fill prescriptions at pharmacies excluded from the dataset, their actual total spending amounts would be higher than the IMS data suggest, which would reduce our estimate of the share with spending high enough to reach the coverage gap or catastrophic coverage. It would also affect our estimate of when enrollees reach the gap.

- Similarly, Part D enrollees in the IMS sample who fill prescriptions through both retail pharmacies and mail order would have higher actual spending than is reported in the IMS data. To the extent that enrollees fill their maintenance medications by mail and fill only one-time or some new prescriptions at retail, spending for these individuals would be substantially underestimated.

- The IMS dataset does not capture the universe of Part D prescription drug claims filled through institutional pharmacies, such as for beneficiaries in full-time residence at assisted living or long-term care (LTC) facilities who may be disproportionately high drug users. The exclusion of Part D enrollees from the sample who use institutional pharmacies could deflate our estimate of the share who reach the coverage gap to the extent such individuals are high users of medications. This effect might be mitigated somewhat by the fact that a large share of nursing home residents are LIS enrollees, and would not be included in the study design.

Factors that could bias our estimates in either direction:

- Several groups are excluded from the IMS sample. They include full-time users of other excluded pharmacies such as mail-order, staff-model HMOs (such as Kaiser Permanente), or pharmacies not submitting data; users of pharmacies that provide inconsistent data; and enrollees in Part D plans that could not be identified. It is unclear whether any of these groups would have drug use higher or lower than average.

- Finally, most of our analyses include only the prescriptions that Part D enrollees filled through their Part D plan. There is some evidence that beneficiaries fill a small number of additional prescriptions outside the Part D benefit. In some cases, these cash transactions may be captured in the IMS data and thus would be counted as if purchased under Part D; in other cases, the cash transactions may not be captured.

Although these data limitations might affect the precision of our estimates of the overall proportion of non-LIS drug users enrolled in Part D plans who reach the coverage gap, we are unable to quantify whether the net bias is upward or downward. Furthermore, we have no reason to think that the IMS data capture an unrepresentative profile of the experience of Part D enrollees once they reach the coverage gap, in terms of the effects on drug therapy changes or drug spending – issues which are central to understanding the overall effect of the coverage gap on Part D enrollees.

Table A5: Listing of Drugs in Selected Drug Classes

Drug Class 1: HMG-CoA Reductase Inhibitors (Statins)

USC	Product	Product Type
32180	ADVICOR	Brand
32110	ALTOPREV	Brand
31800	CADUET	Brand
32110	CRESTOR	Brand
32110	LESCOL	Brand
32110	LESCOL XL	Brand
32110	LIPITOR	Brand
32110	LOVASTATIN	Generic
32110	MEVACOR	Brand
32110	PRAVACHOL	Brand
32110	PRAVASTATIN SOD	Generic
32180	PRAVIGARD PAC	Brand
32180	SIMCOR	Brand
32110	SIMVASTATIN	Generic
32180	VYTORIN	Brand
32110	ZOCOR	Brand

Drug Class 2: Angiotensin-Converting Enzyme (ACE) Inhibitors

USC	Product	Product Type
31111	ACCUPRIL	Brand
31112	ACCURETIC	Brand
31111	ACEON	Brand
31111	ALTACE	Brand
31118	AMLODIP BES/BENAZ HCL	Generic
31111	BENAZEPRIL HCL	Generic
31112	BENAZEPRIL/HCTZ	Generic
31111	CAPOTEN	Brand
31112	CAPOZIDE	Brand
31111	CAPTOPRIL	Generic
31112	CAPTOPRIL/HCTZ	Generic
31111	ENALAPRIL MAL	Generic
31112	ENALAPRIL MAL/HCTZ	Generic
31111	ENALAPRILAT	Generic
31111	FOSINOPRIL SOD	Generic
31112	FOSINOPRIL/HCTZ	Generic
31118	LEXXEL	Brand
31111	LISINOPRIL	Generic
31112	LISINOPRIL/HCTZ	Generic
31111	LOTENSIN	Brand
31112	LOTENSIN HCT	Brand
31118	LOTREL	Brand
31111	MAVIK	Brand
31111	MOEXIPRIL HCL	Generic
31112	MOEXIPRIL HCL/HCTZ	Generic
31111	MONOPRIL	Brand
31112	MONOPRIL HCT	Brand
31111	PRINIVIL	Brand
31112	PRINZIDE	Brand
31111	QUINAPRIL HCL	Generic
31112	QUINAPRIL HCL/HCTZ	Generic
31112	QUINARETIC	Generic
31118	TARKA	Brand
31111	TRANDOLAPRIL	Generic
31112	UNIRETIC	Brand
31111	UNIVASC	Brand
31112	VASERETIC	Brand
31111	VASOTEC	Brand
31112	ZESTORETIC	Brand
31111	ZESTRIL	Brand

Drug Class 3: Angiotensin Receptor Blockers (ARBs)

USC	Product	Product Type
31121	ATACAND	Brand
31122	ATACAND HCT	Brand
31122	AVALIDE	Brand
31121	AVAPRO	Brand
31123	AZOR	Brand
31121	BENICAR	Brand
31122	BENICAR HCT	Brand
31121	COZAAR	Brand
31121	DIOVAN	Brand
31122	DIOVAN HCT	Brand
31123	EXFORGE	Brand
31124	EXFORGE HCT	Brand
31122	HYZAAR	Brand
31121	MICARDIS	Brand
31122	MICARDIS HCT	Brand
31121	TEVETEN	Brand
31122	TEVETEN HCT	Brand

