
Trends in Medicare Part D Coverage of Chronic Condition Medications

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Representatives of Medicare Access for Patients-Rx (MAPRx) offered input during the selection of chronic conditions and commented on the draft analysis.



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Executive Summary

Eighty-three percent of the Medicare population has at least one chronic condition, and receives prescriptions for one or more medications to manage those conditions.¹ Prior to 2006, the Medicare program did not offer coverage of outpatient prescription drugs; however, the Medicare Modernization Act of 2003 expanded Medicare to include a voluntary outpatient prescription drug benefit (“Part D”). The intent of the expansion was to improve beneficiaries’ access to necessary prescription drugs and to better manage their health.

Part D coverage is not uniform for all beneficiaries; it depends on which private health plan the beneficiary enrolls. Each private plan that offers Part D may cover a different set of drugs with different cost-sharing and utilization requirements, as long as the plans meet basic formulary standards. Plans may use a number of techniques, such as prior authorization, quantity limits, step therapy, and cost sharing to manage the cost of insuring their members.

Avalere Health designed this study to evaluate the possible impact of Medicare Part D plans’ formulary designs on beneficiaries’ access to drugs that treat chronic conditions. We conducted an analysis of Part D plan formularies in 2006, 2007, and 2008 using our DataFrame[®] database.² We analyzed plan and formulary designs of all Part D offerings, including standalone Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug (MA-PD) plans. We defined beneficiary access in terms of inclusion on formulary, tier placement, cost sharing, prior authorization, step therapy, and quantity limits. We examined differences between the chronic condition drugs we studied and all Part D drugs, between plans eligible for auto-enrollment of beneficiaries dually eligible for Medicare and Medicaid and all other plans, and between PDPs and MA-PD plans. Our analysis was limited to drugs used to treat four chronic conditions: Alzheimer’s disease and dementia, rheumatoid arthritis, Type 2 diabetes, and schizophrenia/psychosis.

We found since the start of the Part D benefit, the drugs used to treat chronic conditions appear more frequently on plan formularies, but are increasingly likely to have utilization management requirements and higher cost sharing. An average of 62 percent of plans in 2006 and 73 percent of plans in 2008 covered each chronic condition drug, though with greater prior authorization, quantity limits, and step therapy. Cost-sharing requirements from 2006 to 2008 have also increased at a faster rate than other Part D benefit parameters such as the standard deductible and the catastrophic limit.

These trends closely mirror Part D plans’ coverage of all drugs. Part D plans in 2008 cover a greater percentage of all Part D drugs and require utilization management more often, when compared to plans in 2006.

¹ Anderson GF. Medicare and Chronic Conditions. *N Engl J Med* 353 (July 21, 2005): 3.

² DataFrame is Avalere Health’s proprietary database of Medicare Part D plan features.

Our analysis found that plans that qualified for the auto-enrollment of dual eligibles tend to cover slightly fewer chronic condition drugs, but there are no consistent trends in plans' utilization management requirements. Plans that are not eligible for auto-enrollment appear to place some chronic condition drugs on higher cost-sharing tiers than plans that are eligible for auto-enrollment.

Overall, we found few differences in formulary coverage and utilization management requirements for chronic condition drugs between PDPs and MA-PD plans. MA-PD plans are more likely to cover chronic condition drugs than PDPs, and rates of utilization management are similar between the two types of plans.

We also tested whether our results would vary if we weighted our calculations by the number of lives enrolled in each plan. We found that plans with higher enrollment are more likely to cover chronic condition drugs and typically apply utilization management tools less often than low-enrollment plans.

For the chronic condition medications in our analysis, as well as for all Part D drugs, plans tend to provide better access to generic drugs than brand-name medications. Plans cover more chronic condition generic drugs than brand-name versions; an average of 96 percent of Part D plans cover each generic drug versus 64 percent of plans covering each brand-name drug. In addition, Part D plans are more likely to require prior authorization and step therapy and to set quantity limits for the brand-name drugs in our analysis than for generic drugs.

Our findings suggest that beneficiaries, family members, and their advocates should evaluate their plan choices each year, taking into consideration the formulary coverage and utilization management requirements for the specific drugs they are taking. As this paper shows, rates of prior authorization, quantity limits, and step therapy can vary dramatically from drug to drug. Additionally, our findings on formulary changes from 2006 to 2008 indicate that access for a particular drug can change over time. Finally, given the important role of drug therapy in treatment for chronic conditions, policymakers and stakeholders should continue to monitor trends in formulary coverage and access.

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Introduction

Eighty-three percent of the Medicare population has at least one chronic condition, and receives prescriptions for one or more medications to manage those conditions.³ Prior to 2006, the Medicare program did not offer coverage of outpatient prescription drugs; however, the Medicare Modernization Act of 2003 (MMA) expanded Medicare to include a voluntary outpatient prescription drug benefit (“Part D”). The intent of the expansion was to improve beneficiaries’ ability to access necessary prescription drugs and to manage their health.

However, Part D coverage is not uniform for all beneficiaries; it varies based on the private health plan in which the beneficiary enrolls. Each of the private plans that offer the Part D benefit may cover a different set of drugs with different cost-sharing and utilization requirements, as long as the plans meet basic federal standards.

Under the statute and regulations governing Medicare Part D, the plans that offer coverage may use a number of techniques to manage the cost of insuring their members. Part D plans may establish a list of covered drugs (or formulary), different cost-sharing requirements (or tiers), and utilization management techniques. For example, a plan may require step therapy, in which a beneficiary must try one drug before the plan will approve coverage for another.

Avalere Health designed this study to evaluate the possible impact of Medicare Part D plans’ formulary designs on beneficiaries’ access to drugs that treat chronic conditions. Specifically, we sought to investigate the following:

- How often are drugs for chronic conditions listed on Part D plans’ formularies?
- How have formulary coverage and access (including tier placement, cost sharing, and utilization management) for chronic condition drugs changed since the start of the Part D benefit?
- Are there differences in access to drugs for chronic conditions when compared with other drugs?
- How does access to chronic condition drugs compare in different types of Part D plans?
- Are there differences in formulary access based on Part D enrollment?

In order to answer these questions, Avalere Health conducted an analysis of Part D plan formularies in 2006, 2007, and 2008 using our DataFrame[®] database.⁴ We used these data to determine trends in access to prescription drugs under Part D, specifically for those drugs most often prescribed for four chronic conditions: Alzheimer’s disease, rheumatoid arthritis, Type 2 diabetes, and schizophrenia/psychosis.

³ Anderson GF. Medicare and Chronic Conditions. *N Engl J Med* 353 (July 21, 2005): 3.

⁴ DataFrame[®] is Avalere Health’s proprietary database of Medicare Part D plan features.

Standards for Drug Access in Medicare Part D

Under Part D, private plans are responsible for administering the drug benefit. Each plan establishes its own formulary, or list of covered drugs, and each negotiates directly with the drug manufacturers for the price it will pay for drugs. Private plans must operate within standards established by federal law and regulations and are overseen by the Centers for Medicare & Medicaid Services (CMS).

Every Part D plan must get CMS approval before they market to beneficiaries. For each plan, CMS reviews the benefit offered, monthly premiums charged, and the details of the plan's formulary. Plans must meet minimum standards established in law and regulations. The MMA, which created the Part D benefit, requires that plan formularies include a range of drugs so that the formulary does not "substantially discourage" enrollment by any group of beneficiaries.⁵ In addition, CMS will not approve a Part D plan if the cost-sharing or deductible requirement "discriminates based on health status."⁶

Every Part D plan formulary must meet a variety of standards to ensure nondiscrimination. CMS reviews plans' formulary categories and classes to ensure that the formulary covers at least two drugs in each category and class. In addition, CMS requires special coverage for six classes of drugs: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics. Plans must cover "all or substantially all" of the active ingredients in these "six classes of clinical concern." CMS also limits the use of certain utilization management techniques for these medications, prohibiting plans from applying prior authorization or step therapy when a beneficiary is already taking a drug in one of these classes.⁷

Other parts of the formulary review process include comparing the formulary's coverage to widely accepted treatment guidelines for certain conditions and examining how the formulary covers drugs most commonly used by the general Medicare population and by people dually eligible for Medicare and Medicaid.⁸

In addition to reviewing which drugs a plan places on its formulary, CMS evaluates beneficiaries' access to covered drugs through a review of the plan's cost-sharing tiers and other utilization management techniques. For example, if a drug's placement is on a tier with high cost sharing, the plan must place therapeutically similar products on a lower cost-sharing tier.⁹ Other utilization management techniques CMS reviews include:

- Prior authorization, in which the beneficiary must get approval from the insurance plan before filling a prescription.

⁵ Social Security Act, Section 1860D-11(e)(2)(D)(i).

⁶ CMS, Contract Year 2009 Call Letter, March 17, 2008. Available at:

<http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf>.

⁷ Plans may apply prior authorization to drugs in the six protected classes in order to determine payment under Medicare Part B or Part D. CMS, Prescription Drug Benefit Manual, Chapter 6, Section 30.2.5. Available at:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage

⁸ CMS, Prescription Drug Benefit Manual, Chapter 6, Section 30.2.

⁹ CMS, Prescription Drug Benefit Manual, Chapter 6, Section 30.2.7.

- Step therapy, a requirement that the beneficiary first try one treatment for the condition before another.
- Quantity limits, which set a maximum number of days' supply for each prescription filled.

CMS reviews whether a plan's utilization management tools are consistent with other Part D plans, industry best practices, and guidelines from expert organizations.¹⁰

Medicare Beneficiaries with Chronic Conditions

Eighty-three percent of Medicare beneficiaries have at least one chronic condition and 23 percent have five or more chronic conditions.¹¹ Some of the most common chronic conditions include high blood pressure, arthritis, heart disease, mental illness, and diabetes.¹²

Unlike the healthier, working-age population, who may only take prescription drugs for occasional illness or injury, most Medicare beneficiaries take at least one prescription on a regular basis. Three out of four people 65 and older take regular medications for chronic conditions; among seniors, 28 percent of women and nearly 22 percent of men take five or more medicines regularly.¹³ Because of this population's need for regular medications, the cost sharing required for prescriptions can play an important role in determining beneficiary access to needed treatment.

The availability of the Part D coverage has reduced out-of-pocket drug costs for many Medicare beneficiaries.¹⁴ However, enrollees may face financial challenges in accessing covered drugs due to Part D plans' cost-sharing requirements. One study of 2006 claims found that 32 percent of beneficiaries had more than \$750 in annual out-of-pocket prescription costs.¹⁵ Those taking drugs for multiple chronic conditions are likely to have even higher spending.

Studies on drug utilization have consistently found that higher cost sharing correlates with lower adherence to recommended drug treatment. For example, a national survey of Medicare beneficiaries found that nearly 20 percent of Part D enrollees either did not fill a prescription or delayed filling a prescription because of cost.¹⁶ In addition, the more chronic conditions a person has, the more likely they are to not fill a prescription due to

¹⁰ CMS, Prescription Drug Benefit Manual, Chapter 6, Section 30.2.2.

¹¹ Anderson GF. Medicare and Chronic Conditions. *N Engl J Med* 353 (July 21, 2005): 3.

¹² CMS Press Release, "Medicare Drug Cards Provide Significant Savings Now for Beneficiaries With Chronic Conditions." July 13, 2004. Available at: <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1111>.

¹³ Medco Health Solutions, Drug Trend Research Center, "Chronic Medication Nation." May 14, 2008. Available at: <http://medco.mediaram.com/index.php?s=64&cat=23>.

¹⁴ Yin W, et al. The Effect of the Medicare Part D Prescription Benefit on Drug Utilization and Expenditures. *Ann Intern Med* 148(2008):169-177.

¹⁵ Note: Percentage excludes beneficiaries eligible for the Low-Income Subsidy. Wolters Kluwer Health, "Medicare Part D Market Dynamics." July 2007.

¹⁶ Neuman P, et al. Medicare Prescription Drug Benefit Progress Report: Findings from a 2006 National Survey of Seniors. *Health Affairs, Web Exclusive* 26.5 (August 21, 2007): w630-w643.

cost, skip a dose, or take less medication than prescribed to make it last longer.¹⁷ There is also some evidence that utilization management techniques such as quantity limits and prior authorization result in beneficiaries filling fewer prescriptions, but the research is unclear on what impact this might have on beneficiaries' health outcomes.¹⁸

Research Question

Avalere Health designed this research to assess Medicare Part D beneficiaries' access to drugs used to treat chronic conditions. Our goal was to determine whether there is a growing trend among standalone Prescription Drug Plans (PDPs) and/or Medicare Advantage Prescription Drug (MA-PD) plans to use higher beneficiary cost sharing or more active utilization management for drugs used to treat chronic conditions. We also sought to determine if Part D plans treat drugs for chronic conditions differently when compared to all other drugs, or for different groups of beneficiaries including those dually eligible for Medicare and Medicaid.

Methodology and Limitations

For this analysis, we define access as whether a formulary covers a drug and whether there are restrictions caused by utilization tools and cost-sharing amounts. To measure access, we used Avalere's proprietary DataFrame database on the plan and formulary designs of all PDPs and MA-PD plans participating in Part D in 2006, 2007, and 2008. This database is derived, in part, from CMS files on Part D plan features and includes information for more than 4,000 Medicare Part D plans, including formularies, cost-sharing requirements, and benefit structures. The analysis includes only plans that operated in the United States in 2007 and excludes plans operating in U.S. territories (e.g., Puerto Rico, Northern Mariana Islands, American Samoa, U.S. Virgin Islands).

