



Whitepaper

# Medicare Part D - Market Dynamics

Wolters Kluwer Health  
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Medicare Part D, originally enacted in 2003 as part of the Medicare Modernization Act (MMA), began on January 1, 2006. This federal drug program was designed to subsidize the cost of prescription drugs for beneficiaries within the United States. According to CMS, there are currently over 44 million patients eligible for coverage. Since its inception, Medicare Part D (MPD) has been a harbinger of change within the prescription drug industry. Appreciating the impact of MPD is critical in achieving an understanding of the industry direction.

Patients within MPD are broken into two distinct groups, Standard Eligibles and Low Income Subsidies (LIS). There are four classifications under LIS, which include patients eligible for dual coverage under both Medicare and Medicaid. For the purposes of this paper, we will refer to the various LIS patients as one group. The Coverage Gap, or “Donut Hole” as it is also referred to, impacts only standard eligible patients. The Coverage Gap is the phase of the Medicare program where the enrollee is responsible for 100% of out of pocket expenses.

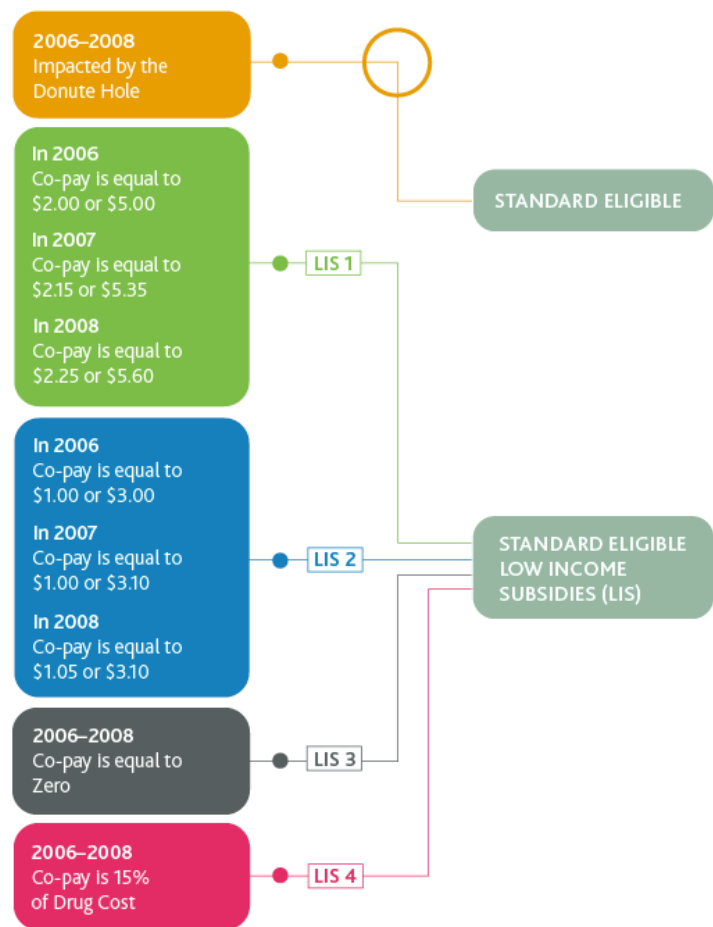
This paper will focus on the impact MPD has on the drug industry, and specifically, how Standard Eligible patients have adapted to changing healthcare costs while living on a fixed income.

## Methodology

Wolters Kluwer Health has developed algorithms for classifying patients into eligibility categories and accurately following standard eligible patients through benefit phases over time. Our tiered approach begins with individual Rx classification and ends with individual patient allocation to an eligibility class.

Standard Eligible and LIS patients are identified through algorithms based on the proportion of their prescription activity matching with known patterns and usage of all available patient activity.

Our resulting MPD patient pools for 2006 and 2007 include all patients whose MPD prescriptions were filled within the respective years. From analysis of the 2006 data, Wolters Kluwer Health identified and classified nearly 8.8 million patients, 4.9 million of which were standard eligibles; 3.9 million were LIS. For 2007, we identified and classified nearly 9.1 million patients, 5.6 million of whom were standard eligibles; 3.5 million were LIS. In addition, over 60% of patients classified in 2006 can be tracked pre-MPD in 2005 through 2007, providing the opportunity for unique longitudinal insight. All of the patients discussed in this study are patients who utilize their Medicare benefit. For the purposes of this paper, all patients mentioned are those with prescription utilization during 2006 and 2007. All other patients were excluded.



## Medicare Part D 2006 to Present

This paper was compiled using Wolters Kluwer Health’s Source® Medicare Part D product suite, a powerful combination of information products designed to offer the most complete perspective on the impact of MPD. A statistical sample of the 2006 and 2007 cohorts was examined and MPD patients were assigned into either Standard Eligible or LIS patient groupings.

The Standard Eligibles patient group has been identified and categorized into defined benefit phases: Deductible, Co-pay/Coinsurance, Coverage Gap and Catastrophic. The Deductible phase is defined as the initial drug spend required by the patient. The Co-Pay/Coinsurance phase is defined as the benefit between the Deductible and the Coverage Gap. The Coverage Gap phase is defined as the financial burden placed on the patient post Co-pay/Coinsurance threshold that subsequently requires a patient to pay 100% Out of Pocket (OOP) for prescription drugs. Once the patient has reached the maximum defined OOP amount, they enter into the Catastrophic phase. In 2007, the Catastrophic Phase patient pay amount was \$2.15 for a generic or preferred drug and \$5.35 for other drugs, or 5% coinsurance, whichever was greater.

The benefit design for the Standard Eligible patient has changed significantly since 2006, with Deductibles, Initial Coverage to the Coverage Gap, Catastrophic thresholds and branded and generic co-pay amounts all increasing.

