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# Medicare Part D

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## Formularies, 2006–2010:

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### A Chartbook

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*A study conducted by staff from NORC at the University of Chicago, Georgetown University, and Social & Scientific Systems, Inc., for the Medicare Payment Advisory Commission*

# Medicare Part D Formularies, 2006-2010: A Chartbook

**NORC**  
at the UNIVERSITY OF CHICAGO

## Report to the Medicare Payment Advisory Commission

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# 1. Background

Over the first five years of the Medicare Part D drug benefit, the Medicare Payment Advisory Commission (MedPAC) has asked NORC, Georgetown University, and Social & Scientific Systems for analysis of the structure and stability of Part D plan formularies. The mix of drugs that Part D plans list on their formularies and the cost sharing they charge are key characteristics Medicare beneficiaries consider when choosing among dozens of plan options. However, each plan's formulary has numerous facets, and it is difficult for beneficiaries to compare them. In this work, we have established various rules and procedures for analyzing formularies in a consistent way across plans and across years. This chartbook outlines our methodological approach and provides some key results from this work.

Some of these results are also presented elsewhere:

- Presentation to MedPAC by Jack Hoadley, January 15, 2010  
<http://www.medpac.gov/transcripts/2010%20Formulary%20Analysis%20for%20MedPAC%20-%20Hoadley.pdf>
- Presentation at the Part D Data Symposium, hosted by the Centers for Medicare & Medicaid Services (CMS), March 18, 2010  
[http://www.cms.gov/PrescriptionDrugCovGenIn/09\\_ProgramReports.asp](http://www.cms.gov/PrescriptionDrugCovGenIn/09_ProgramReports.asp)
- MedPAC's *Report to the Congress: Medicare Payment Policy*, March 2010, Chapter 5  
[http://www.medpac.gov/chapters/Mar10\\_Ch05.pdf](http://www.medpac.gov/chapters/Mar10_Ch05.pdf)
- MedPAC's 2010 data book <http://www.medpac.gov/chapters/Jun10DataBookSec11.pdf>
- Toward meaningful quality and performance measures in Part D, a report to MedPAC by Elizabeth Hargrave (NORC), Jack Hoadley and Laura Summer (Georgetown University), and Katie Merrill (Social & Scientific Systems, Inc.), May 28, 2010 <http://www.medpac.gov/>

Formulary size, measured by the number of drugs listed on a plan's formulary, is an important indicator of the extent to which drugs will be available to beneficiaries. But listing a drug on formulary does not guarantee access to the drug since plans use various tools that may restrict coverage. Formulary size is just one of a number of measures to consider in evaluating drug coverage and beneficiary access to drugs. Even when a drug is *on formulary*, coverage may be restricted. Utilization management tools such as requirements for prior authorization, step therapy, and limits on the quantity of the drug that may be dispensed restrict access to certain medications on plan formularies, depending on whether a particular beneficiary meets the requirements. Placement of drugs on cost-sharing tiers may limit access to drugs on tiers with higher cost-sharing requirements. Even when drugs are *off formulary*, there are certain circumstances when coverage may be possible. Medicare beneficiaries may request formulary exceptions to cover a drug that is off formulary. Furthermore, if they make a transition from one plan to another they may receive a temporary fill of a drug that was on the former plan's formulary, but is not on the formulary for the new plan. Or they may receive a one-time transitional supply without meeting a prior authorization or other requirement.

We report on a variety of measures that help to describe drug coverage in Medicare Part D, each of which is featured in the first four sections of the chartbook:

- The share of drugs listed by a plan
- Plan tier design and cost sharing
- Utilization management requirements
- The share of drugs listed on formulary with and without restrictions

The final two sections apply these measures to a set of drug classes for treating common medical conditions and to a set of the most commonly prescribed brand-name and generic drugs.

Drug plans participate in the Medicare Part D program either as stand-alone prescription drug plans (PDPs) or as drug plans offered as part of Medicare Advantage plans (MA-PDs) that provide both medical and prescription drug benefits. Some MA-PDs are Special Needs Plans (SNPs), a type of Medicare Advantage Plan that is permitted to target their enrollment, for example to beneficiaries with a certain chronic condition. Our analysis for 2010 includes 1,575 PDPs, 1,786 non-SNP MA-PDs, and 519 drug plans offered by SNPs (exact counts vary over time and in different files). We report on these three subsets separately, although not all tables include all three types of plans.