Chronic Conditions and Drugs Studied

We defined drugs used to treat chronic conditions as drugs used to treat Alzheimer's disease and dementia, rheumatoid arthritis, Type 2 diabetes, and schizophrenia/psychosis. Using treatment guidelines, web-based resources, and drug information publications, we identified drugs commonly used to treat each of the four chronic conditions. A pharmacist reviewed these lists for completeness and accuracy.¹⁹ For each condition, we further segmented the drug list based on American Hospital Formulary Service (AHFS) codes.

The drug lists focus on treatments for the primary condition and its symptoms. For example, the list of Alzheimer's disease drugs includes drugs that treat cognitive and functional losses; it excludes drugs used commonly in patients with Alzheimer's disease

¹⁷ Soumerai SB, et al. Cost-Related Medication Nonadherence Among Elderly and Disabled Medicare Beneficiaries. *Arch Intern Med* 166 (2006):1829-1835.

¹⁸ Olson, Bridget M. Approaches to Pharmacy Benefit Management and the Impact of Consumer Cost Sharing. *Clin Ther* 25 (2003):250-272.

¹⁹ Patti Gasdek Manolakis, PharmD. PMM Consulting, Charlotte, NC.

to treat agitation, depression, sleep disturbances, and other associated problems. (For a list of all the drugs used in this analysis, see Appendix.)

Analysis by Condition

We analyzed data on drug coverage at varying levels of aggregation: first, we examined trends across all drugs used to treat each condition, then we narrowed the focus to each AHFS class associated with that condition, and finally for each drug individually. We drew comparisons to summary statistics on access for all drugs on all Part D plans primarily at the highest level of aggregation.

At each level of aggregation, we evaluated how often the product or set of products appeared on plan formularies, tier placement, cost sharing, prior authorization, step therapy, and quantity limits. The term ‘formulary coverage’ in this paper indicates that the drug is listed on a plan’s formulary, whether or not the plan applies a utilization management requirement. We examined several subsets of plans (described below) to assess whether particular types of plans are less, equally, or more restrictive in their coverage of drugs for chronic conditions in comparison to all Part D drugs. For this analysis, our assessment of formulary coverage included whether a drug was included on a plan’s formulary as well as the drug’s tier placement, cost sharing, and presence of any utilization management restrictions.

Analysis by Type of Plan

We conducted a separate analysis of access to drugs in PDPs in comparison to MA-PD plans and throughout this paper, when we refer to “Part D plans,” we mean both standalone PDPs and MA-PD plans.

In order to examine dual-eligible beneficiaries’ access to chronic condition medications, we conducted an analysis of the Part D plans that qualify for automatic enrollment of dual eligibles. Beneficiaries who are eligible for both Medicare and Medicaid are automatically enrolled in a PDP the first year they are eligible for Part D, unless they proactively choose their own plan. In subsequent years, dual eligibles may be automatically reassigned to a new PDP if their current plan’s premium rises above the amount the government will subsidize. Each year, CMS announces this premium subsidy amount after its examination of plan bids; only the PDPs with monthly premiums at or below this subsidy amount are eligible for auto-enrollment. We used CMS’ Landscape Source File for PDPs to compare PDP premiums each year against the premium subsidy in that plan’s operating region; we defined PDPs with premiums lower than the regional subsidy amount as plans that were eligible for auto-enrollment of dual eligibles.

Enrollment Weighting

Although most of the results in this paper are reported as unweighted averages, we also weighted the data by plan enrollment to see how this would change our findings. We used plan-level enrollment from July of each year for this analysis. We label any enrollment-weighted results in this paper; other data we report is unweighted. We

interpreted our enrollment-weighted results as suggesting trends in access among plans with higher enrollment.

Limitations

Although the data CMS releases on Part D plans' formularies includes information on whether a plan requires prior authorization or step therapy or if the plan sets quantity limits for a particular drug, we are unable to identify some of the details about Part D plans' utilization management requirements. For example, if a plan requires prior authorization for a drug, the CMS formulary data does not include specific information about why the plan is requiring a patient to obtain prior authorization, such as to allow the plan to verify whether the drug should be covered under Medicare Part B or Part D.

General Findings

Our analysis of the drugs used to treat the four chronic conditions resulted in six key findings.

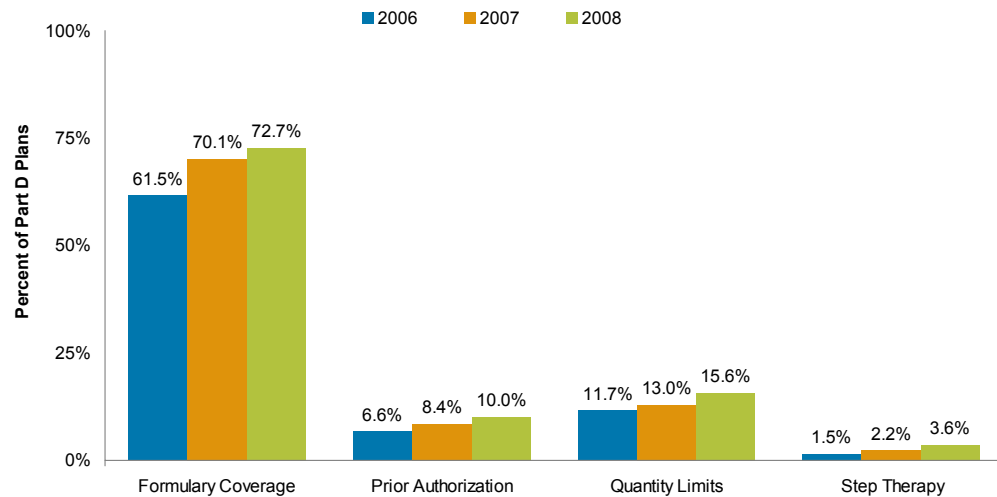
- Since the start of the Part D benefit, plan formularies have more frequently covered drugs used to treat chronic conditions, but these formularies are increasingly likely to have utilization management requirements and higher cost sharing.
- Trends in access to chronic condition drugs are consistent with trends for all Part D drugs.
- Plans that qualified for auto-enrollment of dual eligibles tend to cover slightly fewer chronic condition drugs, but there are no consistent trends in plans' utilization management requirements.
- Overall, we found few differences between standalone PDPs and MA-PD plans in formulary coverage and utilization management requirements for chronic condition drugs.
- Plans with higher enrollment are more likely to cover chronic condition drugs and typically apply utilization management tools less often than lower-enrollment plans.
- For the chronic condition medications in our analysis, as well as for all Part D-covered drugs, plans tend to provide better access to generic drugs than brand-name medications. More Part D plans require prior authorization, quantity limits, and step therapy for the brand-name drugs in our analysis compared to the generic drugs.

This section presents the results associated with these key findings. The sections that follow describe additional details about the analysis for each of the four chronic conditions we studied as well as a comparison of plans that qualified for auto-enrollment of dual-eligible beneficiaries with other plans that did not.

Key Finding 1: Since the start of the Part D benefit, drugs used to treat chronic conditions are covered more frequently on plan formularies, but are increasingly likely to have utilization management requirements and higher cost sharing.

From 2006 to 2008, plans increased their coverage of drugs used to treat Alzheimer's disease, rheumatoid arthritis, Type 2 diabetes, and schizophrenia/psychosis. Each chronic condition drug in our analysis was covered, on average, by 62 percent of PDPs and MA-PD plans in 2006, increasing to an average of 73 percent of plans in 2008 (Figure 1).

FIGURE 1 Access to Chronic Condition Drugs in Medicare Part D, 2006-2008*



*Data reflects average rates of formulary coverage and utilization management for drugs used to treat Alzheimer's disease, arthritis, Type 2 diabetes, and schizophrenia/psychosis.

Part D plans also increased their use of utilization management techniques between 2006 and 2008 for the chronic condition drugs we studied. We found that an average of 7 percent of 2006 plans applied prior authorization to each chronic condition drug as compared to 10 percent of 2008 plans. An average of 12 percent of 2006 plans applied quantity limits to each chronic condition drug; this rose to 16 percent of 2008 plans. The application of step therapy, which is the least common utilization requirement of the three, has doubled since 2006 for the drugs we studied. An average of 2 percent of plans used step therapy on each of the drugs in our analysis; this doubled to 4 percent in 2008.

In all three benefit years, generics were mostly on tier 1, the least expensive cost-sharing tier, while brand-name drugs were on tiers 2 to 4. Most chronic condition drugs have remained on the same cost-sharing tier since the start of Part D, though cost sharing on these tiers has increased faster than other parts of the Part D benefit. For instance, the most common cost-sharing amount among PDPs for drugs on tier 2 was \$20 in 2006 but increased to \$35 in 2008. For tier 4 drugs in MA-PD plan formularies, the most common cost-sharing requirement rose from 25 percent in 2006 to 30 percent in 2008. Although many of the Part D benefit parameters, such as the standard deductible amount, are statutorily required to increase over time, the cost-sharing increases for chronic condition drugs in our study rose at a much faster rate. For example, the standard deductible rose from \$250 in 2006 to \$295 in 2009 – an 18 percent increase. In contrast, the most common cost-sharing amount for drugs on tier 2 rose by 75 percent.

Key Finding 2: Trends in access to chronic condition drugs are consistent with trends for all Part D drugs.

Part D plans in 2008 cover a greater percentage of all Part D drugs, including those used to treat chronic conditions, when compared to plans in 2006. The use of utilization management tools is becoming increasingly common not just for chronic condition drugs, but all Part D drugs in general (Table 1). However, certain groups of drugs are more likely to see the application of certain utilization management tools. The prevalence of step therapy and quantity limits showed a greater increase among chronic condition drugs than for all Part D drugs between 2006 and 2008.

TABLE 1 Utilization Management for All Part D and Chronic Condition Drugs, 2006-2008*

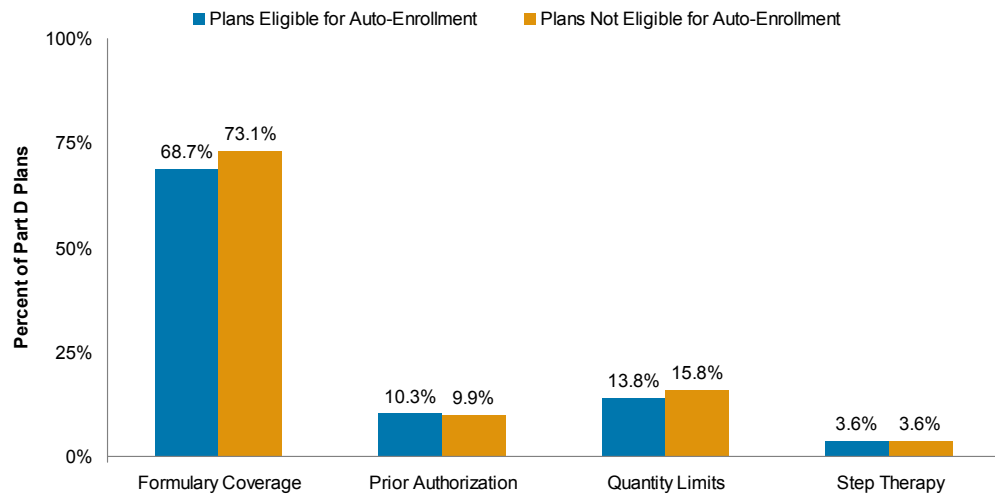
	All Part D Drugs			Chronic Condition Drugs		
	2006	2007	2008	2006	2007	2008
Prior Authorization	10.4%	11.1%	12.3%	6.6%	8.3%	10.0%
Quantity Limits	10.4%	11.1%	13.9%	11.7%	13.0%	15.6%
Step Therapy	1.1%	1.8%	2.6%	1.5%	2.2%	3.6%
Any UM Tool	20.1%	21.5%	24.4%	18.4%	21.1%	25.0%

*Data reflects average rates of utilization management for drugs used to treat Alzheimer's disease, arthritis, Type 2 diabetes, and schizophrenia/psychosis.

Key Finding 3: Plans that qualified for auto-enrollment of dual eligibles tend to cover slightly fewer chronic condition drugs, but there are no consistent trends in plans' use of utilization management requirements.

In 2008, auto-enrollment plans cover fewer of the chronic condition drugs in our analysis than other plans (Figure 2). On average, 69 percent of auto-enrollment plans cover each chronic condition drug, compared to 73 percent of other plans. When we compared drugs' most common placement on cost-sharing tiers by auto-enrollment versus other plans, we found that, overall, auto-enrollment plans and other plans tend to place the drugs in our analysis on similar tiers. However, we found some differences in plans' placement on cost-sharing tiers for specific drugs. Plans not eligible for auto-enrollment are more likely to place some rheumatoid arthritis, diabetes, and schizophrenia/psychosis drugs on higher cost-sharing tiers than plans eligible for auto-enrollment. However, dual eligibles and low-income subsidy beneficiaries have mandated cost sharing and higher or lower tier placement does not affect them.