Standard Design Benefit Parameters	2006	2007	2008
Deductible	\$250.00	\$265.00	\$275.00
Initial Coverage Limit	\$2,250.00	\$2,400.00	\$2,510.00
Out of Pocket Threshold (Includes Donut Hole)	\$3,600.00	\$3,850.00	\$4,050.00
Total Covered Part D Drug Spend At OOP Threshold	\$5,100.00	\$5,451.25	\$5,726.25
Minimum Cost Sharing in Catastrophic Coverage Portion of Benefit			
Generic Preferred Multi-source Drug	\$2.00	\$2.15	\$2.25
Other	\$5.00	\$5.35	\$5.60

Standard Eligible patients represent the majority of patients within the MPD eligibility classifications. These patients face the most plan choices, most variation in benefit design, and the biggest financial risk when taking the Coverage Gap into account. Between 2006, when MPD started, and 2008, the OOP spend by the patient to the Coverage Gap has risen from \$2250.00 in 2006 to \$2400.00 in 2007 to \$2510.00 for 2008. Additionally, the maximum allowed by the Coverage Gap increased \$626.25 from 2006 to present.

The Coverage Gap for 2007 is detailed as the gap in coverage between the total drug costs of \$2400.00 to \$3850.00. This gap of \$1450 is to be covered by the patient through direct OOP expense, paying full price for drug coverage after exceeding the \$2400.00 limit up until their total drug expenditure reaches \$3850.00. In order to limit their financial exposure e.g., the Coverage Gap, deductible, patients also have the option of purchasing an enhanced Part D benefit.

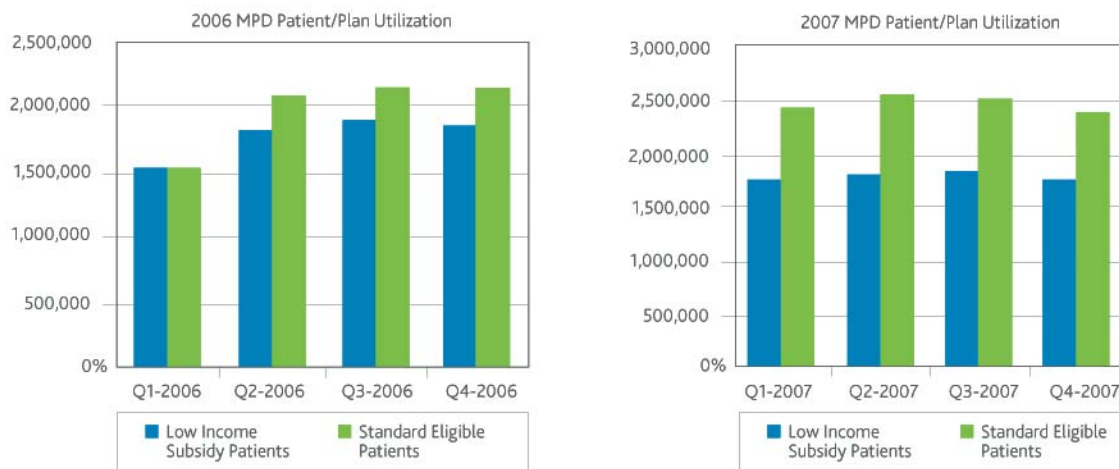
According to CMS, the actuarial value of the standard Part D benefit is estimated to have increased by approximately 6.86% from 2006 through 2007. Wolters Kluwer Health data shows that in addition to this overall increase, from 2006 to present the deductible has risen 10%, the initial coverage limit has risen 11.56% and the Catastrophic coverage threshold has risen 12.28%.

## MPD Patients and Behavioral Impact

2007 was the first year a full 12-month impact analysis of all MPD patients was possible, due to the fact that in 2006, initial patient enrollment in the MPD program was allowed up to May 15<sup>th</sup> for all eligible patients. For 2007, the enrollment period for eligible patients was between November 15<sup>th</sup> and December 31<sup>st</sup> for benefits to be available on January 1<sup>st</sup> (unless patients qualified for eligibility throughout the year). For 2007, patients, pharmaceutical companies and insurance organizations had a chance to digest what they learned from 2006 and apply it to their plan choices, benefit design and drug utilization. Wolters Kluwer Health data is collected and maintained around the Part D patient population who utilize their medical benefits.

### MPD Patient Count in 2006 and 2007 by Quarter

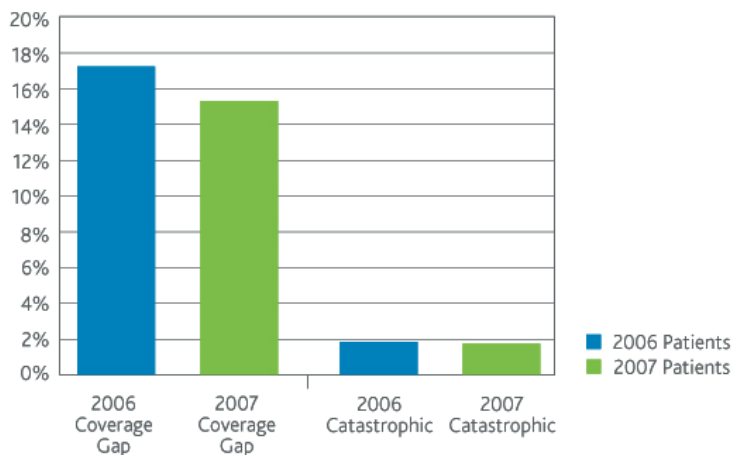
(Includes only Medicare patients who had an MPD claim in the time period)



The biggest change in the current MPD patient population from 2006 was not the distribution of the LIS versus the Standard Eligible patient population, but the timing of their benefit utilization. In 2007, patients were much more likely to utilize their benefits during the 1<sup>st</sup> Quarter than in 2006, with 83% of patients for 2007 utilizing their benefits during the first 3 months versus 63% for 2006. One reason for this difference is likely due to patient enrollment volume, as patients had until much later in the year (May 15<sup>th</sup>) in 2006 to enroll in MPD plans without risk of penalty.

The impact of being able to delay enrollment in 2006 was that patients were able to postpone the start of the patient out of pocket costs and by doing so, may have been able to delay the start of the Coverage Gap. There are

many other reasons, such as the increase in generic over branded utilization, plan choices by the patient and patient persistency by the MPD group.