Drug Class 4: Anti-Depressants

USC	Product	Product Type
64330	APLENZIN	Brand
64330	BUDEPRION SR	Generic
64330	BUDEPRION XL	Generic
64330	BUPROPION HCL	Generic
64330	BUPROPION HCL SR	Generic
64330	BUPROPION HCL SR W	Generic
64330	BUPROPION HCL XL	Generic
64340	CELEXA	Brand
64340	CITALOPRAM HBR	Generic
64350	CYMBALTA	Brand
64330	DESYREL	Brand
64350	EFFEXOR	Brand
64350	EFFEXOR XR	Brand
64340	FLUOXETINE HCL	Generic
64340	FLUVOXAMINE MAL	Generic
64340	LEXAPRO	Brand
64340	LUVOX	Brand
64340	LUVOX CR	Brand
64330	NEFAZODONE HCL	Generic
64340	PAROXETINE HCL	Generic
64340	PAROXETINE HCL ER	Generic
64340	PAXIL	Brand
64340	PAXIL CR	Brand
64340	PEXEVA	Brand
64350	PRISTIQ	Brand
64340	PROZAC	Brand
64340	PROZAC WEEKLY	Brand
64340	RAPIFLUX	Brand
64340	SARAFEM	Brand
64340	SELFEMRA	Brand
64340	SERTRALINE HCL	Generic
64330	SERZONE	Brand
64330	TRAZAMINE	Brand
64330	TRAZODONE HCL	Generic
64350	VENLAFAXINE HCL	Generic
64350	VENLAFAXINE HCL ER	Generic
64330	WELLBUTRIN	Brand
64330	WELLBUTRIN SR	Brand
64330	WELLBUTRIN XL	Brand
64340	ZOLOFT	Brand

Drug Class 5: Alzheimer's Disease Treatments

USC	Product	Product Type
20400	ARICEPT	Brand
20400	ARICEPT ODT	Brand
20400	COGNEX	Brand
20400	EXELON	Brand
20400	GALANTAMINE HBR	Generic
20400	GALANTAMINE HBR ER	Generic
20400	NAMENDA	Brand
20400	RAZADYNE	Brand
20400	RAZADYNE ER	Brand

Drug Class 6: Oral Anti-Diabetics

USC	Product	Product Type
39241	ACARBOSE	Generic
39211	ACETOHEXAMIDE	Generic
39280	ACTOPLUS MET	Brand
39230	ACTOS	Brand
39211	AMARYL	Brand
39280	AVANDAMET	Brand
39280	AVANDARYL	Brand
39230	AVANDIA	Brand
39211	CHLORPROPAMIDE	Generic
39211	DIABETA	Brand
39211	DIABINESE	Brand
39280	DUETACT	Brand
39220	FORTAMET ER	Brand
39211	GLIMEPIRIDE	Generic
39211	GLIPIZIDE	Generic
39211	GLIPIZIDE ER	Generic
39211	GLIPIZIDE XL	Generic
39280	GLIPIZIDE/METFORM	Generic
39220	GLUCOPHAGE	Brand
39220	GLUCOPHAGE XR	Brand
39211	GLUCOTROL	Brand
39211	GLUCOTROL XL	Brand
39280	GLUCOVANCE	Brand
39220	GLUMETZA	Brand
39211	GLYBURIDE	Generic
39211	GLYBURIDE MICRO	Generic
39280	GLYBURIDE/METFORM	Generic
39211	GLYCRON	Brand
39211	GLYNASE PRESTAB	Brand
39240	GLYSET	Brand
39280	JANUMET	Brand
39260	JANUVIA	Brand
39280	METAGLIP	Brand
39220	METFORMIN HCL	Generic
39220	METFORMIN HCL ER	Generic
39211	MICRONASE	Brand
39271	NATEGLINIDE	Generic
39261	ONGLYZA	Brand
39272	PRANDIMET	Brand
39212	PRANDIN	Brand
39240	PRECOSE	Brand
39220	RIOMET	Brand
39213	STARLIX	Brand
39211	TOLAZAMIDE	Generic
39211	TOLBUTAMIDE	Generic

Drug Class 7: Osteoporosis Treatments

USC	Product	Product Type
59210	ACTONEL	Brand
59210	ACTONEL W/ CALC	Brand
59210	ALENDRONATE SOD	Generic
59210	AREDIA	Brand
59290	BONISARA	Brand
59210	BONIVA	Brand
59220	CALCITONIN-SALMON	Generic
59210	DIDRONEL	Generic
59210	ETIDRONATE DISOD	Generic
59290	EVISTA	Brand
59230	FORTEO	Brand
59220	FORTICAL	Generic
59210	FOSAMAX	Brand
59210	FOSAMAX PLUS D	Brand
59290	FOSTEUM	Brand
59220	MIACALCIN	Brand
59210	PAMIDRONATE DISOD	Generic
59210	RECLAST	Brand
59220	SALMON CALCITONIN	Generic
59210	SKELID	Brand
59210	ZOMETA	Brand