FIGURE 2 Access to Chronic Condition Drugs in Plans Eligible, Not Eligible for Auto-Enrollment, 2008



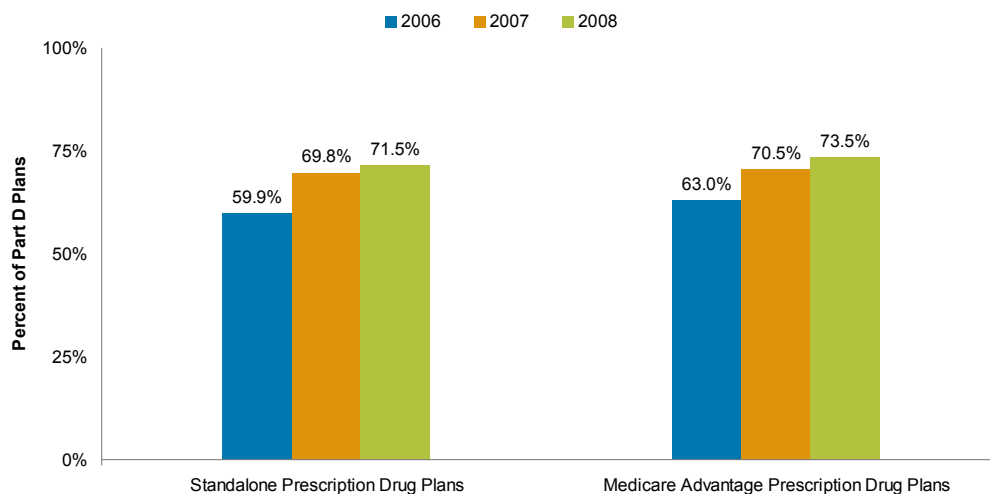
*Data reflects average rates of formulary coverage and utilization management for drugs used to treat Alzheimer's disease, arthritis, Type 2 diabetes, and schizophrenia/psychosis.

We also compared rates of utilization management techniques between plans eligible and not eligible for auto-enrollment. We found that there are few, if any, differences between the two types of plans. Chronic condition drugs are slightly less likely to face quantity limits in plans that are eligible for auto-enrollment than in other plans. The same proportion of both types of plans requires prior authorization and step therapy.

Key Finding 4: Overall, we found few differences between standalone Prescription Drug Plans and Medicare Advantage Prescription Drug plans in formulary coverage and utilization management requirements for chronic condition drugs.

We found that formulary coverage for the chronic condition drugs included in our analysis does not vary drastically between PDPs and MA-PD plans. In 2008, an average of 72 percent of PDPs and 74 percent of MA-PD plans cover each chronic condition drug (Figure 3). The slightly higher proportion of MA-PD plans is primarily due to MA-PD plans' better coverage of rheumatoid arthritis drugs. Arthritis drugs such as Avinza[®], Azasan[®], Trexall[®], and Indocin[®] are more likely to be on MA-PD plans' formularies than PDP formularies. There are few differences in the most common tier placement and cost sharing for chronic condition drugs between PDPs and MA-PD plans.

FIGURE 3 Average Percentage of PDP and MA-PD Plans Covering Each Chronic Condition Drug, 2006-2008*



*Data reflects average rates of formulary coverage for drugs used to treat Alzheimer's disease, arthritis, Type 2 diabetes, and schizophrenia/psychosis.

Overall, MA-PD plans are slightly more likely to employ utilization management techniques for chronic condition drugs than PDPs (Table 2). On average, prior authorization is required for each chronic condition drug by 10 percent of MA-PD plans and 10 percent of PDPs. Similarly, an average of 17 percent of MA-PD plans and 14 percent of PDPs apply quantity limits to each chronic condition drug. The percentage of plans requiring step therapy for chronic condition drugs is almost the same between PDPs and MA-PD plans.

TABLE 2 Average Percentage of PDP and MA-PD Plans Employing Utilization Management Techniques for Each Chronic Condition Drug, 2008

Chronic Condition Drugs	Prior Authorization		Quantity Limits		Step Therapy	
	PDPs	MA-PD Plans	PDPs	MA-PD Plans	PDPs	MA-PD Plans
Alzheimer's Disease	15.2%	9.6%	51.0%	49.9%	0.0%	0.2%
Arthritis	12.1%	12.8%	11.4%	15.9%	4.1%	4.0%
Type 2 Diabetes	7.1%	7.8%	12.1%	14.5%	3.7%	4.3%
Schizophrenia/ Psychosis	4.5%	5.1%	19.1%	19.7%	2.0%	1.4%

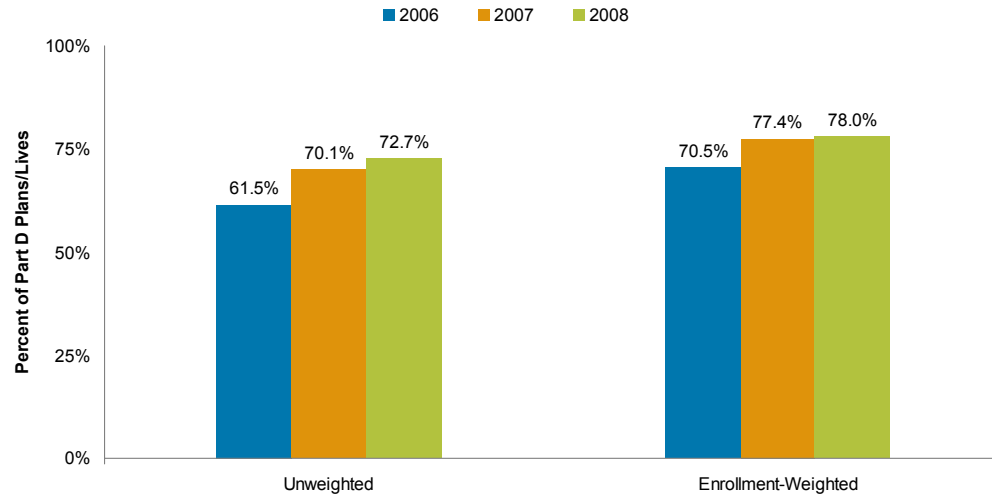
*Data reflects average rates of utilization management for drugs used to treat Alzheimer's disease, arthritis, Type 2 diabetes, and schizophrenia/psychosis.

Key Finding 5: Plans with higher enrollment are more likely to cover chronic condition drugs and typically use utilization management tools less often than lower-enrollment plans.

Plans offering Part D coverage have varying levels of enrollment; we tested whether our results would vary if we weighted our calculations by the number of lives enrolled in each plan. Our enrollment-weighted results produced some differences in our findings

on chronic condition drugs' inclusion on formularies and utilization management requirements. For unweighted plans, an average of 73 percent of plans covered each drug (Figure 4); when weighted by enrollment, plans with 78 percent of lives cover each drug.

FIGURE 4 Weighted and Unweighted Average Percentage of Part D Plans Covering Each Chronic Condition Drug, 2006-2008*

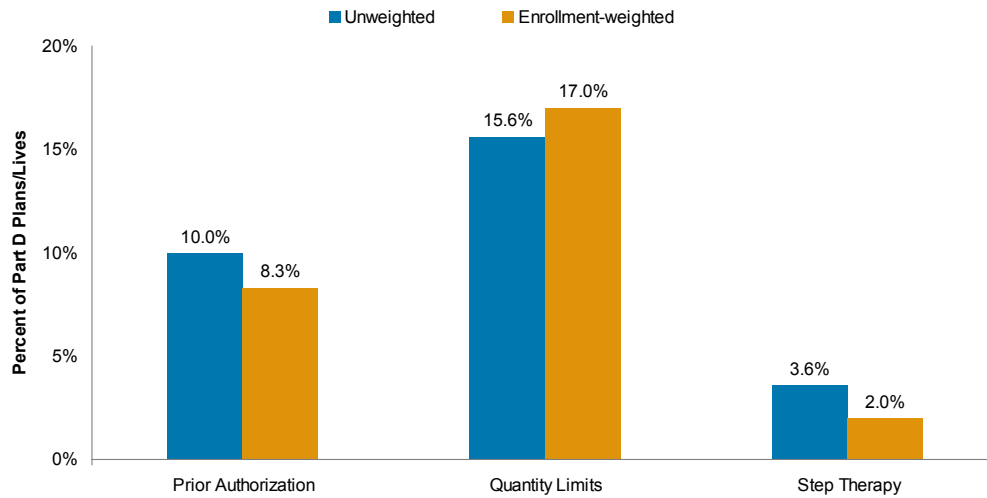


*Data reflects average rates of formulary coverage for drugs used to treat Alzheimer's disease, arthritis, Type 2 diabetes, and schizophrenia/psychosis.

We found that the enrollment-weighted calculations led to lower rates of most utilization management techniques (Figure 5). We found that, on average, 8 percent of Part D lives are in plans that require prior authorization for each chronic condition drug, compared to an average of 10 percent of plans. Similarly, an average of 2 percent of Part D lives are in plans that require step therapy for each chronic condition drug, compared to an average of 4 percent of plans. These findings suggest that plans with more enrollees are less likely to require prior authorization and step therapy for chronic condition drugs than smaller plans. In contrast, when weighted by enrollment, the average percentage of lives in plans that use quantity limits is higher than the average percentage of plans, indicating that plans with larger enrollment are more likely to have quantity limits for chronic condition drugs than smaller plans.

It is important to note the influence on enrollment-weighted calculations by the formularies of two sponsors, UnitedHealth Group and Humana. Together, these sponsors hold more than 40 percent of total PDP enrollment as of September 2008. Any trends in the formularies offered by these two sponsors are likely to have a significant impact on our enrollment-weighted results.

FIGURE 5 Weighted and Unweighted Average Percentage of Plans Employing Utilization Management Techniques for Each Chronic Condition Drug, 2008

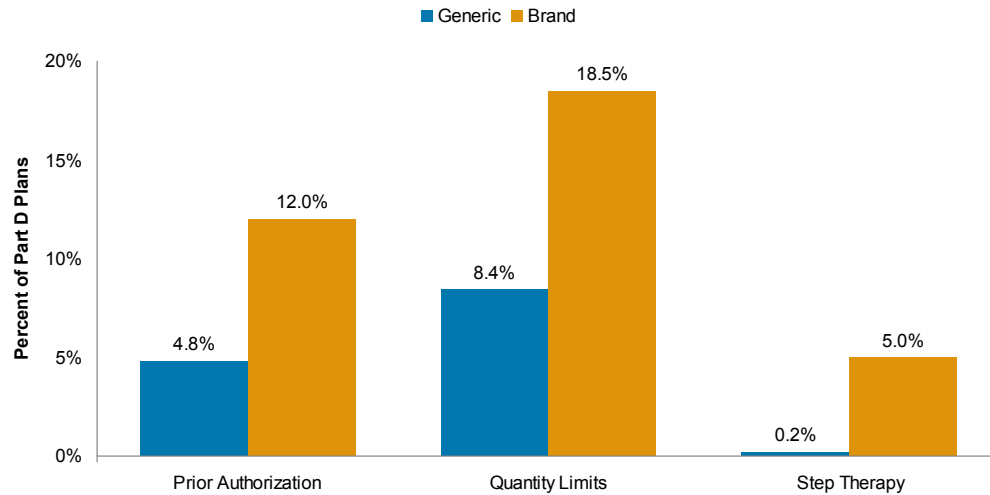


*Data reflects average rates of utilization management for drugs used to treat Alzheimer's disease, arthritis, Type 2 diabetes, and schizophrenia/psychosis.

Key Finding 6: For the chronic condition medications in our analysis, as well as for all Part D covered drugs, plans tend to provide better access to generic drugs than brand-name medications. Rates of prior authorization, quantity limits, and step therapy are more than double for the brand-name drugs in our analysis relative to generic drugs.

A number of our findings indicate that Part D plans are encouraging the use of generic drugs by requiring utilization management for brand-name drugs more often than for generics, as well as listing brands on formularies less often than generics. Rates of prior authorization and quantity limits for brands are more than double the rates for the generics in our analysis (Figure 6). An average of 8 percent of plans applies quantity limits to each generic drug, while an average of 19 percent of plans apply these limits to each brand-name drug. This equates to an 11-percentage-point difference between brand and generic drugs. When we restrict the analysis to drugs that have both a generic and brand-name version and to plans that cover both versions, the rate of quantity limits for generic drugs is 9 percent and the rate of quantity limits for brand-name drugs is 13 percent. The narrower gap—4 percentage points instead of 11 percentage points—between brand and generic drugs in this analysis suggests that plans are more likely to apply quantity limits to brands that do not have generic alternatives. Step therapy is very rare for generic drugs in our analysis, while 5 percent of plans subject brand-name drugs to step therapy.

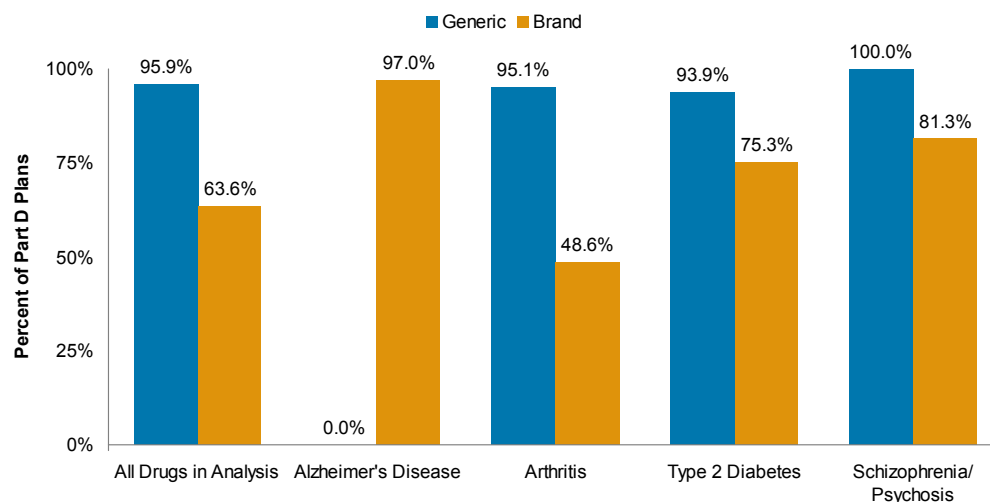
FIGURE 6 Average Percentage of Plans Using Utilization Management Tools for Each Brand and Generic Chronic Condition Drug, 2008



*Data reflects average rates of utilization management for drugs used to treat Alzheimer's disease, arthritis, Type 2 diabetes, and schizophrenia/psychosis.