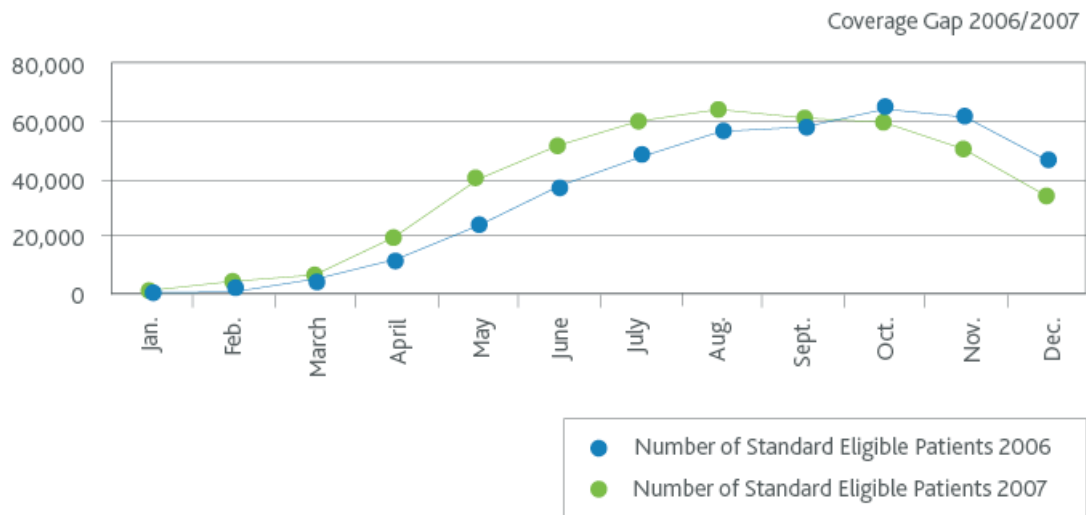


## The Coverage Gap

During 2006, 17.06% of patients entered the Coverage Gap versus 15.50% in 2007. These percentages are based only on patients who utilized their Part D drug benefit during 2006 and/or 2007. With the cost of drugs rising and the Coverage Gap looming, Standard Eligible patients were better able to manage their drugs costs to avoid the Coverage Gap. This was reflected in the claim reports as we followed the impact of the Coverage Gap.

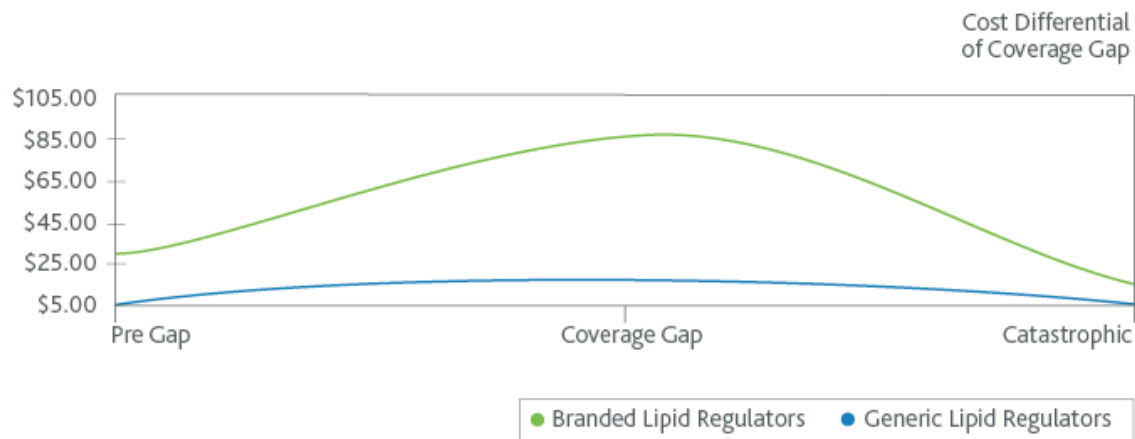
Patients in 2007 entered the Coverage Gap, on average, earlier during the year than in 2006. When analyzing patient enrollment as well as the timing of the Coverage Gap, patients were more apt in 2007 to enroll in the MPD benefit earlier in the year than in 2006, and, in turn, patients were also more likely to enter and exit the Coverage Gap earlier in the year in 2007 than in 2006.

For 2007, patients started to enter the Coverage Gap in significant numbers beginning in April, with 4% of all Coverage Gap patients entering during that month and peaking in August with 14% of the Coverage Gap population entering during that month. Additionally, the third quarter of 2007 represented the peak of total MPD patients within the Coverage Gap, entering in a more compressed timeframe than in 2006, between July and November for the vast majority. Since more patients also entered the program later in 2006 than in 2007, it would seem that the Coverage Gap would become a larger issue later in the year for those patients. The longer a patient spends time in the Coverage Gap, the more likely he or she is to eventually reach catastrophic coverage. According to CMS, patients had access to 13% more drugs in 2007 than in 2006. This eliminated pre-authorization and offered more Coverage Gap benefits. This would contribute to the trends seen in the timing of the patients entering the gap.



Patient counts of those who entered the Catastrophic phase of MPD were relatively consistent between 2006 and 2007. In 2006, 11.91% of patients entered the Coverage Gap and 1.91% of all Standard Eligible patients entered the Catastrophic Phase. In 2007, 12.33% of all Coverage Gap patients and 1.95% of the Standard Eligible population entered the Catastrophic phase. The largest variance between 2006 and 2007 was within the days patients spent within the Coverage Gap. In 2007, patients spent an average of 35 additional days within the Coverage Gap than in 2006. This change in time spent in the gap would potentially influence many parts of the patient's treatment decisions, from switching to brands vs. generics or a change in medication compliance.

Cost also becomes a large factor for patients entering the Coverage Gap. There is a significant difference for the patient when choosing a brand over a generic in all phases of the benefit. For example, when analyzing the Lipid market, the difference in cost of a branded versus a generic is significant. For Standard Eligible patients, the average cost of 30 days of branded therapy is \$30.89 versus \$7.06 for a generic. If a patient enters the Coverage Gap, this increases to \$88.44 for brands and \$16.14 for generics. With this level of cost differential, it becomes obvious why patients are moving away from brands to the more affordable generics.