Drug Class 8: Proton Pump Inhibitors (PPIs)

USC	Product	Product Type
23420	ACIPHEX	Brand
23430	HELIDAC	Brand
23420	KAPIDEX	Brand
23420	NEXIUM	Brand
23420	NEXIUM IV	Brand
23420	OMEPRAZOLE	Generic
23420	OMEPRAZOLE (OTC)	Generic
23420	OMEPRAZOLE (RX)	Generic
23420	PANTOPRAZOLE SOD	Generic
23420	PREVACID	Brand
23420	PREVACID I.V.	Brand
23420	PREVACID SOLUTAB	Brand
23430	PREVPAC	Brand
23420	PRILOSEC	Brand
23420	PRILOSEC (OTC)	Brand
23420	PROTONIX	Brand
23420	PROTONIX IV	Brand
23430	PYLERA	Brand
23430	TRITEC	Brand
23420	ZEGERID	Brand

Drug Class 9: Drugs Used to Treat Breast Cancer

USC	Product	Product Type
30570	ARIMIDEX	Brand
30570	AROMASIN	Brand
30570	FEMARA	Brand
30550	TAMOXIFEN CIT*	Generic

* Tamoxifen is not a Aromatase inhibitor but a competitor to the Aromatase inhibitors in the breast cancer market.

APPENDIX B: COMPARING OUR FINDINGS TO CMS PRESCRIPTION DRUG EVENT DATA

Our estimates correspond closely with estimates from the Centers for Medicare & Medicaid Services (CMS) of the portion of Part D non-LIS enrollees reaching the coverage gap in 2007 and 2008, the latest years for which CMS estimates are available.

In our last report, we found that 26.4 percent of Part D non-LIS enrollees with at least one prescription reached the gap in 2007. Based on PDE data, CMS reported that 23.8 percent reached the gap in 2007 – somewhat lower than our estimate. Both our analysis and that conducted by CMS use paid claims over the course of the year, and so both are comparable in not counting people without any drug claims throughout the year. Similarly, we find that 23.3 percent reach the gap in 2008, identical to the CMS estimate for that year. Calculations made using PDE data by the CMS Chronic Condition Warehouse (released in May 2011) differ because they include Part D enrollees who fill no prescriptions during the year. That analysis shows 23.4 percent of Part D non-LIS enrollees reaching the coverage gap spending level in 2007, 19.3 percent in 2008, and 17.5 percent in 2009. Adjusting those figures to exclude those who fill no prescriptions lowers the shares to 26 percent, 21 percent, and 19 percent – quite similar to our estimates from the IMS data.[56]

Table B1: Comparison of Findings Using IMS Claims Data and Medicare Prescription Drug Event (PDE) Data, 2007-2008

	Non-LIS Enrollees, 2007		Non-LIS Enrollees, 2008		LIS Enrollees, 2008	
	IMS data	PDE data	IMS data	PDE data	IMS data	PDE data
Share of Part D enrollees reaching the coverage gap spending level	26.4%	23.8%	23.3%	23.3%	37.0%	43.8%
Share of Part D enrollees reaching catastrophic coverage level	4.3%	2.7%	3.9% / 2.0%*	2.6%	12.9%	18.6%

NOTE: For the 2007 PDE numbers, the breakout of LIS and non-LIS is estimated from the numbers presented by CMS. *3.9% is the estimate based on our original method for determining catastrophic coverage; 2.0% is the estimate based on our alternate definition.
SOURCE: For IMS data: Georgetown/NORC/Kaiser Family Foundation analysis of IMS Health LRx database, 2010. For PDE data: Anita Varghese, "Beneficiary Experience in the Coverage Gap and Catastrophic Phase," presentation at the 2010 Part D Symposium, CMS, March 2010; Christopher Powers, "Beneficiary Experience: Average Cost for Beneficiaries and by Sub-Population as well as Analysis of the Initial Coverage Limit," presentation at the 2008 Part D Symposium, CMS, October 2008. Presentations found at http://www.cms.gov/PrescriptionDrugCovGenIn/09_ProgramReports.asp#TopOfPage.

Our estimates for the numbers reaching catastrophic coverage are somewhat higher than those calculated by CMS. In our last report, we found that 4.3 percent of Part D non-LIS enrollees reached catastrophic coverage in 2007, whereas CMS found that 2.7 percent reached catastrophic coverage that year. Our comparable number for 2008 is 3.9 percent, versus 2.6 percent for CMS. We tested an alternate methodology for measuring catastrophic coverage in 2008, yielding an estimate of 2.0 percent – lower than the CMS calculation (see Appendix A above for further details). The chance for errors, using either estimation method, is likely to increase for the high-spending beneficiaries who reach catastrophic coverage. For example, they are more likely to use off-formulary prescriptions or to fill prescriptions at different pharmacies.

Our estimates for the LIS population are somewhat lower than CMS numbers. Whereas we found that 37 percent of LIS enrollees reached the spending level associated with the coverage gap in 2008, CMS found that 43.8 percent reached that level. The higher proportion in our analysis likely reflects the challenges we face in estimating who qualified for the LIS. Our methodology is likely to misclassify some low-spending non-LIS enrollees as LIS enrollees. Additional discussion of these comparisons is found in Appendix C.