In our analysis, Part D plans cover an average of 96 percent of each generic drug, compared to 64 percent for each brand-name drug (Figure 7). The smallest proportion of plans covers each brand-name rheumatoid arthritis drug at an average of 49 percent of plans. The largest proportion of plans covers each brand-name drug used to treat Alzheimer's disease; this is likely because there are no generic alternatives for these brand-name drugs.

FIGURE 7 Average Percentage of Plans Covering Each Brand and Generic Chronic Condition Drug, 2008



*There are no generic equivalents for the Alzheimer's disease drugs in this study.

Condition-Specific Findings

Beneficiaries with Alzheimer’s Disease and Dementia

Dementia is a general term that describes a group of symptoms caused by changes in brain function. The most common form of dementia among older people is Alzheimer’s disease (AD), which affects parts of the brain that control thought, memory, and language. Common symptoms of AD include memory loss, difficulty performing normal tasks, problems with language, disorientation to time and place, and other cognitive deficits. AD affects an estimated 4.5 million Americans.²⁰

As a person ages, the risk of developing AD increases. The disease affects about 200,000 people under age 65 and about 5 million people age 65 and over.²¹ Researchers estimate that AD may affect about half of people aged 85 and older.²²

While there is no cure for AD, drug treatment may reduce the symptoms for a limited time in patients in the early and middle stages of the disease. There are five prescription drugs for the treatment of AD symptoms: four fall into the category of cholinesterase inhibitors, and the fifth is an N-methyl-D-aspartate (NMDA) receptor agonist.²³

Prescriptions for cholinesterase inhibitors are for treating symptoms related to memory, thinking, language, judgment, and other thought processes. Commonly prescribed cholinesterase inhibitors include Aricept[®], Exelon[®], and Razadyne[®], formerly known as Reminyl[®].²⁴ Of these, Aricept is the only cholinesterase inhibitor approved for the treatment of moderate to severe AD. Cognex[®], the first cholinesterase inhibitor approved by the Food and Drug Administration (FDA), is not part of our analysis because of its lack of use caused by numerous side effects.²⁵

Our analysis also included one NMDA receptor antagonist, Namenda[®]. The drug works to improve memory, attention, reason, language, and the ability to perform simple tasks; doctors prescribe it to treat moderate to severe AD.²⁶

Formulary Coverage

In general, we found broad coverage of AD drugs among Part D plans from 2006 to 2008 (Figure 8). In 2008, more than 90 percent of Part D plans cover each of the AD drugs. Since Part D’s start in 2006, most plans have covered drugs like Aricept, Exelon, and

²⁰ National Institute on Aging, Alzheimer’s Disease Education and Referral (ADEAR) Center. Available at: <http://www.nia.nih.gov/Alzheimers/>

²¹ Alzheimer’s Association, “2008 Alzheimer’s Disease Facts and Figures.” Available at: http://www.alz.org/national/documents/report_alzfactsfigures2008.pdf

²² National Institute on Aging, ADEAR Center.

²³ Alzheimer’s Association, “Standard Treatments.” Available at: http://www.alz.org/alzheimers_disease_standard_prescriptions.asp

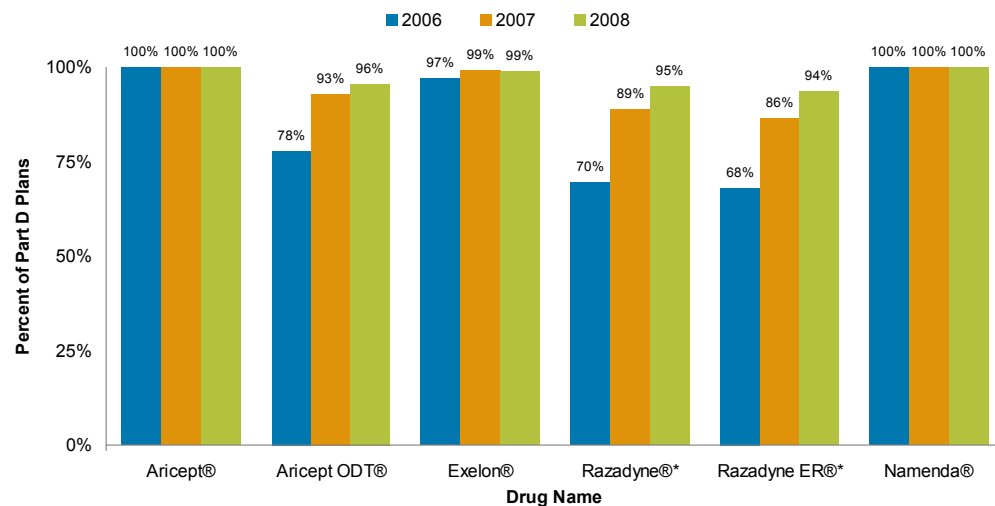
²⁴ Alzheimer’s Association, “Standard Treatments.” Available at: http://www.alz.org/alzheimers_disease_standard_prescriptions.asp

²⁵ National Institute on Aging, ADEAR Center.

²⁶ National Institute on Aging, ADEAR Center.

Namenda. For the other drugs, coverage has improved; for example, 78 percent of plans covered Aricept ODT²⁷ in 2006 and 96 percent in 2008.

FIGURE 8 Average Percentage of Part D Plans Covering Each Alzheimer's Disease Drug, 2006-2008



*Galantamine was marketed under the brand name Reminyl® until 2005, when it became known as Razadyne. Data on Razadyne and Razadyne ER does not include plans that listed this drug as Reminyl on their formularies.

Tier Placement and Cost Sharing

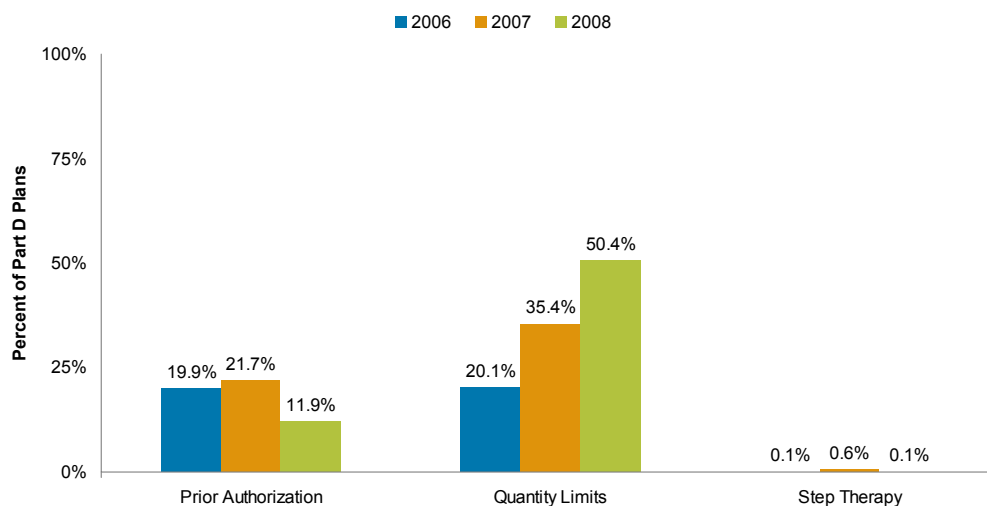
Since the beginning of the Part D benefit, Part D plans typically place AD drugs on cost-sharing tier 2 of their formularies, a tier most often reserved for preferred brand-name drugs. In 2008, the average copayment amount for an AD drug is \$37.51 per prescription. Medicare beneficiaries may pay more or less than \$37.51 depending on their specific prescription and Part D plan. In contrast, the average copayment amount for an AD drug in 2006 was \$30.22.

Utilization Management

Prior authorization In 2008, an average of 12 percent of Part D plans requires prior authorization for each AD drug (Figure 9). The average percentage of plans requiring prior authorization for AD drugs has declined since 2006; in the first year of Part D, an average of 20 percent of plans require prior authorization for each AD drug. This is contrary to the general trend in the Part D market of increasing use of prior authorization. The percentage of plans requiring prior authorization decreased for all AD drugs studied.

²⁷ ODT = Orally Disintegrating Tablets.

FIGURE 9 Average Percentage of Plans Using Utilization Management Tools for Each Alzheimer’s Disease Drug, 2006-2008



We found that PDPs are more likely than MA-PD plans to require prior authorization for AD drugs. Of the drugs studied, Namenda is most frequently subject to prior authorization requirements. Namenda is for the treatment of moderate to severe AD and not approved to treat mild AD. Presumably, plans may be using prior authorization requirements to ensure that only beneficiaries with diagnoses of moderate to severe AD are using this drug.

Quantity limits Each AD drug is subject to quantity limits by an average of 50 percent of plans in 2008. In 2006, each AD drug was subject to quantity limits by an average of 20 percent of plans.

Step therapy Very few Part D plans require step therapy for AD drugs since there are currently no generic alternatives for these drugs.

Beneficiaries with Rheumatoid Arthritis

Approximately 46 million people in the United States (about 1 in 5) have arthritis, including about half of people age 65 and over.²⁸ The term *arthritis* describes more than 100 diseases and conditions that affect joints, the tissues surrounding the joints, and other connective tissues. The pattern, severity, and location of symptoms vary depending on the specific form of the disease, but typically, all types of arthritis feature pain and stiffness in and around the joints. The most common form of arthritis is osteoarthritis; other frequently occurring forms include rheumatoid arthritis, lupus, fibromyalgia, and gout.²⁹ Because of the large number of arthritis treatments, this

²⁸ Centers for Disease Control and Prevention (CDC). “Prevalence of Doctor-Diagnosed Rheumatoid arthritis and Rheumatoid arthritis-Attributable Activity Limitation – United States, 2003-2005.” *Morbidity and Mortality Weekly Report* October 13, 2006. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5540a2.htm?s_cid=mm5540a2_e.

²⁹ CDC, “Rheumatoid arthritis Basics.” Available at: [http://www.cdc.gov/rheumatoid arthritis/rheumatoid arthritis/index.htm](http://www.cdc.gov/rheumatoid%20arthritis/rheumatoid%20arthritis/index.htm).

analysis focused on drugs used to treat rheumatoid arthritis, which can range from over-the-counter pain relievers and inexpensive prescription drugs to newer biologic treatments with annual costs of up to \$18,000 per year.³⁰

People with arthritis commonly use drug therapy to ease the symptoms of the disease. Most drugs focus mainly on relieving pain, but some relieve inflammation or aim to slow disease progression. One of the largest classes of arthritis treatments is nonsteroidal anti-inflammatory drugs (NSAIDs), which relieve pain and inflammation. NSAIDs are prescribed to treat both osteoarthritis and rheumatoid arthritis.³¹

Another large group of treatments for rheumatoid arthritis are disease modifying anti-rheumatic drugs (DMARDs). DMARDs relieve pain and swelling, and also slow joint damage. The original development of many DMARDs focused on other indications, such as cancer or organ transplantation.³² Therefore, these drugs appear in this analysis in the following classes:

- Antimalarials, such as Plaquenil[®]
- Antineoplastic Agents, such as Rheumatrex[®]
- Gold Compounds, such as Ridaura[®]
- Sulfonamides, such as Azulfidine[®]
- Miscellaneous Therapeutic Agents, including Arava[®] and Neoral[®]

Biologic response modifiers, also sometimes classified as DMARDs, appear in this analysis in the Miscellaneous Therapeutic Agents class. These include Orencia[®], Humira[®], Kineret[®], Enbrel[®], and Remicade[®]. The biologic response modifiers block part of the immune system to address the inflammation related to rheumatoid arthritis.³³

This analysis includes two other classes of treatments for rheumatoid arthritis: Opiate Agonists (analgesics), which relieve pain, and Adrenals (corticosteroids), which reduce inflammation and regulate the immune system.³⁴

Formulary Coverage

An average of 64 percent of Part D plans in 2008 cover each rheumatoid arthritis drug. This represents a slight increase from the average of 54 percent of plans offering such

³⁰ Brody, Jane E. "Living Better with Rheumatoid Rheumatoid arthritis." *New York Times*. August 11, 2008.

³¹ National Institute of Rheumatoid arthritis and Musculoskeletal and Skin Diseases, "Handout on Health: Rheumatoid Rheumatoid arthritis." Available at: http://www.niams.nih.gov/Health_Info/Rheumatic_Disease/default.asp#ra_16, and National Institute of Rheumatoid arthritis and Musculoskeletal and Skin Diseases, "Handout on Health: Osteorheumatoid arthritis." Available at: http://www.niams.nih.gov/Health_Info/Osteorheumatoid_arthritis/default.asp#7.