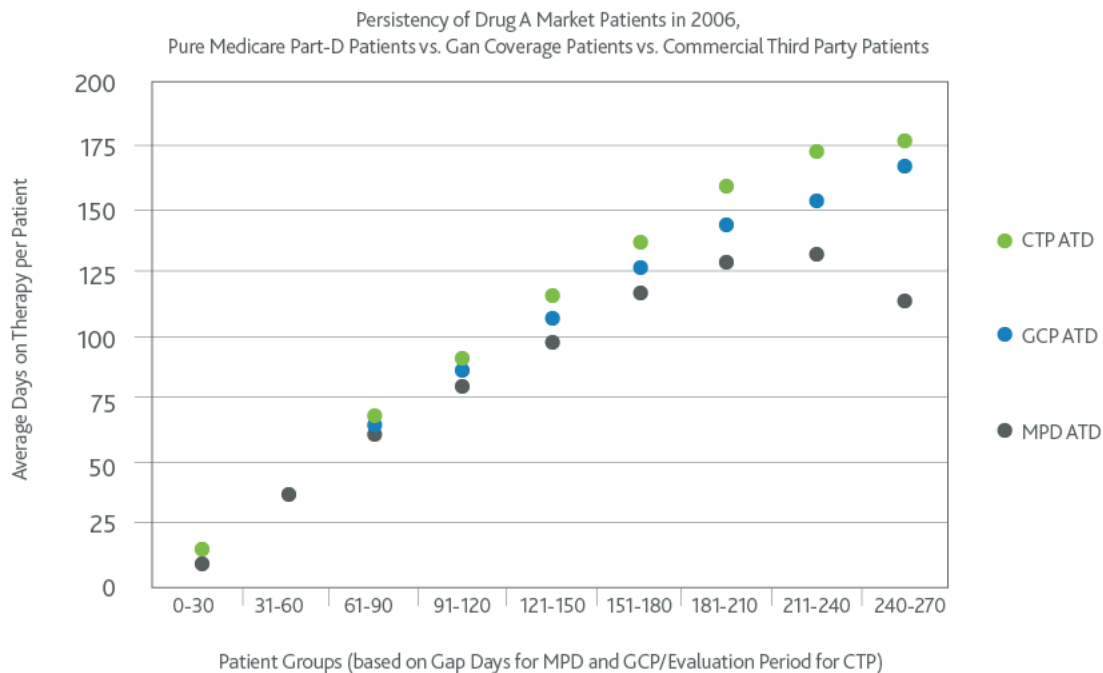


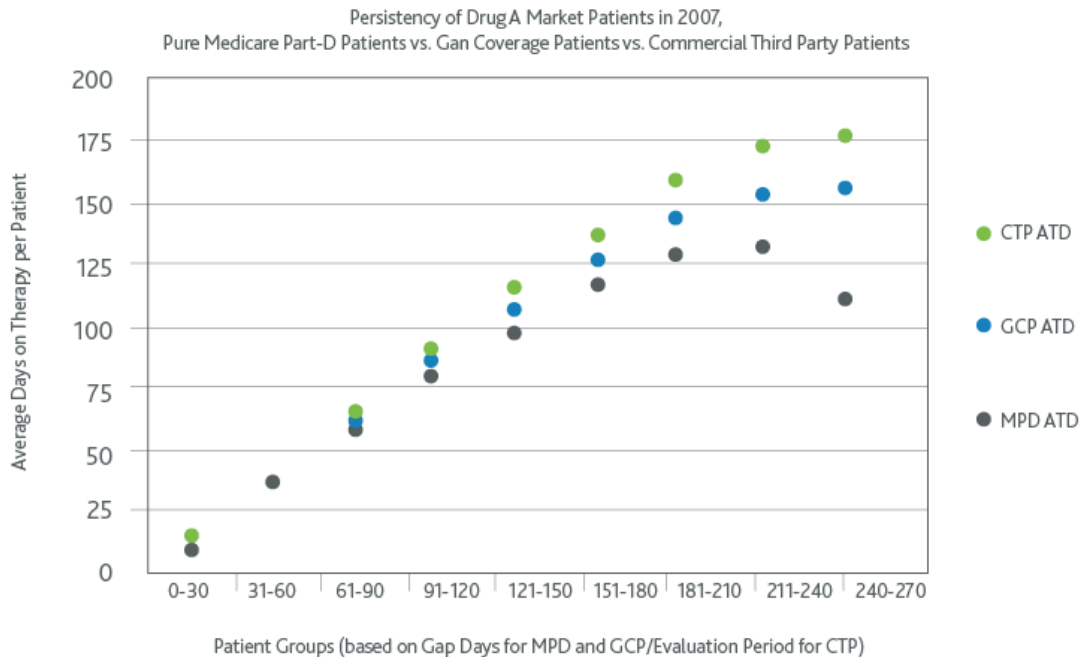
## Patient Persistency in Gap

Understanding patient persistency within the Coverage Gap is an important metric when attempting to understand the overall impact of MPD. The Persistency study focused on creating a control group within Commercial plans to compare to Medicare patients. Each patient in the control group, the Prescription Drug Coverage (PDP) group and the Medicare Advantage Prescription Drug Plan (MA-PD) group were followed for 360 days of therapy to determine their persistency within the Coverage Gap.

Patients who enter the Coverage Gap have many treatment options. They can decide to stay in their current therapy until moving through the Gap to the Catastrophic phase and the prospect for additional government assistance, switch to lower cost generic options to lessen the economic burden, or choose to stop therapy because of cost.