Although CMS has not yet reported a complete analysis from prescription drug events for 2009 or 2010, it did report that about 3.8 million people received $250 rebate checks in 2010 based on reaching the coverage gap at some point during the year.[57] This is somewhat higher than our estimate that 3.4 million people reached the gap in 2009, perhaps party because the number of beneficiaries increases each year. Knowing CMS's official estimate for the number of those reaching the coverage gap in 2009 and 2010 would make it easier to understand the trends over time.

APPENDIX C: OTHER RESEARCH ON THE COVERAGE GAP

Since our first report on the coverage gap was released in 2008, there has been a growing body of evidence on how many Part D enrollees reach either the coverage gap or catastrophic coverage. At the time of our last report, no calculation based on Medicare claims data was available. Our analysis was based on retail pharmacy claims collected by IMS Health, while other researchers produced estimates from subsets of enrollees, such as those with diabetes and enrollees in a Medicare Advantage plan in Northern California.[58] Since that time, researchers at the Centers for Medicare & Medicaid Services (CMS) have released calculations from Medicare claims data on how many people reached the gap and catastrophic coverage each year from 2006 to 2008.[59] The CMS calculation of the share of beneficiaries reaching the gap is nearly identical to the share we reported in the earlier report and those reported here. More details on this comparison are found in Appendix B above.

Other studies have also been done on the changes that Medicare beneficiaries make in the drugs they take either once they reach the Part D coverage gap or when they anticipate reaching that stage of the drug benefit. In our first report, we found that about 20 percent of enrollees who were taking drugs in one of eight drug classes and who reached the coverage gap in 2007 either stopped taking a medication in that drug class, reduced their medication use (e.g., skipped doses), or switched to a different medication in that class when they reached the gap. Other literature has also reported evidence of changes in drug use after reaching the gap. A literature review published in 2010 found that across six studies, researchers found that entry into the coverage gap was associated with 9 percent to 16 percent less drug use and that out-of-pocket spending was up by as much as 89 percent.[60] The studies reviewed also included findings that those reaching the gap were between 5 percent and 11 percent more likely to discontinue, switch, or fail to initiate a medication and increased their use of generic drugs by 20 percent. One of the studies reviewed compared enrollees in Medicare Advantage plans and employer plans offered by a large Pennsylvania insurer in 2006. Those lacking coverage in the Part D coverage gap reduced their drug use by 14 percent once reaching the gap.[61] Another study included in the review looked at claims data from three pharmacy chains between 2005 and 2006, focusing on four drug classes. Those reaching the gap saw a drop in use of 5 to 6 percentage points relative to the baseline.[62] Another study, published more recently, looked at beneficiaries with diabetes in one staff-model and one network-model Medicare Advantage plan in 2006. Researchers found that overall drug spending was about 3 to 4 percent lower for beneficiaries with a gap versus those with full or generic-only gap coverage. Those with a gap in coverage also experienced lower adherence to drugs in three chronic drug classes.[63] Finally, a study by the HHS Office of the Inspector General (OIG), based on an analysis of 2006 Medicare drug claims, found that about 69 percent of those reaching the gap decreased their average number of drugs after reaching the gap from 4.5 to 3.8 monthly prescriptions (although another 29 percent increased their average from 4.3 to 5.6 prescriptions).[64]

Most available data sources are limited to a look at drugs obtained through paid prescriptions – whereas some beneficiaries may be substituting free samples or drugs bought for cash from cheaper sources. Drug use data alone do not allow researchers to answer questions of whether any changes are appropriate and whether they have further consequences. Several studies use surveys or focus groups with beneficiaries to provide some additional evidence on behavior changes by beneficiaries who reach the gap and the consequences of those changes. One such study reported on a 2007 survey of enrollees in a Medicare Advantage plan. About 26 percent reported some type of cost-coping behavior, while 15 percent said they reduced adherence to their drug regimens.[65] That survey also found over half of all Medicare beneficiaries were unaware that the benefit included a gap – although anecdotal evidence would suggest that awareness has increased over time. Another study also based on a survey of enrollees with diabetes who were affiliated with a particular insurer found that those in a plan offering some coverage for generics in the gap were less likely to report cost-related non-adherence behaviors than those with no gap coverage at all.[66] The OIG study reported on a 2008 survey of beneficiaries in the gap without financial assistance, finding that 38 percent sought a less costly option, 15 percent sought financial help from another source, 33 percent either stopped at least one drug or switched to another (some said they took more than one of these steps).[67] In focus groups conducted for the Medicare Payment Advisory Commission (MedPAC) in 2009, beneficiaries who reached the gap reported on a wide array of coping strategies and adjustments to lower their overall costs, especially if they had also reached the gap in earlier years, including

behaviors that would show up in drug data such as switching drugs, stopping a medication or skipping doses, as well as others that might not, such as using free samples and shopping for drugs in Canada.[68] Finally, an analysis of more than 100,000 replies to the Medicare Consumer Assessment of Healthcare Providers & Systems Survey (CAHPS) in 2007 found that beneficiaries whose spending put them in the coverage gap were 34 percent more likely to not adhere to their drug regimen because of cost. By contrast, low-income beneficiaries who receive help in paying for drugs in the coverage gap were more likely to adhere to their regimens.[69]

ENDNOTES

[1] See for example, Kaiser Family Foundation, "Comparison of Medicare Provisions in Deficit-Reduction Proposals," April 2011, http://www.kff.org/medicare/8124.cfm. "Proposed Changes to Medicare in 'Path to Prosperity'': Overview and Key Questions," April 2011, http://www.kff.org/medicare/8179.cfm.