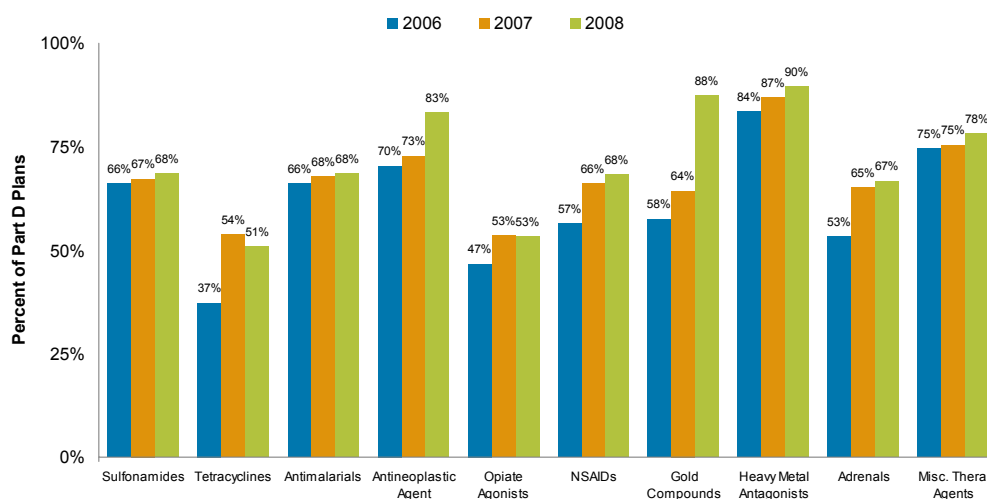
³² Rheumatoid arthritis Foundation, "Take Medicines Wisely." Available at: http://www.rheumatoid_arthritis.org/taking_meds.php, and National Institute of Rheumatoid arthritis and Musculoskeletal and Skin Diseases, "Handout on Health: Rheumatoid Rheumatoid arthritis."

³³ Rheumatoid arthritis Foundation, "Take Medicines Wisely," and National Institute of Rheumatoid arthritis and Musculoskeletal and Skin Diseases, "Handout on Health: Rheumatoid Rheumatoid arthritis."

³⁴ Johns Hopkins Rheumatoid arthritis Center, "Rheumatoid Rheumatoid arthritis Treatment." Available at: http://www.hopkins-rheumatoid_arthritis.org/rheumatoid_arthritis-info/rheumatoid-rheumatoid_arthritis/rheum_treat.html, and Rheumatoid arthritis Foundation, "Take Medicines Wisely."

coverage in 2006. Figure 10 shows that for most types of rheumatoid arthritis drugs studied in this paper, coverage has increased since 2006.

FIGURE 10 Average Percentage of Part D Plans Covering Rheumatoid Arthritis Drugs by AHFS Class, 2006-2008



As in other classes, when both brand and generic versions of a drug are available, Part D plans are far more likely to cover the generic rather than the brand-name version. For example, 37 percent of plans in 2008 cover Azulfidine, a brand-name drug, while all plans cover its generic equivalent, sulfasalazine.

Tier Placement and Cost Sharing

Part D plans most commonly place brand-name rheumatoid arthritis drugs on cost-sharing tier 3 and generic rheumatoid arthritis drugs on tier 1. Because cost sharing for tier 3 drugs is generally higher than cost sharing for tier 1 drugs, beneficiaries are required to pay higher cost-sharing amounts for brand-name drugs than for generic drugs. The most common tier placement for several brand-name rheumatoid arthritis drugs is higher in 2008 than in 2006. For example, Arava, Azasan, Indocin IV[®],³⁵ and Rheumatrex were most often on tier 2 in 2006 but they are primarily on tier 3 in 2008.

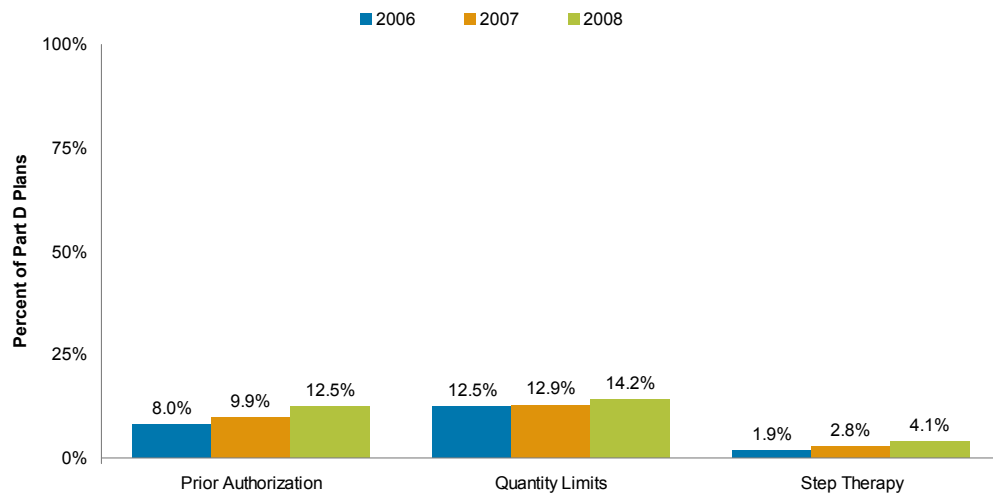
All of the biologic response modifiers (also referred to as biologics) used to treat rheumatoid arthritis, such as Rituxan[®], Remicade, Orenzia, Kineret, Humira, and Enbrel, are most commonly placed on cost-sharing tier 4. Part D plans often designate tier 4 as a “specialty tier,” reserved for higher cost Part D drugs including biologic drugs and injections. Tier 4 most often has a significant coinsurance requirement. In 2008, the average coinsurance rate on tier 4 of four-tier plans is 30 percent, meaning beneficiaries taking drugs assigned to this tier must pay 30 percent of the drugs’ costs. For a drug that costs \$10,000 annually, 30 percent coinsurance could mean \$250 per month in out-of-pocket spending.

³⁵ IV = Intravenous.

Utilization Management

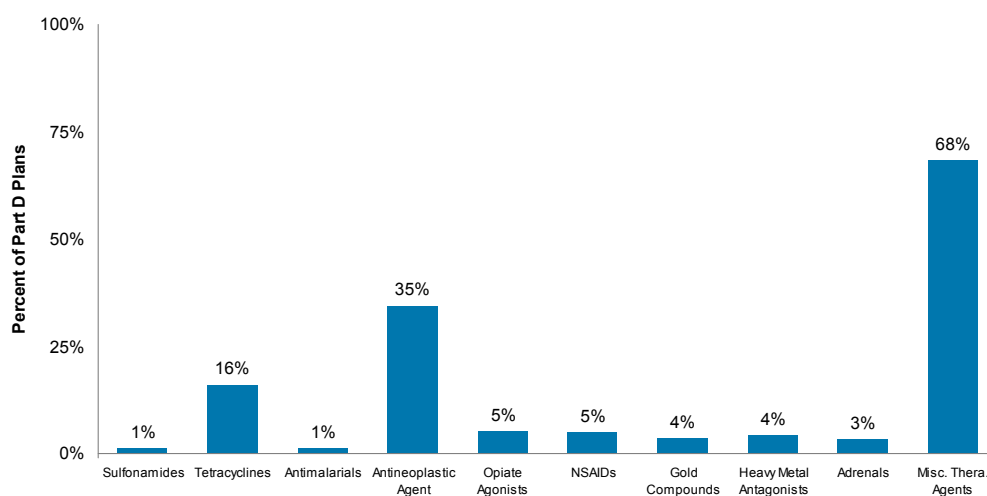
Over the three years of the Part D benefit, the percentage of plans employing utilization management techniques for rheumatoid arthritis drugs has increased slightly (Figure 11). These changes are consistent with overall trends of the increasing use of these techniques for all Part D drugs.

FIGURE 11 Average Percentage of Plans Using Utilization Management Tools for Each Rheumatoid Arthritis Drug, 2006- 2008



Prior authorization Each rheumatoid arthritis drug is subject to prior authorization, on average, by 13 percent of plans in 2008; this represents a 5-percentage point increase from 2006. While the overall use of prior authorization has risen only slightly over the past three years, certain rheumatoid arthritis drugs are subject to prior authorization by significantly more plans in 2008 than in 2006. Ultram[®] and Percocet[®] saw the most notable increases; about 25 to 30 percent of plans required prior authorization for these drugs in 2008, compared to only about 1 percent in 2006.

Since the beginning of the Part D benefit, most plans require prior authorization for biologics, brands with generic equivalents, and COX-2 inhibitors. COX-2 inhibitors are a subset of NSAIDs, and the FDA has identified potential increased risks for cardiovascular events and potential gastrointestinal bleeding. Rheumatoid arthritis drugs are unique in that many classes of drugs treat this condition, and plans may treat different types of drugs differently on their formularies. Overall, each rheumatoid arthritis drug is subject to prior authorization by an average of 13 percent of plans, but about 70 percent of plans require prior authorization for biologics, which fall under the AHFS class of “Miscellaneous Therapeutic Agents” (Figure 12).

FIGURE 12 Average Percentage of Plans Requiring Prior Authorization by AHFS Class, 2008

Quantity limits As with prior authorization, each rheumatoid arthritis drug is subject to quantity limits, on average, by 14 percent of plans in 2008, an increase from an average of 9 percent of plans in 2006. Certain rheumatoid arthritis drugs are subject to quantity limits by a significantly higher percentage of plans. For example, 72 percent of Part D plans apply quantity limits to Celebrex[®]. In addition, more than half of Part D plans in 2008 apply quantity limits to Oxycontin[®], oxycodone hydrochloride extended release (ER), and Avinza. Plans may limit the number of pills a patient can receive at one time in an attempt to minimize the potential for abuse.

Step therapy Each rheumatoid arthritis drug is subject to step therapy by an average of 3 percent of plans, an increase from 2006 when an average of 1 percent of plans required step therapy for each rheumatoid arthritis drug. Many of the rheumatoid arthritis drugs included in our analysis have no step therapy requirements, but for a small number of drugs, step therapy is common. For example, 52 percent of plans require step therapy for Mobic[®], and 42 percent of plans require step therapy for Celebrex.

Compared to the drugs in other classes studied in this paper, certain drugs used to treat rheumatoid arthritis are more likely to be subject to multiple utilization management techniques. Mobic, Celebrex, and Ultram ER[®] all have high rates of step therapy, prior authorization, and quantity limits.

Beneficiaries with Type 2 Diabetes

Diabetes is one of the most common chronic conditions today. According to the Centers for Disease Control and Prevention, 24 million Americans have diabetes, and 57 million

people are now “pre-diabetic;”³⁶ studies show that many people with pre-diabetes will develop Type 2 diabetes within 20 years.³⁷

There are two types of diabetes. For people with Type 1 diabetes, the pancreas fails to produce insulin needed to take sugar from the blood to the cells. The majority of people with diabetes have Type 2, in which the body is unable to properly use insulin. There is no cure for Type 2 diabetes, but diet, exercise, and medication therapy can keep the disease under control.³⁸

Even though diabetics in many situations can lead normal lives, those without access to proper treatment can face serious and life threatening consequences, including heart attacks and strokes, kidney disease, eye complications, and amputations.³⁹

Our analysis included the four largest classes of drugs used to treat the disease:⁴⁰

- Insulins, which replace or supplement the body’s natural insulin
- Sulfonylureas, used to improve insulin production
- Biguanides, used to regulate the release of glucose by the liver
- Thiazolidinediones (TZDs), to lessen insulin resistance

Our analysis also included drugs classified as Alpha-Glucosidase Inhibitors, Amylinomimetics, Incretin Mimetics, Meglitinides, and Antidiabetic Agents, Miscellaneous.

Formulary Coverage

An average of 67 percent of Part D plans covered each diabetes drug in 2006; in 2008, the average is 78 percent of plans. Coverage of diabetes drugs by Part D plans varies substantially; for example, all plans cover metformin HCl, while only 35 percent of plans cover Diabinese[®]. Consistent with our findings for other conditions, Part D plans cover generic diabetes drugs more often than brand-name drugs: an average of 94 percent of plans covers each generic drug, while an average of 75 percent of plans covers each brand-name drug. Glucophage[®] and Fortamet[®], brand-name drugs with generic equivalents, are covered by an average of 40 percent of plans in 2008.

Tier Placement and Cost Sharing

The diabetes drugs included in our analysis on usually appear on cost-sharing tier 2, which is commonly reserved for preferred brands and has an average copayment of \$35 for 2008. Generic diabetes drugs, as in other classes, appear on tier 1 and have the lowest

³⁶ CDC Press Release, “Number of People with Diabetes Increases to 24 Million.” June 24, 2008. Available at: <http://www.cdc.gov/media/pressrel/2008/ro80624.htm>.

³⁷ CDC At A Glance, “Diabetes: Disabling Disease to Double by 2050.” January 2008. Available at: <http://www.cdc.gov/nccdphp/publications/aag/pdf/diabetes.pdf>.

³⁸ American Diabetes Association. Available at: www.diabetes.org.

³⁹ National Diabetes Information Clearinghouse (NDIC). Available at: <http://www.diabetes.niddk.nih.gov/complications/index.htm>.

⁴⁰ American Diabetes Association. Available at: www.diabetes.org.