Overall, our studies indicate patients are willing to stay on current therapies without interruption upon entering the Coverage Gap for the first 60-90 days. Once this time threshold has passed, however, patients begin to drop off therapy. In both 2006 and 2007, MPD patients were more likely to fall off therapy following 60-90 days of therapy within the Coverage Gap than the control group. This gap between the control and MPD patient widened the longer the patient was faced with the economic burden of the Coverage Gap. A trend seen developing in 2007 related to persistency with branded medications indicates that patients who continue therapy beyond the first 90 days were less likely to stay on therapy for a longer period of time within a Medicare patient population than the commercial patient population. In both 2006 and 2007, patients who were on commercial plans showed greater persistency over the MPD group. These trends indicate that the Coverage Gap overall has a negative impact on patient persistency.



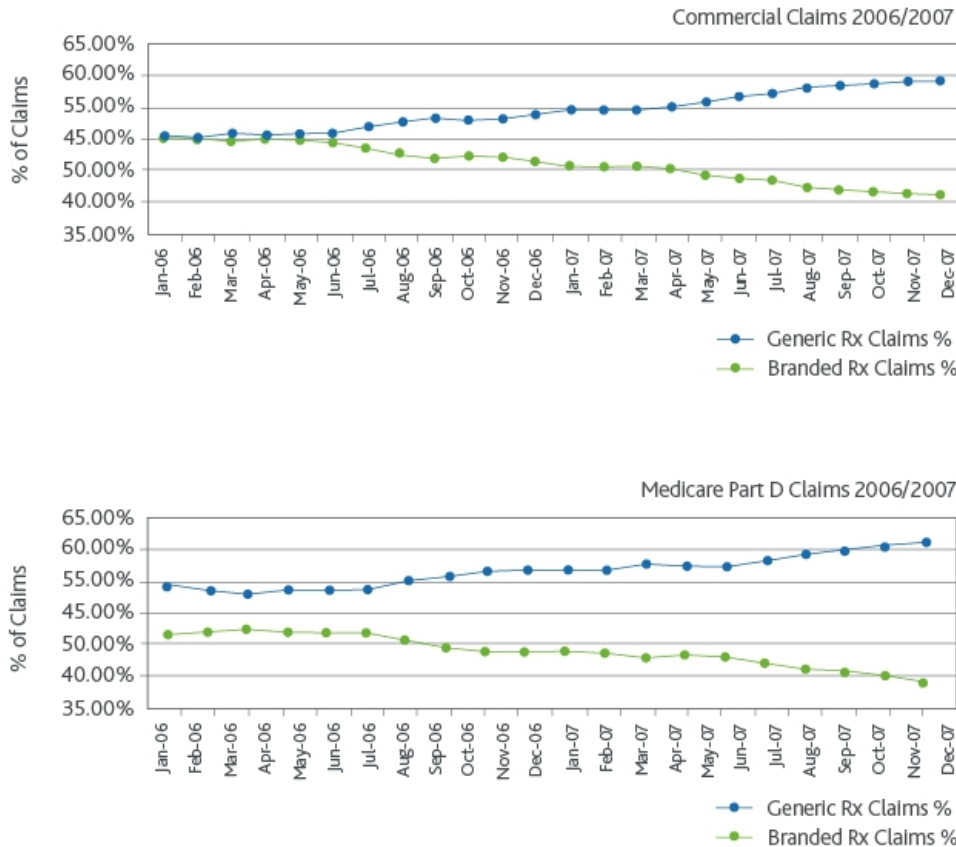


## Branded Versus Generic Utilization in MPD

Determining the impact of MPD on the utilization of branded or generic medications is one of the core measures in understanding how MPD is shaping treatment decisions. By analyzing the distribution of branded and generic drugs in the commercial population versus the usage in the MPD population, Wolters Kluwer Health is able to measure the impact of brand versus generic. For this analysis, Commercial patients are defined as those patients who have prescription coverage through a third party (typically a health plan or employer), but are not associated with an MPD Plan or Medicaid.

The move to generics within the MPD patient population is accelerating much faster than within the Commercial population. In December of 2005, prior to MPD, the commercial population had a roughly 50% market share for both branded and generic drugs. For the MPD population in January of 2006, this shifted to generics having 7.58% more market share than brands. By the end of 2006, generic had 13.48% more market share than brands. This trend continued in 2007, with generics moving from 14.78% more market share than brands in January 2007 to 25.24% more market share during December 2007.

## Commercial and Medicare Part D Claims for 2006/2007



Within the MPD trends for generic use, there is a correlation between increased generic use and the Coverage Gap. As the number of patients within the Coverage Gap increases, the generic market share within Medicare increases as well. At the beginning of 2007, within the Medicare population, we see that the market share for generics and brands stay relatively flat. Between January and March, the market share was 42% for brands and 57% for generics. Only when patients began entering the Coverage Gap in April did we begin to see an upward trend of generic utilization in the market place. Between July and October of 2007, there were between 13.22% and 14.20% of Standard eligible patients entering the Coverage Gap each month. This peak in the Coverage Gap coincides with the peak in generic market share moving from 59.78% in June to 62.62% through the end of the year.

There are many factors that contributed to these trends. The chasm between the use of branded and generic is growing larger each month, especially within the MPD patient population. Pharmacies are encouraging generic use by offering \$4.00 options for generic drugs when available. Over the last 2 years, there has also been an increase in billion dollar drugs entering the generic market place. These include Ambien (zolpidem tartrate), Norvasc (amlodipine besylate), Lotrel (amlodipine besylate and benazepril HCl), Zocor (simvastatin) and Zoloft (sertraline HCl), each of which had over \$1.5 billion in sales entering 2006. The impact of Medicare benefit design, enhanced generic programs at the pharmacy and more and more billion dollar drugs losing patent protection results in an explosion of generic utilization.