[2] The share of Part D enrollees with spending in the coverage gap could be lower than this estimate because the IMS data exclude people who do not take medications and because of the relatively large share of Part D enrollees categorized as Low-Income Subsidy recipients; the actual share in the coverage gap could also be higher because the IMS data does not include the universe of pharmacies and excludes all mail order expenditures under Part D plans. See Appendix A for further discussion of these issues.

[3] Adjusting for some upward bias in the two-year sample lowers the estimate of those reaching the gap in one or both years from 34 percent to 27 percent Part D non-LIS enrollees.

[4] Bruce Stuart et al., "Riding The Rollercoaster: The Ups And Downs In Out-Of-Pocket Spending Under The Standard Medicare Drug Benefit," *Health Affairs* 24(4): 1022-1031, July/August 2005.

[5] See for example, Thomas Rice and Karen Y. Matsuoka, "The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors," *Medical Care Research and Review*, 61(4): 415-452, December 2004.

[6] Part D enrollees who qualify for the Low-Income Subsidy (LIS), including beneficiaries dually eligible for Medicare and Medicaid, are generally not responsible for costs in the coverage gap beyond their usual copayment.

[7] For information about the coverage gap in 2011, see Jack Hoadley et al, "Medicare Part D 2011 Data Spotlight: The Coverage Gap," Kaiser Family Foundation, August 2011.

[8] Beneficiaries who reached the gap in 2010 received a $250 rebate payment.

[9] Kaiser Family Foundation, "Proposed Changes to Medicare in 'Path to Prosperity': Overview and Key Questions," April 2011, http://www.kff.org/medicare/8179.cfm.

[10] Jack Hoadley, Elizabeth Hargrave, Juliette Cubanski, and Tricia Neuman, "The Medicare Part D Coverage Gap: Cost and Consequences in 2007," Kaiser Family Foundation publication 7811 (August 2008).

[11] In our 2008 report, we reported that an estimated 3.4 million or 14 percent of all Part D enrollees reached the coverage gap in 2007. This estimate was based on the total number of Part D enrollees in 2007 at a single point in time (24.2 million), adjusted for total LIS enrollment, the number of non-drug users, and the number with full gap coverage from their plans. For calculations in this report, we use the total number of beneficiaries who file at least one drug claim during the year – a larger total than the point-in-time estimate – and thus need to adjust only for LIS enrollment and the number with full gap coverage from their plans. The corresponding number of Part D enrollees for 2007 is 26.2 million. Based on this number, our revised estimate of those who reached the gap in 2007 is 4.0 million or 15 percent of all Part D enrollees.

[12] The program's first year (2006) is viewed as atypical since a substantial share of beneficiaries first enrolled after January 1, 2006.

[13] Beneficiaries qualifying for the Low-Income Subsidy are protected from the gap and continue to be responsible for pre-gap cost-sharing payments. Medicare beneficiaries in commercial plans typically have no gap in coverage, although there may be a few plans with some type of coverage gap.

[14] In 2008, the coverage gap begins when a beneficiary's total drug spending reaches $2,510 and ends when a beneficiary has spent $4,050 out of pocket (the equivalent of $5,726 in total drug spending).

[15] See Elizabeth Hargrave, Jack Hoadley, Juliette Cubanski, and Tricia Neuman, "Medicare Part D 2009 Data Spotlight: Medicare Prescription Drug Plans in 2009 and Key Changes Since 2006: Summary of Findings," Kaiser Family Foundation publication 7917 (June 2009).

[16] These calculations exclude plans that cover just a "few" drugs in the gap; "few" is defined by CMS as less than 10 percent of drugs on a plan's formulary. Elizabeth Hargrave et al., "Medicare Part D 2009 Data Spotlight: Medicare Prescription Drug Plans in 2009 and Key Changes Since 2006: Summary of Findings."

[17] Because IMS does not collect information about Part D enrollees' LIS participation, we used copayment information associated with each claim as a proxy indicator for LIS enrollment (see details in Appendix A). Although the amounts used are typically lower than copayments paid by non-LIS enrollees in Part D plans, use of these proxy rules may incorrectly categorize some non-LIS enrollees who take only very low-cost medications as LIS enrollees.

[18] The IMS data provide estimates of the number of commercial enrollees in each drug class. We derived this estimate by assuming the degree of overlap across drug classes for this population matched that for Part D non-LIS enrollees.

[19] Christopher Powers, "Beneficiary Experience," presentation at the Medicare Prescription Drug Benefit Symposium, CMS, October 2008; Anita Varghese, "Beneficiary Experience in the Coverage Gap and Catastrophic Phase," presentation at the 2010 Part D Symposium, CMS, March 2010.