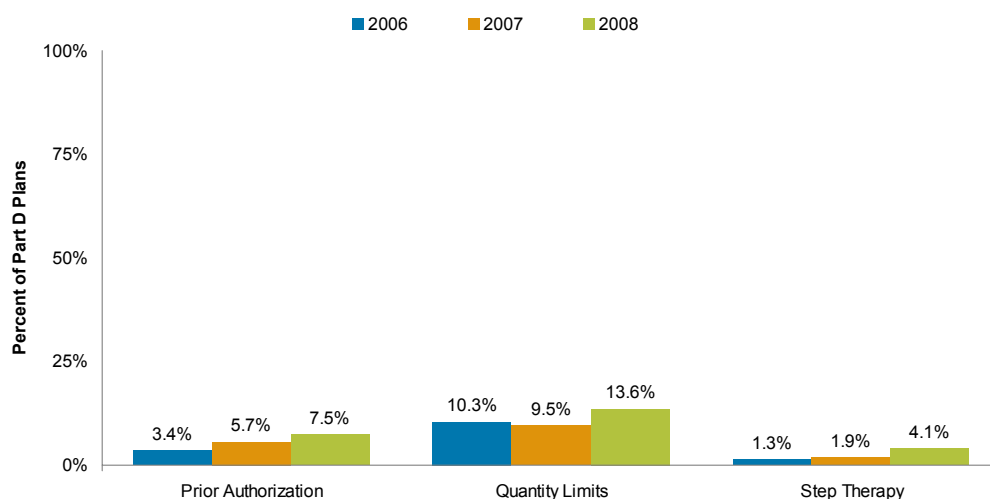
cost-sharing requirements. The most common tier placement has not changed for diabetes drugs since 2006.

Although tier placement has been relatively stable from 2006 to 2008, cost-sharing responsibilities for diabetes drugs have increased. Beneficiaries in Part D pay an unweighted average of \$36.51 per prescription in cost sharing for diabetes drugs in 2008. This represents a 13-percent increase since 2006, when the unweighted average cost-sharing amount for diabetes drugs in Part D was \$32.28 per prescription. As previously noted, a beneficiary's cost sharing may be more or less than this average, depending on his or her specific prescription and Part D plan.

Utilization Management

While tier placement has remained mostly consistent from 2006 to 2008, utilization management has increased for diabetes drugs (Figure 13). More Part D plans have prior authorization, quantity limits, and step therapy requirements for diabetes drugs in 2008; although diabetes drugs are generally subject to fewer utilization management techniques than the other classes we studied.

FIGURE 13 Average Percentage of Plans Using Utilization Management Tools for Each Type 2 Diabetes Drug, 2006-2008



Prior authorization Overall, we found that more plans require prior authorization for diabetes drugs in 2008 than in 2006 (Figure 13). Each diabetes drug is subject to prior authorization by an average of 8 percent of plans in 2008, a 5-percentage-point increase since 2006. While the overall rate of prior authorization is fairly low, there is great variation in the application of prior authorization for this class.

Plans tend to manage diabetes drugs individually rather than as a class or group. For example, in 2006 only 2 percent of plans required prior authorization for Glucotrol[®] XL while 31 percent of plans do so in 2008. A generic version of the drug, glipizide extended release, was approved in 2003 and Part D plans appear to increasingly require prior authorization for Glucotrol XL.

Prior authorization rates are especially high for drugs including Symlin[®] and Byetta[®]. About 60 percent of Part D plans require prior authorization for Symlin. This drug is used with insulin and carries a “black box” warning from the FDA because of risks for patients with Type 1 diabetes.⁴¹ Nearly a third of all Part D plans require prior authorization for Byetta. Byetta is an injection product and the first in a class called incretin mimetics.

Quantity limits Overall, each diabetes drug is subject to quantity limits by 14 percent of Part D plans, a 4-percentage-point increase since last year. Similar to prior authorization requirements, the rate of quantity limits varies widely by drug. Examples of drugs with higher rates of quantity limits are Duetact[®], Actos[®], Avandia[®], and Byetta. All of these drugs, with the exception of Actos, received approval in or after 2005, and some have FDA warnings about potentially serious side effects.

Step therapy Diabetes drugs have higher rates of step therapy, or fail first programs, than the other chronic condition drugs analyzed, possibly due to the wide availability of generic alternatives. Again, although step therapy is not very common—each diabetes drug is subject to step therapy by an average of 4 percent of plans—a small number of drugs have much higher rates of step therapy. Since step therapy is often required to determine if a patient can take a lower-cost drug instead of a more expensive one, drugs with new routes of administration or mechanisms of action may have higher rates of step therapy. For example, as previously stated, Byetta is an injection and the first in a class called incretin mimetics. Almost 40 percent of plans require step therapy for Byetta in 2008. Table 3 identifies the diabetes drugs that are most likely to have utilization management requirements.

TABLE 3 Type 2 Diabetes Drugs Most Likely to Have Utilization Management Requirements, 2008

>25% of Plans Require Prior Authorization	>30% of Plans Apply Quantity Limits	>20% of Plans Require Step Therapy
Symlin [®] (58%) Januvia [™] (35%) Glucotrol [®] XL (31%) Janumet [™] (29%) Byetta [®] (27%)	Duetact [®] (56%) Actos [®] (54%) Avandia [®] (53%) Byetta [®] (51%) Avandaryl [®] (46%) Avandamet [®] (43%) Januvia [™] (41%) Actoplus Met [®] (41%) Janumet [™] (37%) Symlin [®] (37%) Glucophage [®] XR (31%)	Byetta [®] (40%) Glumetza [®] (27%) Avandaryl [®] (22%) Avandamet [®] (21%)

⁴¹ Amylin Pharmaceuticals, Inc., “Symlin[®] (pramlintide acetate).” Available at: <http://www.amylin.com/pipeline/symlin.cfm>.

Beneficiaries with Schizophrenia/Psychosis

Schizophrenia is a severe, lifelong form of mental illness that affects about 1 percent of Americans.⁴² People with schizophrenia may hear voices, hallucinate, or believe that others are reading or controlling their minds. The causes of schizophrenia are unknown, but genetic and environmental factors play a role, according to experts.⁴³

Antipsychotic medications have been used since the 1950s to treat symptoms of schizophrenia; while they alleviate symptoms, they do not cure schizophrenia. The first products that were created to treat schizophrenia—often referred to first-generation or conventional antipsychotics—were effective in alleviating symptoms but caused unpleasant side effects such as rigidity, muscle spasms, tremors, and restlessness. In the 1990s, new drugs—referred to as novel, atypical, or second-generation antipsychotics—were developed that produced fewer side effects. Patients diagnosed with schizophrenia or who undergo psychotic episodes often receive second-generation drugs for treatment. These drugs include Risperdal[®], Zyprexa[®], Seroquel[®], Geodon[®], and Abilify[®]. According to the National Institute of Mental Health, if a patient has not responded to other drugs, doctors can prescribe another second-generation drug, Clozaril[®].⁴⁴

Patients respond differently to antipsychotic medications and sometimes a doctor may prescribe several different drugs before finding the right drug or combination of drugs for a patient. As one study noted, “unlike other chronic conditions... disrupting psychiatric medications can have immediate health consequences resulting in symptoms, functional impairment, and accelerated use of health services.”⁴⁵

Formulary Coverage

In 2006, CMS designated antipsychotic drugs—those used to treat schizophrenia or psychosis—as a protected class. Because beneficiaries with certain conditions may need more medication choices, CMS requires Part D plans to cover all or substantially all of the active ingredients in six drug classes, including antipsychotics. It is important to note that while CMS requires plans to cover drugs in the protected classes, plans must cover all active ingredients, not all individual drugs marketed for sale. If a plan covers the generic version of a drug, the plan is not required to cover the brand.

Coverage of antipsychotic drugs improved slightly from 2006; in 2008, an average of 90 percent of Part D plans covers each schizophrenia/psychosis drug, an increase from 76 percent of plans in 2006. Part D plans cover the various types of schizophrenia/psychosis drugs differently. As stated, there are two kinds of schizophrenia/psychosis drugs: conventional antipsychotic drugs, which are generally older, such as Prolixin[®], Mellaril[®],

⁴² National Institute of Mental Health, “Schizophrenia.” Available at: <http://www.nimh.nih.gov/health/publications/schizophrenia/complete-publication.shtml>.

⁴³ National Institute of Mental Health, “Schizophrenia.”

⁴⁴ National Institute of Mental Health, “Schizophrenia.”

⁴⁵ Morden NE and Garrison Jr. LP. Implications of Part D for Mentally Ill Dual Eligibles: A Challenge for Medicare. *Health Affairs* 25;2 (2006): 491–500.

and Thorazine[®]; and atypical antipsychotics, such as Abilify, Geodon, and Risperdal, which are newer and tend to have fewer side effects.⁴⁶

Of the schizophrenia/psychosis drugs studied for this paper, atypical antipsychotics (which are mostly brand-name drugs) and generic versions of conventional antipsychotics were covered more often than branded conventional antipsychotics. All Part D plans in 2008 cover several atypical antipsychotics, including Abilify, Abilify Discmelt[®], FazaClo[®], Geodon, Risperdal, Risperdal Consta[®], Risperdal M-Tab, Seroquel, Zyprexa, and Zyprexa Zydis[®].

Only 41 percent of plans cover Clozaril. Again, while CMS requires plans to cover drugs in the protected classes, plans must cover all active ingredients, not all individual drugs marketed for sale. Clozaril was the first FDA-approved atypical antipsychotic drug, and a generic version—clozapine—has been available since 1998. Part D plans may cover clozapine instead of Clozaril.

The manufacturers of several brand-name conventional antipsychotic drugs have stopped, such as for Prolixin, Mellaril, and Thorazine. However, generic versions are available and all plans cover these three drugs in 2008.

Tier Placement and Cost Sharing

Part D plans typically place generic schizophrenia/psychosis drugs on cost-sharing tier 1 and brand-name drugs on cost-sharing tiers 2 and 3.

We found the most common tier placement for some schizophrenia/psychosis drugs has increased since 2006. Coverage of Abilify and FazaClo was most often on cost-sharing tier 2 in 2006 and 2007, but in 2008, the most common placement is cost-sharing tier 3, usually designated for non-preferred brands. In 2006, Risperdal Consta, the only long-acting atypical drug, saw coverage primarily on tier 2, but in 2007 and 2008 the most common placement is on cost-sharing tier 4.

Changes in cost-sharing tier placement for schizophrenia/psychosis drugs highlight another important aspect of the six protected classes. While CMS requires plans to cover either the brand or generic for almost drugs in each class, plans may place these drugs on any cost-sharing tier.

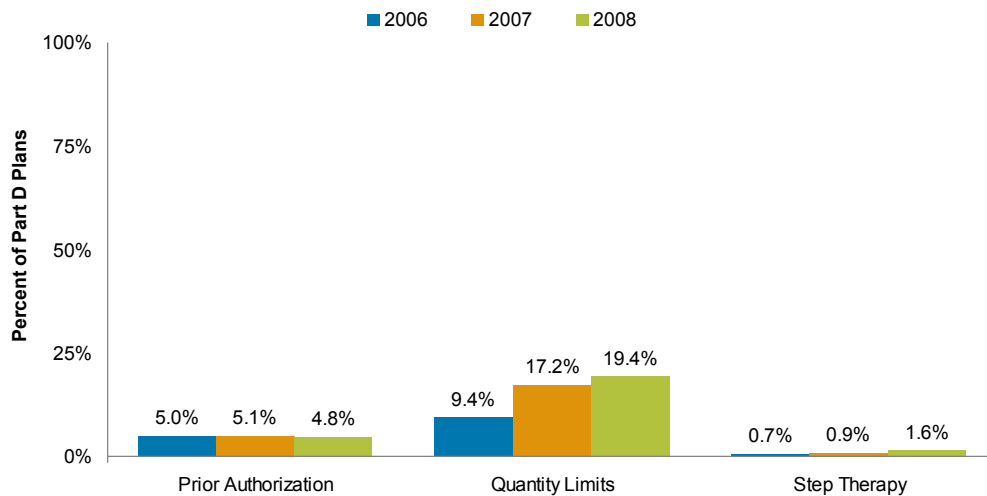
Utilization Management

Few Part D plans require prior authorization or step therapy for schizophrenia/psychosis drugs. This may be due to CMS' requirement that plans not to apply prior authorization or step therapy to these medications if an enrollee was already taking the medication. Figure 14 shows the average percentage of plans that have prior authorization, quantity limit, and step therapy requirements for schizophrenia/psychosis drugs. Each schizophrenia/psychosis drug is subject to prior authorization and step therapy, on average, by fewer than 5 percent of plans. Quantity limits are slightly more common,

⁴⁶ National Institute on Mental Health, "Medications."
<http://www.nimh.nih.gov/health/publications/medications/complete-publication.shtml#pub6>

though the average percentage of plans applying quantity limits for each drug is still below 20 percent. Rates of prior authorization and step therapy have remained relatively stable but have increased for quantity limits since 2006.

FIGURE 14 Average Percentage of Plans Using Utilization Management Tools for Each Schizophrenia/Psychosis Drug, 2006-2008



Prior authorization Part D plans are most likely to apply utilization management tools to branded atypical antipsychotic drugs. Table 4 shows the 10 atypical antipsychotics with the highest rates of prior authorization.