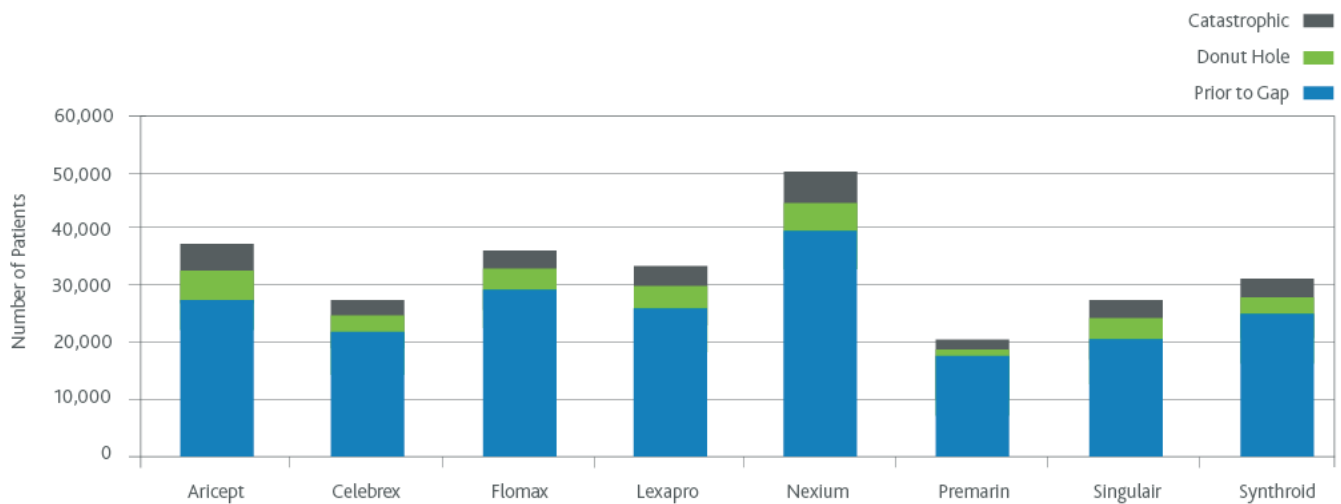
## MPD Impact on Top 30 Drugs

The impact MPD has had on branded pharmaceutical medicines in the first two years of the program is significant. The top 30 drugs (right) are defined as those products with the highest sales for each year, 2006 and 2007. Looking at the Wolters Kluwer Health Standard Eligible patient population of 4.9 million in 2006, the average decrease in the number of MPD patients on a top 30 drug therapy who entered the Coverage Gap was 11.12% and the average decrease in claims was 12.23%. Once patients were through the Coverage Gap and into the catastrophic phase, the drugs, on average, regained only 4% of the patients who discontinued therapy of the brand. The trend did not improve in 2007. Of the 5.6 million Standard Eligible patients within our database in 2007, there was an average decrease of 16.08% of patients on a top 30 drug when they entered the Coverage Gap and overall claims for top 30 drugs decreased 15.88%. Additionally, brands were only able to gain back 6% of their patients during the catastrophic phase. These statistics are taken from Wolters Kluwer Health's Standard Eligible patient population, which is a sub-population of the entire MPD universe.

Taken as a whole, MPD has a significant impact on the behaviors of patients within certain therapeutic classes. Pharmaceutical manufacturers must plan strategically to stay competitive in an environment of increasing government subsidization. As patients are forced to choose products within their financial means, the trends show they will increasingly choose generic alternatives or they may seek alternative OTC therapies to lessen the economic burden.

Top 30 Medicare Part D Drugs	
LIPITOR	LANTUS
PLAVIX	EFFEXOR XR
NEXIUM	CYMBALTA
FOSAMAX	LEVAQUIN
VYTORIN	ZYRTEC
ZETIA	SEROQUEL
PROTONIX	RISPERDAL
ADVAIR DISKUS	LAMICTAL
ACTOS	ZYPREXA
LEXAPRO	TOPAMAX
CRESTOR	VALTRES
PREVACID	ABILIFY
TRICOR	ENBREL
SINGULAIR	HUMIRA
CELEBREX	COPAXONE

## 2007 Patient Counts for Top MPD Drugs



## MPD Impact on Therapy Costs

MPD has a significant impact on the overall cost of medications for the patient. When analyzing the top 10 Therapy Classes to understand the impact, we found significant differences in the overall patient cost when comparing Commercial and Medicare Claims. In 2006, Medicare patients paid, on average, \$17.58 for a 30-day supply of branded drugs in the top 10 therapeutic categories. Comparing this to the average patient pay of \$37.54 for commercial patients, there is a significant cost savings for the Medicare patient in 2006. For 2006, a Medicare patient paid, on average, \$19.96 less for the same brands as commercial patients. Additionally, in 2006, Medicare represented 20% of the overall branded business.

Leading Therapy Classes by Part D 2006				
	% MPD Claims	% Commercial Claims	Ave. MPD 30 Day Supply	Ave. Commercial 30 Day Supply
1. Antihypertensives	26%	74%	\$16.16	\$30.79
2. Lipid Regulators	23%	77%	\$17.82	\$35.67
3. Antidepressants	18%	82%	\$11.47	\$28.86
4. Gastrointestinal Therapy	20%	80%	\$17.41	\$43.53
5. Respiratory Therapy	17%	83%	\$17.73	\$36.01
6. Diabetes Therapy	26%	74%	\$17.88	\$37.18
7. Diuretics	25%	75%	\$2.37	\$17.35
8. Anti-infectives	10%	90%	\$38.98	\$59.94
9. Hormone Therapy	15%	85%	\$14.05	\$32.06
10. Analgesics	12%	88%	\$21.90	\$53.97
<b>% Total Claims:</b>	<b>20%</b>	<b>80%</b>		
<b>Average Cost 30 Day Supply</b>			<b>\$17.58</b>	<b>\$37.54</b>

Leading Therapy Classes by Part D 2007				
	% MPD Claims	% Commercial Claims	Ave. MPD 30 Day Supply	Ave. Commercial 30 Day Supply
1. Antihypertensives	29%	71%	\$20.41	\$22.34
2. Lipid Regulators	26%	74%	\$23.07	\$24.16
3. Antidepressants	20%	80%	\$14.74	\$24.21
4. Gastrointestinal Therapy	23%	77%	\$21.86	\$26.63
5. Respiratory Therapy	19%	81%	\$22.23	\$24.01
6. Diabetes Therapy	28%	72%	\$23.83	\$26.20
7. Diuretics	28%	72%	\$2.16	\$3.41
8. Anti-infectives	12%	88%	\$49.49	\$45.07
9. Hormone Therapy	17%	83%	\$16.78	\$23.99
10. Analgesics	14%	86%	\$25.35	\$43.11
<b>% Total Claims:</b>	<b>23%</b>	<b>77%</b>		
<b>Average Cost 30 Day Supply</b>			<b>\$21.99</b>	<b>\$26.31</b>