[20] Estimating the total number of Part D enrollees who reached the coverage gap in 2009 requires taking into account the limitations in our dataset by adjusting for such factors as total LIS enrollment and the number who had full gap coverage from their plans. In 2009, about 18.0 million out of 28.9 million Part D enrollees potentially faced the full cost of medications if they reached the coverage gap because they did not receive the Low-Income Subsidy or have full gap coverage for brands and generics from their plan. Applying our 19 percent estimate to this total suggests that about 3.4 million beneficiaries reached the coverage gap and faced the full cost of their prescriptions in 2009. The comparable figure for 2008 is 3.9 million beneficiaries (23 percent of Part D non-LIS enrollees with no gap coverage, or 14 percent of the total population of Part D enrollees). For these calculations, we use the total number of beneficiaries who file at least one drug claim during the year – a larger total than is reported elsewhere for the number of Part D enrollees at a point time during the year. This approach is consistent with IMS data and with similar estimates by CMS (see Appendix B).

[21] Somewhat similar results were obtained in an analysis of claims data by a CMS researcher, using diagnosis indicators based on broader information available in Medicare claims (CCW Chronic Condition flags). That analysis showed high rates of reaching the gap for people with Alzheimer's disease and depression as compared to lower rates for osteoporosis. Christopher Powers, "Chronic Conditions and Progression Through Part D Benefit Phases," presentation at AcademyHealth Annual Meeting, Boston, June 28, 2010.

[22] The population base for the two-year analysis is smaller than that used for either the 2008 or 2009 analysis. Individuals included in the two-year analysis were enrolled in Part D as a non-LIS enrollee both years and must have filled a prescription in both years. Furthermore, they must have filled prescriptions in pharmacies that are tracked in the IMS database and report reliable data for both years. The resulting group of beneficiaries has higher average drug spending and is somewhat more likely to reach the coverage gap. For example, whereas our estimate for 2009 is that 19 percent of Part D enrollees reached the gap, 26 percent of the two-year sample reached the gap in 2009. We adjusted our estimate based on the relative difference in the sample result for each year based on the percentage difference for that year and for the two-year overlap group based on the average percentage difference across the two years. See Appendix A for more information on the data sets used in this analysis.

[23] One study showed that prescription drug expenditures are highly persistent over a two year period – far more so than other health expenditures. "About half of the variation in prescription drug expenditures can be predicted using information from the previous year, including therapeutic categories based on drug utilization." Jessica S. Banthin and G. Edward Miller, "Persistence in Medicare Prescription Drug Expenditures by Treatment Class," Agency for Healthcare Research and Quality Working Paper No. 06006, September 2006.

[24] Because our analysis is restricted to two years, we cannot tell how many of those we characterize as new to the coverage gap in 2009 previously reached the gap in 2006 or 2007, but then did not do so in 2008. These could include people whose health circumstances have fluctuated over time as well as those with spending close to the gap threshold.

[25] Conversely, many beneficiaries under age 65 qualify for LIS, a greater share of whom reach this threshold of total drug spending than older LIS enrollees.

[26] Calculations from Part D claims show a similar decline from 2007 to 2009 (23.4 percent, 19.3 percent, and 17.5 percent). These levels are lower than those in our analysis because they include Part D non-LIS enrollees who fill no prescriptions during the year. After adjusting for that group, the trend calculated from claims (26 percent, 21 percent, and 19 percent) would be quite similar to those in Exhibit 8. "CMS Chronic Condition Data Warehouse (CCW) Medicare 5% Sample: Medicare Part D Prescription Drug Costs for 2006 Through 2009," May 2011, http://www.ccwdata.org/cs/groups/public/documents/document/wls_ucm1-000782.pdf.

[27] Calculations from Part D claims also show a modest decline in the number of Part D non-LIS enrollees reaching catastrophic coverage from 2007 to 2009: 2.6 percent, 2.5 percent, and 2.2 percent. "CMS Chronic Condition Data Warehouse (CCW) Medicare 5% Sample: Medicare Part D Prescription Drug Costs for 2006 Through 2009," See Appendix B for more information on comparisons with CMS data.

[28] Department of Health and Human Services, "The Affordable Care Act Reduces Out-of-Pocket Drug Costs for Millions of People with Medicare," Report, Healthcare.gov, March 2011.

[29] Among the coping mechanisms reported by enrollees, some made short-term adjustments while in the gap (such as skipping pills on some days) and then returned to normal regimens in the next year. Others made adjustments (such as asking their doctors for less expensive options) that they could use to delay or eliminate reaching the gap in the future. See Elizabeth Hargrave, Jack Hoadley, Laura Summer, and Ayesha Mahmud, "Findings from Beneficiary and Physician Focus Groups," contractor report on 2009 focus groups, submitted to MedPAC, October 2009. http://www.medpac.gov/documents/May10_FocusGroup_CONTRACTOR_JS.pdf

[30] Unpublished study by IMS Health, private communication.

[31] Anne Martin et al., "Recession Contributes to Slowest Annual Rate of Increase in Health Spending in Five Decades," *Health Affairs* 30(1) 11-22, January 2011.

[32] Bruce Stuart et al., "Riding The Rollercoaster: The Ups And Downs In Out-Of-Pocket Spending Under The Standard Medicare Drug Benefit," *Health Affairs* 24(4): 1022-1031, July/August 2005.