TABLE 4 Antipsychotic Drugs with Highest Rates of Prior Authorization

	2006	2007	2008
All Drugs in Class			
Prior Authorization	5%	5%	5%
Quantity Limits	12%	18%	20%
Step Therapy	1%	1%	2%
Conventional Antipsychotics and Generics			
Prior Authorization	5%	3%	3%
Quantity Limits	3%	4%	4%
Step Therapy	0%	0%	1%
Atypical Antipsychotics			
Prior Authorization	5%	9%	8%
Quantity Limits	28%	46%	48%
Step Therapy	2%	2%	3%

Though the overall rate of prior authorization remained stable since 2006, a closer look at prior authorization at the drug level revealed subtle shifts in the way Part D plans apply this utilization management tool. More plans require prior authorization for

atypical drugs in 2008 than in 2006. In contrast, plans are removing prior authorization requirements for conventional antipsychotic drugs and generics.

Trends in the use of prior authorization vary between plans eligible and not eligible for auto-enrollment. In 2006, each atypical drug was subject to prior authorization by an average of 10 percent of plans eligible for auto-enrollment. In 2008, each atypical drug is subject to prior authorization by an average of 8 percent of such plans. The trend reversed among plans not eligible for auto-enrollment. In 2006, each atypical drug was subject to prior authorization by an average of 5 percent of plans. In 2008, each atypical drug is subject to prior authorization by an average of 9 percent of plans.

Quantity limits Quantity limits are the most commonly used utilization management tool for schizophrenia/psychosis drugs, and we found that more plans have placed quantity limits on these drugs over time. In 2006, each schizophrenia/psychosis drug was subject to quantity limits by, on average, 9 percent of Part D plans. In 2008, such drugs are subject to quantity limits by an average of 19 percent of plans. This is perhaps because CMS has not placed a restriction on the use of quantity limits as it has on prior authorization and step therapy. Similar to prior authorization, more plans place quantity limits on atypical antipsychotic drugs than on conventional antipsychotics or generic drugs.

Step therapy Overall, each schizophrenia/psychosis drug is subject to step therapy by an average of 2 percent of plans in 2008. Atypical antipsychotics are subject to step therapy by, on average, 7 percent of plans in 2008, again revealing more common use of utilization management tools for atypical antipsychotic drugs. When generics become available, brand drugs often see step therapy applied.⁴⁷

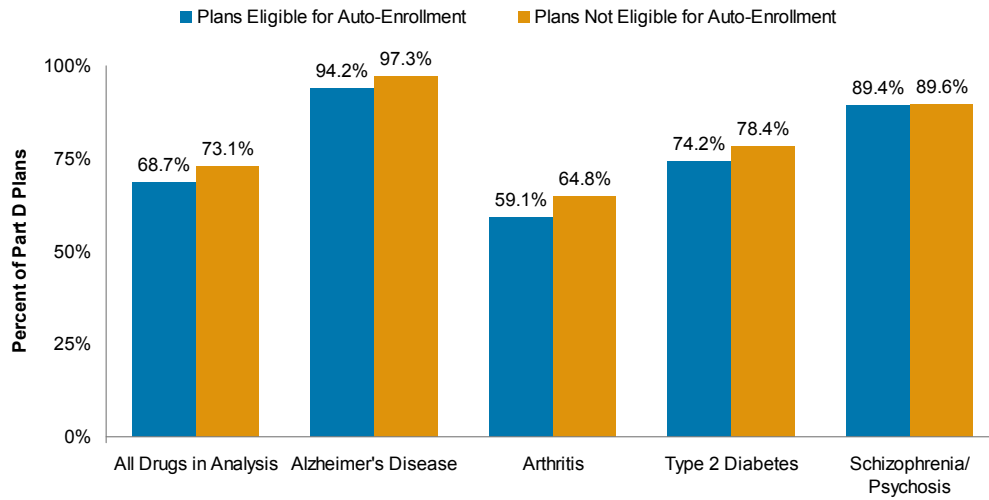
Plans Eligible and Not Eligible for Auto-Enrollment

Formulary Coverage

In 2008, auto-enrollment plans cover fewer of the drugs in our analysis than other plans (Figure 15). Across the four groups of drugs that we analyzed, an average of 69 percent of auto-enrollment plans and 73 percent of other plans covers each chronic condition drug. The difference between the two types of plans is attributable to auto-enrollment plans' slightly lower rates of coverage of AD, rheumatoid arthritis, and diabetes drugs.

⁴⁷ National Institute of Mental Health, "Schizophrenia."

FIGURE 15 Average Percentage of Plans Covering Each Chronic Condition Drug by Condition, Plans Eligible and Not Eligible for Auto-Enrollment of Dual Eligibles, 2008



Auto-enrollment plans include an average of 83 of 140 rheumatoid arthritis drugs on their formularies, and other plans include an average of 91 drugs. Of 83 diabetes drugs, auto-enrollment plans include an average of 62 drugs and other plans include an average of 65 drugs on their formularies. For dual eligibles with these conditions, the differences in the average number of drugs on plan formularies may make it more difficult to access particular drugs. The two types of plans, on average, cover the same number of drugs used to treat schizophrenia/psychosis; Part D plans are required to cover all or substantially all of the active ingredients in the antipsychotics “protected” class.

Utilization Management

Prior authorization Overall, plans eligible and not eligible for auto-enrollment appear to require similar rates of prior authorization for the drugs in our analysis (10 percent, on average). However, larger differences arise at the condition-specific level (Figure 16) and drug level (Table 5). In general, AD and rheumatoid arthritis drugs are subject to prior authorization by a greater percentage of auto-enrollment plans than other plans.

FIGURE 16 Average Rate of Prior Authorization for Each Chronic Condition Drug by Condition, Plans Eligible and Not Eligible for Auto-Enrollment, 2008

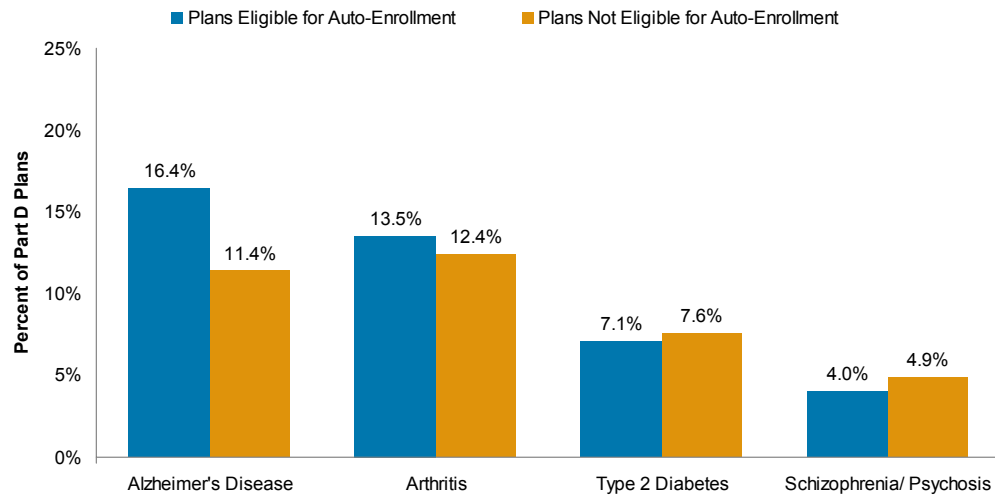
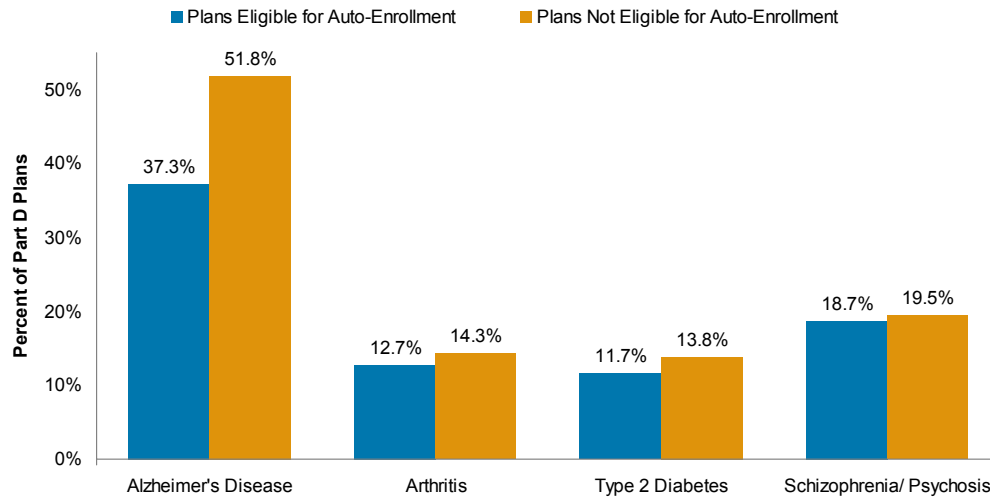


TABLE 5 Drugs with Greatest Differences in Average Rate of Prior Authorization, 2008

Drug Name	Chronic Condition	Plans Eligible for Auto-Enrollment	Plans Not Eligible for Auto-Enrollment
Imuran®	Rheumatoid Arthritis	74%	51%
Azasan®	Rheumatoid Arthritis	66%	45%
Azathioprine	Rheumatoid Arthritis	68%	48%
Trexall®	Rheumatoid Arthritis	53%	35%
Arava®	Rheumatoid Arthritis	53%	38%
Mobic®	Rheumatoid Arthritis	23%	37%
Orencia®	Rheumatoid Arthritis	89%	77%
Neoral®	Rheumatoid Arthritis	85%	72%
Kineret®	Rheumatoid Arthritis	93%	81%
Symlin®	Type 2 Diabetes	49%	59%

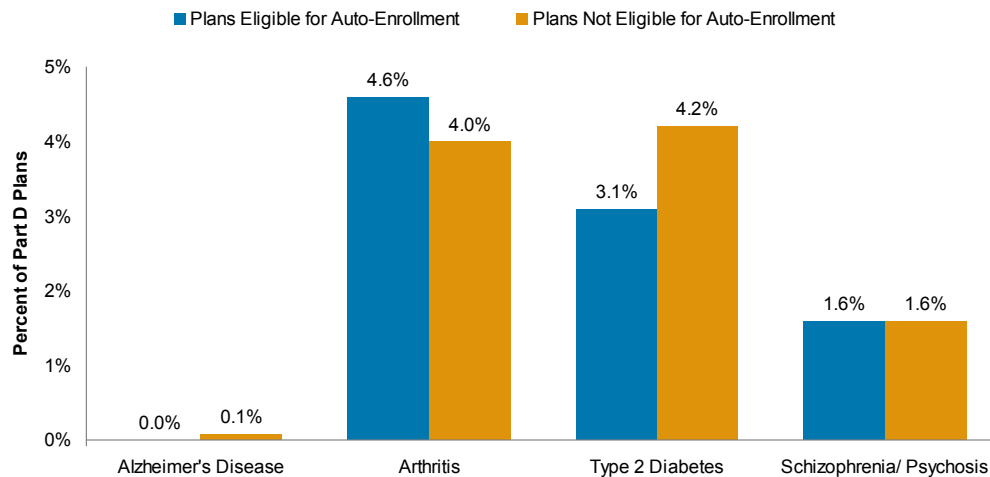
Quantity limits Rates of quantity limits for the drugs in our analysis also vary between the two types of plans (Figure 17). Plans that are not eligible for auto-enrollment are more likely to apply quantity limits to chronic condition drugs than plans that are eligible. AD drugs see the most pronounced difference between the two types of plans. Each AD drug is subject to quantity limits, on average, by 52 percent of plans that are not eligible for auto-enrollment, compared to 37 percent of plans that are eligible. The difference in rates of quantity limits is least pronounced for drugs used to treat schizophrenia/psychosis. The average rate of quantity limits for chronic condition drugs remained steady at 14 percent of plans from 2006 to 2008 in auto-enrollment plans and increased from 11 to 16 percent of other plans.

FIGURE 17 Average Rate of Quantity Limits for Each Chronic Condition Drug by Condition, Plans Eligible and Not Eligible for Auto-Enrollment



Step therapy Overall, rates of step therapy are low and there are only slight differences between plans eligible and not eligible for auto-enrollment (Figure 18). Plans that are not eligible for auto-enrollment are slightly more likely to require step therapy than auto-enrollment plans. The greatest difference in rates of step therapy between the two plans is for diabetes drugs. The difference is driven by the high percentage of plans that are not eligible for auto-enrollment that require step therapy for certain diabetes drugs, such as Byetta and Duetact. Only 21 percent of auto-enrollment plans require step therapy for Byetta compared to 42 percent of other plans.

FIGURE 18 Average Rate of Step Therapy for Each Chronic Condition Drug by Condition, Plans Eligible and Not Eligible for Auto-Enrollment



Conclusion

Because the majority of the Medicare population takes drugs for chronic conditions, most Part D enrollees are affected by issues of formulary access. This analysis focused on changes in access to drugs over the first three years of the Medicare drug benefit across dimensions such as formulary coverage, tier placement, cost sharing and utilization management. We did not find evidence of a trend among plans to restrict access to drugs for the four chronic conditions we studied relative to all Part D drugs in the aggregate, but certain aspects of access are changing across all drugs. Formulary coverage has improved for these chronic condition drugs and tier placement has remained relatively stable, but cost sharing has increased and plans generally are placing more utilization management requirements on the drugs in our analysis.