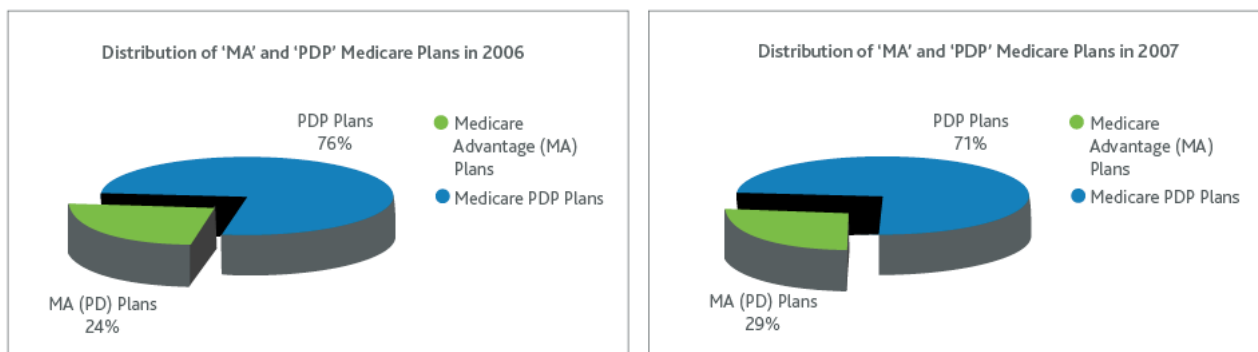
The trends within leading therapy classes are moving towards a more neutral position in 2007. While the Medicare portion of the branded drug business in the top 10 therapies trended upward, representing 23% of the total, the gap in the patient pay amount for a 30-day supply has closed considerably. Medicare patients paid an average of \$21.99 for a 30-day supply, versus \$26.31 for the commercial population, a savings of only \$4.32 for each 30-day supply.

While the availability of branded products are increasing within the Medicare population, the cost of that availability is rising as well, making it more difficult for this patient population to choose branded over generic therapy.

## MPD Patient Plan Choices

Choosing a MPD Plan can be an area of confusion for some seniors. The ability to choose the plan that is right for each patient and each situation can be daunting, especially with the potential financial impact of the Coverage Gap looming if the calculations leading to their choice turn out to be incorrect. One area many patients have chosen to help offset this risk is by enrolling in Medicare Advantage Plans, or MA-PDs. Medicare Advantage Plans offer patients Medicare Part A and B benefits. These plans provide medical coverage in addition to the drug benefit of Part D. Additionally, they can help control costs through negotiated pricing in a way that Part D Plans (PDP) cannot. Subsidized patients are eligible to enroll for Special Need Plans that offer programs and services tailored to their needs.

In 2006, 24% of all Medicare Plans were MA-PD's. These plans processed 7.23% of all Medicare claims. For 2007, 29% of all plans were MA-PDs, with 9.86% of all Medicare Claims associated with this plan type. Although claims from MA-PD plans are still small in comparison to the claims generated by PDPs, we expect the trend toward their usage to continue increasing. The trend toward the usage of MA-PD plans could help explain the closing gap in average co-pay differences between Commercial and Medicare Part D from 2006 to 2007.



## Conclusion

In attempting to understand Medicare Part D trends, Wolters Kluwer Health conducted in-depth behavioral analysis of the Standard Eligible patient population. The Coverage Gap, Persistency and Compliance, Induced Demand, and the impact on drug choices and usage were analyzed for the timing, cost and overall impact on patients, insurers and pharmaceutical drug manufacturer impact. With the publication of the Wolters Kluwer Health White Paper in 2007 and now, in 2008, we are committed to recognizing the trends within the industry as it relates to MPD.

In comparing the first two years of the program (2006 - 2007), we see more patients enrolling in Medicare Part D, and expect continued future enrollment in the program to increase. As these patients learn how to navigate through the benefit and select the plan most appropriate to their needs, the percentage of patients entering the Coverage Gap should continue to decrease, as we observed with 17.06% of patients in 2006 versus 15.5% of patients in 2007.

Significant trends are also beginning to take shape within this large patient population. Generic utilization has increased considerably over the first two years of MPD, with roughly 50% market share for both branded and generics within the Commercial patient population at the end of 2005 to almost 63% generic market share in the MPD patient population at the end of 2007.

The substantial cost difference between brands and generics for patients within the Coverage Gap most likely influences patients' drug choice as well. In the Lipid Market alone, there is a \$72 difference between the cost of a 30-day supply to the patient between a brand and a generic in the Coverage Gap.

Additionally, our analysis has shown that patients are willing to stay on their branded medication while in the Coverage Gap for the first 60 to 90 days. However, with the average stay in the gap increasing to over 100 days and the overall cost of branded medications rising, these patients are choosing a generic alternative. Within our sample, only 6% of patients who entered the Coverage Gap and discontinued use of the branded therapy in 2007 went back to their branded medication after they reached Catastrophic coverage.

Plan design is also having a large impact on the MPD environment. Insurers are updating their plans in order to continue to meet patient needs. This is recognized within the increase in MA-PD plans as well as the decrease in patients entering the Coverage Gap.

The entire drug industry continues to face change brought on by the impact of Medicare Part D. In order to navigate through an environment of increasing government subsidization, both patients and companies impacted by MPD must understand the changing influences that impact therapy decisions.