[33] Other analysis has also found higher drug utilization and spending for LIS enrollees. For example, MedPAC has reported that LIS enrollees averaged $324 in drug spending per month in 2008 (although only responsible for $7 out of pocket), compared to $159 for the average Part D non-LIS enrollee (who spent $57 out of pocket). See MedPAC, "Healthcare Spending and the Medicare Program: A Data Book," June 2010. Compared to the MedPAC results, our data show lower total spending for Part D LIS enrollees and higher out-of-pocket spending. Some of the difference may be due to the absence of actual LIS designations in our data. In Appendix B, we report further on comparisons between our data and the data from the MedPAC data book.

[34] Kaiser Family Foundation, "Medicare Chartbook," fourth edition, 2010, http://www.kff.org/medicare/8103.cfm.

[35] We cannot show comparisons for the overall populations of the commercially insured population over age 65 and the two groups of Part D enrollees because our analysis only includes the commercially insured individuals subgroups who used drugs from select drug classes.

[36] Note that our database excludes those under age 65 from the commercial population. If we restricted the comparison to those Part D non-LIS enrollees over 65, the differences would be reduced.

[37] Some literature supports the idea that many patients are not totally adherent with their medications in any circumstance. In particular, there is some evidence that adherence declines over time – especially after the first six months of a given therapy. Of course, this tendency would apply to both those who experience the coverage gap and those who do not; accordingly, it does not weaken our conclusion that the coverage gap has a separate effect on adherence. Carmel M. Hughes, "Medication Non-Adherence in the Elderly: How Big is the Problem?" *Drugs & Aging* 21(12): 793-811, November 12, 2004; Lars Osterberg

and Terrence Blaschke, "Adherence to Medication," *New England Journal of Medicine* 353(5): 487-497, August 4, 2005; Sandra van Dulmen et al., "Patient Adherence to Medical Treatment: a Review of Reviews," *BMC Health Services Research* 7(55), April 17, 2007.

[38] Totals for Exhibit 14 are slightly different from Exhibit 13 because IMS used a different base for the calculations. The data for Exhibit 14 include only prescriptions for which someone presented their Part D card at the pharmacy, while data for Exhibit 13 include all prescriptions.

[39] Elizabeth Hargrave, Jack Hoadley, Laura Summer, and Ayesha Mahmud, "Findings from Beneficiary and Physician Focus Groups."

[40] Another 5 percent switched to an alternative drug in the class.

[41] Another 4 percent of beneficiaries immediately switched medications after reaching the coverage gap spending level. But since this level is consistent across the three groups, it may just represent normal patterns of drug switching and not the impact of reaching the gap.

[42] An example of reduced medication use is when beneficiaries taking two different anti-diabetes drugs stopped taking one but continued taking the other. Conversely, some beneficiaries may find cheaper drugs to switch to in another class, such as switching from PPIs to H2 antagonists. These individuals are reported as stopping therapy because their therapeutic substitution is outside the class being studied. Some individuals shown as discontinuing, reducing, or switching medications might have done so for clinical reasons coincidental with the time of reaching the gap. This analysis considers only medication changes within the classes selected for study. We are unable to tell if enrollees who reached the gap stopped taking or reduced medications in another drug class in order to continue taking medication within the classes in our study, nor are we able to tell if enrollees were receiving free samples from their physicians. For more information, see Appendix B.

[43] The third measure required a full stoppage of the drug being taken in the drug class, not a reduction in use of that drug (e.g., taking a pill every other day). The direction of results from the third measure is consistent with that for the new measures – and thus reinforces our results.

[44] Our results are similar to those calculated by CMS from 2008 claims data. The average Part D non-LIS enrollee reached the gap in 7.6 months and stayed there for 3.9 months, compared to our finding of 7.2 and 4.1 months for 2008. Anita Varghese, "Beneficiary Experience in the Coverage Gap and Catastrophic Phase," presentation at the 2010 Part D Symposium, CMS, March 2010.

[45] Although a much larger share of Part D LIS enrollees reach the catastrophic coverage spending level, they are not at that level of spending much longer on average (4.5 months).

[46] CMS has similar results. Christopher Powers, "Chronic Conditions and Progression Through Part D Benefit Phases," presentation at AcademyHealth Annual Meeting, Boston, June 28, 2010.

[47] The comparable average spending for all beneficiaries who take a breast cancer drug – not just those reaching the gap – is $1,239 per year.

[48] Dana P. Goldman, Geoffrey F. Joyce, and Yuhui Zheng, "Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health," *Journal of the American Medical Association* 298(1): 61-69, July 4, 2007; Thomas Rice and Karen Y. Matsuoka, The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors," *Medical Care Research and Review*, 61(4): 415-452, December 2004.

[49] See, for example, William H. Shrank and Niteesh K. Choudhry, "Time to Fill the Doughnuts – Health Care Reform and Medicare Part D," *New England Journal of Medicine* 364(7): 598-601, February 17, 2011.

[50] IMS captures a larger share of all retail prescriptions in its largest database, but not all of these can be linked at the person level for the LRx database.

[51] Most of these beneficiaries purchase only low-cost generic drugs for which the drug's total cost may not exceed the cost-sharing amount. As a result, we cannot definitively classify them into either the LIS or non-LIS group.