Our findings indicate that beneficiaries or their family members should evaluate their plan choices each year, considering all types of access—formulary coverage, tier placement, cost sharing, and utilization management requirements—to the specific drugs they are taking. As this paper shows, access can vary dramatically from drug to drug, and access for a particular drug can change over time. Therefore, beneficiaries must decide which access factor is most important in selecting a Part D plan, and reevaluate their plan choice each year.

Given the important role of drug therapy in treatment for chronic conditions, policymakers and stakeholders should continue to monitor trends in formulary coverage and potential limitations on access in the coming years. In particular, these groups may want to consider the following questions:

- How will access to AD and schizophrenia/psychosis drugs change over the next few years as brand-name drugs lose their patent exclusivity and generic versions enter the market?
- Will the Medicare Improvements for Patients and Providers Act of 2008, which codifies CMS's protected drug classes policy in Part D, affect the classes that are designated as "protected"?
- Will Part D plans change their coverage of rheumatoid arthritis drugs in response to CMS' recent clarification that arthritis products are not included in the agency's definition of the protected immunosuppressant drug class?⁴⁸

⁴⁸ CMS, Prescription Drug Benefit Manual, Chapter 6, Section 30.2.5.

Appendix: Drugs Included in This Analysis

Note: Brand-name drugs appear in capital letters; generics appear in lowercase.

TABLE A1 Alzheimer's Disease and Dementia

AHFS Class	Drug Name
Parasympathomimetic (120400)	ARICEPT®
	ARICEPT ODT®
	EXELON®
	RAZADYNE®
	RAZADYNE ER®
	REMINYL®
Central Nervous System Agents, Misc (289200)	NAMENDA®
	NAMENDA TITRATION PAK®

TABLE A2 Rheumatoid Arthritis

AHFS Class	Drug Name
Sulfonamides (081220)	sulfasalazine
	sulfazine
	sulfazine ec
	sulfasalazine ec
	AZULFIDINE®
	AZULFIDINE EN-TABS®
Tetracyclines (081224)	minocycline hcl
	MINOCIN®
	MINOCIN PAC®
	DYNACIN®
Antimalarials (083008)	hydroxychloroquine sulfate
	PLAQUENIL®
Antineoplastic Agents (100000)	methotrexate
	methotrexate sodium
	methotrexate sodium lpf
	RHEUMATREX®
	RITUXAN®
	TREXALL®
Nonsteroidal Anti-inflammatory Agents (280804)	choline magnesium trisalicylate
	tricosal
	diclofenac potassium
	diclofenac sodium

AHFS Class	Drug Name
	diclofenac sodium ec
	diclofenac sodium dr
	diclofenac sodium xr
	diclofenac sodium er
	diclofenac sodium sr
	diflunisal
	etodolac
Nonsteroidal Anti-inflammatory Agents (280804) – continued	etodolac er
	flurbiprofen
	ibuprofen
	indomethacin
	indomethacin er
	indomethacin cr
	indomethacin sa
	indomethacin sr
	ketoprofen
	ketoprofen er
	meclofenamate sodium
	mefenamic acid
	meloxicam
	nabumetone
	naproxen
	naproxen sodium
	piroxicam
	salflex
	mono-gesic
	salsalate
	amigesic
	sulindac
	tolmetin sodium
	ANAPROX [®]
	ANAPROX DS [®]
	ANSAID [®]
	ARTHROTEC 50 [®]
	ARTHROTEC 75 [®]
	CATAFLAM [®]
	CELEBREX [®]

AHFS Class	Drug Name
	CLINORIL [®]
	DISALCID [®]
	DOLOBID [®]
	FELDENE [®]
	INDOCIN [®]
	INDOCIN IV [®]
	INDOCIN IV SDV [®]
	INDOCIN SR [®]
	LODINE [®]
	LODINE XL [®]
	MOBIC [®]
	MOTRIN [®]
	MOTRIN [®]
	NALFON [®]
	NAPRELAN [®]
	NAPROSYN [®]
	NAPROSYN [®]
Nonsteroidal Anti-inflammatory Agents (280804) – continued	ORUDIS [®]
	ORUVAIL [®]
	PONSTEL [®]
	RELAFEN [®]
	TOLECTIN [®]
	TOLECTIN DS [®]
	TRILISATE [®]
	VOLTAREN [®]
	VOLTAREN-XR [®]
Opiate Agonists (280808)	acetaminophen/codeine #3
	acetaminophen/codeine
	acetaminophen/codeine #2
	acetaminophen/codeine #4
	codeine phosphate/acetaminophen
	hydrocet
	hydrocodone/acetaminophen
	ceta plus
	margesic-h
	dolorex forte

AHFS Class	Drug Name
	dolacet
	lorcet-hd
	stagesic
	dolagesic
	morphine sulfate cr
	morphine sulfate er
	oxycodone hcl
	eth-oxydose
	oxyfast
	percolone
	oxycodone hcl er
	oxycodone hcl cr
	propoxyphene hcl
	propoxyphene-n/acetaminophen
	propoxacet-n
	roxicet
	oxycodone/acetaminophen
	oxycodone-apap
	endocet
	narvox
	tramadol hcl
	tramadol hydrochloride/acetaminophen
	vicodin hp
	co-gesic
	hydrocodone bitartrate/acetaminophen
	anexsia
	hydrocodone bitartrate/apap
	hydrocodone/apap
Opiate Agonists (280808) – continued	hydrocodone/acetaminophen-hs
	vanacet
	AVINZA®
	ALCET®
	ANEXSIA®
	BALACET 325®

AHFS Class	Drug Name
	BANCAP-HC [®]
	DARVOCET A500 [®]
	DARVOCET-N 100 [®]
	DARVOCET-N 50 [®]
	DARVON [®]
	DARVON-N [®]
	HYCET [™]
	LIQUICET [™]
	LORCET 10/650 [®]
	LORCET PLUS [®]
	LORCET-HD [®]
	LORTAB [®]
	LORTAB 10 [®]
	LORTAB 2.5 [®]
	LORTAB 5 [®]
	LORTAB 7.5 [®]
	MAGNACET [®]
	MAXIDONE [®]
	MS CONTIN [®]
	NORCO [®]
	ORAMORPH SR [®]
	OXYCONTIN [®]
	OXYIR [®]
	PERCOCET [®]
	PERLOXX [®]
	ROXICET [®]
	ROXICODONE [™]
	ROXICODONE INTENSOL [™]
	STAGESIC-10
	TRYCET [®]
	TYLENOL/CODEINE #3 [®]
	TYLENOL/CODEINE #4 [®]
	ULTRACET [®]
	ULTRAM [®]
	ULTRAM ER [®]
	VICODIN [®]
	VICODIN ES [®]

AHFS Class	Drug Name
	VOPAC [®]
	XODOL [®]
	ZYDONE [®]
Nonsteroidal Anti-inflammatory Agents (520820)	VOLTAREN [®]
Gold Compounds (600000)	gold sodium thiomalate
	MYOCHRYSINE [®]
	RIDAURA [®]
Heavy Metal Antagonists (640000)	CUPRIMINE [®]
	DEPEN TITRATABS [®]
Adrenals (680400)	deltasone
	prednisone
	dexamethasone
	hydrocortisone
	methylprednisolone
	methylprednisolone dose pack
	prednisolone
	prednisolone sodium phosphate
	CELESTONE [®]
	CELESTONE SOLUSPAN [®]
	CORTEF [®]
	DECADRON [®]
	DEXPAK 13 DAY [®]
	DEXPAK JR 10 DAY [®]
	HYDROCORTONE [®]
	MEDROL [®]
	MEDROL DOSEPAK [®]
	PEDIAPRED [®]
	PRELONE [®]
	STERAPRED [®]
STERAPRED 12 DAY [®]	
STERAPRED DS [®]	
Miscellaneous Therapeutic Agents (920000)	azathioprine
	gengraf
	cyclosporine modified
	leflunomide
	ARAVA [®]

AHFS Class	Drug Name
	AZASAN [®]
	ENBREL [®]
	ENBREL [®] SURECLICK [™]
	HUMIRA [®]
	HUMIRA PEN [®]
	HUMIRA PEN-CROHNS DISEASESTARTER [®]
	IMURAN [®]
	KINERET [®]
	NEORAL [®]
	ORENCIA [®]
	REMICADE [®]
Pharmaceutical Aids (960000)	meclofenamate sodium

TABLE A3 Type 2 Diabetes

AHFS Class	Drug Name
Alpha-Glucosidase Inhibitors (682002)	GLYSET [®]
	PRECOSE [®]
Amylinomimetics (682003)	SYMLIN [®]
Biguanides (682004)	metformin hcl
	metformin hcl er
	FORTAMET [®]
	GLUCOPHAGE [®]
	GLUCOPHAGE XR [®]
	GLUMETZA [®]
	RIOMET [®]
Incretin Mimetics (682006)	BYETTA [®]
Insulins (682008)	APIDRA [®]
	EXUBERA [®] COMBINATION PACK 12
	EXUBERA [®] COMBINATION PACK 15
	EXUBERA [®] KIT
	EXUBERA [®] PATIENT PACK
	HUMALOG [®]
	HUMALOG [®] MIX 50/50
	HUMALOG [®] MIX 50/50 PEN
	HUMALOG [®] MIX 75/25

AHFS Class	Drug Name
	HUMALOG [®] MIX 75/25 PEN
	HUMALOG [®] PEN
	HUMULIN [®] 50/50
	HUMULIN [®] 70/30
	HUMULIN [®] 70/30 PEN
	HUMULIN [®] N
	HUMULIN [®] N U-100 PEN
	HUMULIN [®] R
	HUMULIN [®] R U-500 (CONCENTRATED)
	LANTUS [®]
	LANTUS [®] OPTICLIK [®]
	LANTUS [®] SOLOSTAR [®]
	LEVEMIR [®]
	LEVEMIR [®] FLEXPEN [®]
	NOVOLIN [®] 70/30
	NOVOLIN [®] 70/30 INNOLET [®]
	NOVOLIN [®] 70/30 PENFILL [®]
	NOVOLIN [®] N
	NOVOLIN [®] N INNOLET [®]
	NOVOLIN [®] N U-100
	NOVOLIN [®] N U-100 PENFILL [®]
	NOVOLIN [®] R
	NOVOLIN R [®] INNOLET [®]
	NOVOLIN [®] R U-100
Insulins (682008) – continued	NOVOLIN [®] R U-100 PENFILL [®]
	NOVOLOG [®]
	NOVOLOG [®] FLEXPEN [®]
	NOVOLOG MIX 70/30
	NOVOLOG [®] MIX 70/30 PENFILL [®]
	NOVOLOG [®] MIX 70/30 PREFILLED FLEXPEN [®]
	NOVOLOG [®] PENFILL [®]
	RELION [®] 70/30
	RELION [®] 70/30 INNOLET [®]
	RELION [®] N
	RELION [®] N INNOLET [®]

AHFS Class	Drug Name
	RELION [®] R
	VELOSULIN [®] BR
Meglitinides (682016)	PRANDIN [®]
	STARLIX [®]
Sulfonylureas (682020)	chlorpropamide
	glimepiride
	glipizide
	glipizide er
	glipizide xl
	glipizide/metformin hcl
	glyburide
	glyburide micronized
	glyburide/metformin hcl
	tolazamide
	tolbutamide
	AMARYL [®]
	DIABETA [®]
	DIABINESE [®]
	GLUCOTROL [®]
	GLUCOTROL [®] XL
	GLUCOVANCE [®]
	GLYCRON
	GLYNASE [®]
	METAGLIPT [™]
	MICRONASE [®]
	TOLINASE [®]
Thiazolidinediones (682028)	ACTOPLUS MET [®]
	ACTOS [®]
	AVANDAMET [®]
	AVANDARYL [®]
	AVANDIA [®]
	DUETACT [®]
Antidiabetic Agents, Miscellaneous (682092)	JANUMET [™]
Unknown Therapeutic Class (999999)	JANUVIA [™]

TABLE A4 Schizophrenia/Psychosis

AHFS Class	Drug Name
Antipsychotics (281608)	chlorpromazine hcl
	clozapine
	fluphenazine decanoate
	fluphenazine hcl
	haloperidol
	haloperidol decanoate
	haloperidol lactate
	loxapine succinate
	perphenazine
	prochlorperazine
	compro
	prochlorperazine edisylate
	prochlorperazine maleate
	thioridazine hcl
	thioridazine hcl intensol
	thiothixene
	trifluoperazine hcl
	ABILIFY [®]
	ABILIFY DISCMELT [®]
	CLOZARIL [®]
	COMPAZINE [®]
	FAZACLO [®]
	GEODON [®]
	HALDOL [®]
	HALDOL [®] DECANOATE 50
	HALDOL [®] DECANOATE-100
	LOXITANE [®]
	MELLARIL [®]
	MELLARIL [®] CONCENTRATE
	MOBAN [®]
	NAVANE [®]
	ORAP [®]
	PROLIXIN [®]
PROLIXIN [®] DECANOATE	
RISPERDAL [®]	
RISPERDAL [®] CONSTA [®]	

AHFS Class	Drug Name
	RISPERDAL [®] M-TAB
	SEROQUEL [®]
	SEROQUEL [®] XR
	THORAZINE [®]
	ZYPREXA [®]
	ZYPREXA [®] ZYDIS [®]

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