## Reports

Wolters Kluwer Health utilized reports from the Medicare Part D product suite focused on both market wide trends and in-depth patient analysis of specific drugs and markets in this paper. These reports include:

- MPD Eligibility and Phasing
- Coverage Gap Assessment
  - Patient Behaviors
  - Timing of Coverage Gap
  - Brand vs. Generic Utilization
  - Plan differentiation within patient population
  - TrOOP impact of Coverage Gap
- Co-pay analysis
- Persistency and Compliance
  - Induced Demand Reports
- Induced Demand based on Plan; Plan Switching reports
- Pharmaceutical
  - Drug classes
  - Companies impacted
  - Coverage Gap behavior of drugs
- Insurer
  - The patient pay cycle impact
  - Commercial and MPD plan analysis

## Authors and Contributors

### Steven Pieri (Author)

Steven manages the Source® Medicare Part D product suite and Dynamic Claims National Trends product in the Managed Markets practice area for Wolters Kluwer Health. Prior to his appointment with Wolters Kluwer Health, he held positions of increasing management responsibility at a leading pharmaceutical company, including district sales management, sales operations, brand marketing and managed markets. Through managing the commercial development and execution of a brand in the diabetes therapy area, Steven developed expertise in managed markets strategies, including execution of payer pull through initiatives and pricing and reimbursement strategies.

In his current role, he leads the team of analysts, statisticians and developers responsible for the methodology and production of the Medicare Part D insights and provides consultative insight to the impact of Medicare Part D on the pharmaceutical industry. Steven holds a Bachelor's of Science in Sociology from St. Joseph's University in Philadelphia, PA, and is currently a student in the University's EMBA program for Pharmaceutical Marketing.

### Dea Belazi, PharmD, MPH (Contributor)

Dea is a Practice Lead in the Managed Markets practice area for Wolters Kluwer Health. Prior to his appointment, he consulted for multiple pharmaceutical companies, health plans and pharmacy benefit management companies in the area of managed care and payer marketing, utilization management, pharmacy benefit management, health outcomes research and formulary strategies. Dea has extensive prior experience in senior level positions within the pharmacy benefit management and health plan industries including roles at FutureScripts, a wholly owned PBM of Independence Blue Cross and Family of Companies, PerformRx and Keystone Mercy, and AmeriHealth Mercy Health Plans.

Dea is a reviewer for numerous publications, including *Journal of Managed Care Pharmacy*, *Value in Health*, *American Journal of Managed Care and Clinical Therapeutics*. He also is an adjunct faculty member at the University of Rhode Island College of Pharmacy and Thomas Jefferson University, Department of Health Policy.

Dea received his doctor of pharmacy degree at the University of Rhode Island. He completed a health economics and outcomes research post-doctoral fellowship at Thomas Jefferson University in Philadelphia and at Abbott Laboratories in Chicago. Dea also received a master's of public health degree from Johns Hopkins University, School of Public Health.

### **Bharath Venugopal (Technical Contributor)**

Bharath is a Statistician in the Managed Markets and Brand Analytics practice areas of Wolters Kluwer Health. He has extensive experience in the pharmaceutical industry in analyzing consumer profiles, forecasting, consumer segmentation, price sensitivity modeling, persistency analysis and in developing Medicare Part D methodologies. His areas of technical expertise include multivariate statistical methods, data mining, regression, predictive modeling and experimental design.

Bharath holds a Master of Science in Industrial Engineering and Graduate Certificate in Statistics from Arizona State University, and a Bachelor of Industrial Engineering from Visveswararajah Technological University, India.

### **Brent Erbe (Technical Contributor)**

Brent Erbe is a Senior Analyst working in the Managed Markets and Brand Analytics practice areas of Wolters Kluwer Health. Prior to Wolters Kluwer Health, Brent spent ten years working and consulting in the financial industry, focusing primarily on new product development, data mining and analysis, data integration and warehousing, process reengineering, and workflow optimization. His specific areas of technical expertise include database process design and development on various platforms.

In his current role, Brent consults on primary and secondary research, identification of industry standards and trends, development of core methodologies, and design and implementation of technical solutions. Brent holds a Bachelor of Science degree in Computer Information Systems from Arizona State University.

## Appendix

### Methodology

Wolters Kluwer Health has developed algorithms for classifying patients into eligibility categories and accurately following standard eligible patients through benefit phases over time. Multiple data elements are used to validate classification and track patients through benefit phases. Our tiered approach begins with individual Rx classification and ends with individual patient allocation to an eligibility class.

Low-income subsidy (LIS) patients are assigned first, based upon the proportion of their prescription activity that matches with known LIS patterns using an algorithm that also takes into account total out-of-pocket expenditures for the year. By allocating these patients first, Wolters Kluwer Health substantially reduces the chance that patients will be misclassified as standard eligibles, thus reducing noise in the data.

We further reduce noise by removing a group of patients whose prescription activity matches both an LIS pattern and a Standard Eligible pattern, as well as identifying those patients who passed away during the study phase. We label these patients as Unknown, and exclude them from studies where appropriate.

LIS patients are classified under four distinct groups, all of which can include "Dual Eligible" patients. CMS classifies a "Dual Eligible" patient as one who receives both Medicare and Medicaid coverage. The four classifications, LIS 1, LIS 2, LIS 3 and LIS 4, include the Federal Poverty Limit (FPL) < 135%, Traditional Dual Eligibles, Long Term Care patients, and FPL >150%. For the purposes of this paper, they have been grouped as one under LIS, but can be separated for further analysis.

For standard eligible benefit phase assignment, Wolters Kluwer Health uses all available patient activity and makes use of patient Co-pay/coinsurance amount, total patient pay amount, and processor total paid percentage in an algorithm that also takes into account cumulative expenditures to date. Using all available cost elements on the prescription lessens the chance of misallocating a patient to a phase in the event where we have not captured all of the patient's activity.

Our resulting MPD patient pools for 2006 and 2007 include all patients whose MPD prescriptions were filled within the respective years. From analysis of the 2006 data, Wolters Kluwer Health identified and classified nearly 8.8 million patients, 4.9 million of which were standard eligibles; 3.9 million were LIS. For 2007, we identified and classified nearly 9.1 million patients, 5.6 million of whom were standard eligibles; 3.5 million were LIS. In addition, over 60% of patients classified in 2006 can be tracked into 2007, providing the opportunity for unique longitudinal insight.