[52] MedPAC, "Healthcare Spending and the Medicare Program: A Data Book," June 2010.

[53] For monthly prescriptions this would be the prescription filled in the month before the individual reached the gap. But for those filling prescriptions less often, the benchmark prescription might have been filled a month or two earlier.

[54] The Centers for Medicare and Medicaid Services (CMS) currently makes available to researchers prescription drug event data collected from Part D plans for the 2008 coverage year; 2009 data will be available later in 2011.

[55] An estimated 9 percent of seniors enrolled in Part D plans in 2006 did not fill any prescriptions. See Patricia Neuman et al., "Medicare Prescription Drug Benefit Progress Report: Findings from a 2006 National Survey of Seniors," *Health Affairs* 26(5): w630-w643, September 2007.

[56] "CMS Chronic Condition Data Warehouse (CCW) Medicare 5% Sample: Medicare Part D Prescription Drug Costs for 2006 Through 2009," May 2011, http://www.ccwdata.org/cs/groups/public/documents/document/wls_ucm1-000782.pdf.

[57] Department of Health and Human Services, "The Affordable Care Act Reduces Out-of-Pocket Drug Costs for Millions of People with Medicare," Report, Healthcare.gov, March 2011.

[58] Zeynal Karaca et al., "The Impact of Medicare Part D on Beneficiaries with Type 2 Diabetes," Avalere Health, 2008. http://www.avalerehealth.net/research/docs/The_Impact_of_Medicare_Part_D_Diabetes_Takeda.pdf; and John Hsu et al., "Medicare Beneficiaries' Knowledge of Part D Prescription Drug Program Benefits and Responses to Drug Costs," *JAMA* 299(16): 1929-1936, April 23/30, 2008.

[59] Christopher Powers, "Beneficiary Experience," presentation at the Medicare Prescription Drug Benefit Symposium, CMS, October 2008; Anita Varghese, "Beneficiary Experience in the Coverage Gap and Catastrophic Phase," presentation at the 2010 Part D Symposium, CMS, March 2010.

[60] Jennifer M. Polinski et al., "Changes in Drug Use and Out-of-Pocket Costs Associated with Medicare Part D Implementation: A Systematic Review," *Journal of the American Geriatrics Society* 58(9): 1764-1779, September 2010.

[61] Yuting Zhang et al., "The Effects of the Coverage Gap on Drug Spending: A Closer Look at Medicare Part D," *Health Affairs* 28(2): w317-w325, March/April 2009.
[62] Sebastian Schneeweiss et al., "The Effect of Medicare Part D Coverage on Drug Use and Cost Sharing among Seniors without Prior Drug Benefits," *Health Affairs* 28(2): w305-w316, March/April 2009.
[63] Vicki Fung et al., "Falling into the Coverage Gap: Part D Drug Costs and Adherence for Medicare Advantage Prescription Drug Plan Beneficiaries with Diabetes," *Health Services Research* 45(2): 355-375, April 2010.
[64] Office of the Inspector General (OIG), DHHS, "Effect of the Part D Coverage Gap on Medicare Beneficiaries Without Financial Assistance in 2006," March 2009.
[65] John Hsu et al., "Medicare Beneficiaries' Knowledge of Part D Prescription Drug Program Benefits and Responses to Drug Costs,"
[66] O. Kenrik Duru et al., "Generic-Only Drug Coverage in the Medicare Part D Gap and Effect on Medication Cost-Cutting Behaviors for Patients with Diabetes Mellitus," *Journal of the American Geriatrics Society* 58(5): 822-828, May 2010.
[67] OIG, "Effect of the Part D Coverage Gap on Medicare Beneficiaries Without Financial Assistance in 2006."
[68] Elizabeth Hargrave, Jack Hoadley, Laura Summer, and Ayesha Mahmud, "Findings from Beneficiary and Physician Focus Groups," contractor report on 2009 focus groups, submitted to MedPAC, October 2009 http://www.medpac.gov/documents/May10_FocusGroup_CONTRACTOR_JS.pdf; Elizabeth Hargrave, Bhumika Piya, Jack Hoadley, Laura Summer, and Jennifer Thompson, " Experiences Obtaining Drugs under Part D: Focus Groups with Beneficiaries, Physicians, and Pharmacists." (PDF) Contractor report on 2007 focus groups, submitted to MedPAC, March 2008 http://www.medpac.gov/documents/May08_PartDFocusGroup_CONTRACTOR_JS.pdf.
[69] Iris Wei, DrPH, "Part D Benefit Design and Cost-Related Non-adherence top Rx in the Medicare CAHPS Sample," presentation at the Medicare Part D Symposium, CMS, March 18, 2010; found at http://www.cms.gov/PrescriptionDrugCovGenIn/09_ProgramReports.asp#TopOfPage.

THE HENRY J. KAISER FAMILY FOUNDATION

Headquarters
2400 Sand Hill Road
Menlo Park, CA 94025
Phone 650-854-9400 Fax 650-854-4800

Washington Offices and
Barbara Jordan Conference Center
1330 G Street, NW
Washington, DC 20005
Phone 202-347-5270 Fax 202-347-5274

www.kff.org

This report (#8221) is available on the Kaiser Family Foundation's website at www.kff.org.