Certain plans are excluded from the group of plans used for our analysis, such as employer-only plans and all plans that operate in the US territories. In addition, drug plans offered by certain non-standard Medicare Advantage plans, including demonstration plans and cost-contract plans, are also excluded from the analysis. Plan characteristics used in this chartbook are generally taken from CMS plan landscape files, but have been adapted and modified to create consistency over time; specific measures are explained for charts where they are used.

The charts in this chartbook are based on the universe of plans in February 2010 CMS formulary files merged with February 2010 enrollment data and with plan characteristics from landscape files released by CMS in September 2009. Historical data are generally provided for 2007 through 2010; for the most part we excluded our analysis of the 2006 plan offerings and formularies. Data for earlier years are also taken from the appropriate CMS files for formulary data, enrollment data, and landscape data. In the program's first year, some information (especially the plan formularies) was provided in a less standardized format; thus results for 2006 on formulary characteristics are not comparable.

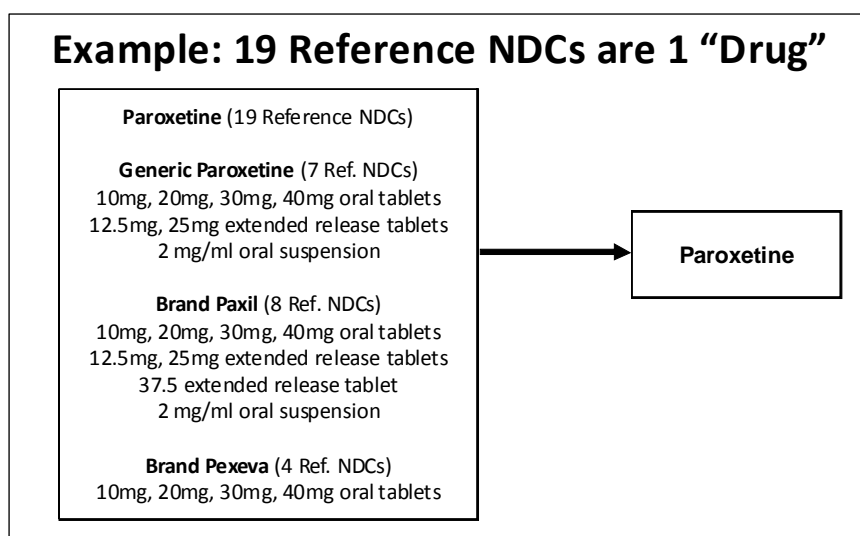
## 2. Share of Drugs in Plan Formularies

Formulary size, or the number of drugs listed, is an important indicator of the extent to which beneficiaries have access to drugs. This section presents information on the share of drugs listed on plan formularies from 2007 through 2010.

In order to provide accurate descriptions and to make meaningful comparisons among formularies it is necessary to make decisions about how drugs will be defined. We define “drug” as a unique chemical entity. Each of the chemical entities we identify includes all forms and strengths of the drug and all trade names by which drug is marketed.

To develop a list of drugs for the 2010 formularies we started with the 4,825 reference National Drug Codes (NDCs) included on the CMS formulary reference file. This file includes a set of reference (proxy) NDCs intended as a list of all Part D-covered drugs that may be included on Part D formularies (CMS began using a reference file in 2007). The codes on the reference file represent multiple forms and strengths of drugs, but not every manufacturer or package size for a particular drug. After combining codes for the same chemical entities we identified 1,107 “drugs” for 2010.

This is illustrated in the accompanying table, which shows 19 separate entries in the reference file the antidepressant paroxetine. These reference NDCs represent different strengths (10mg versus 20 mg), forms (oral tablets versus oral suspensions), and different brand or generic status (generic paroxetine versus Paxil or Pexeva). For our purposes, these 19 reference NDCs constitute a single drug.



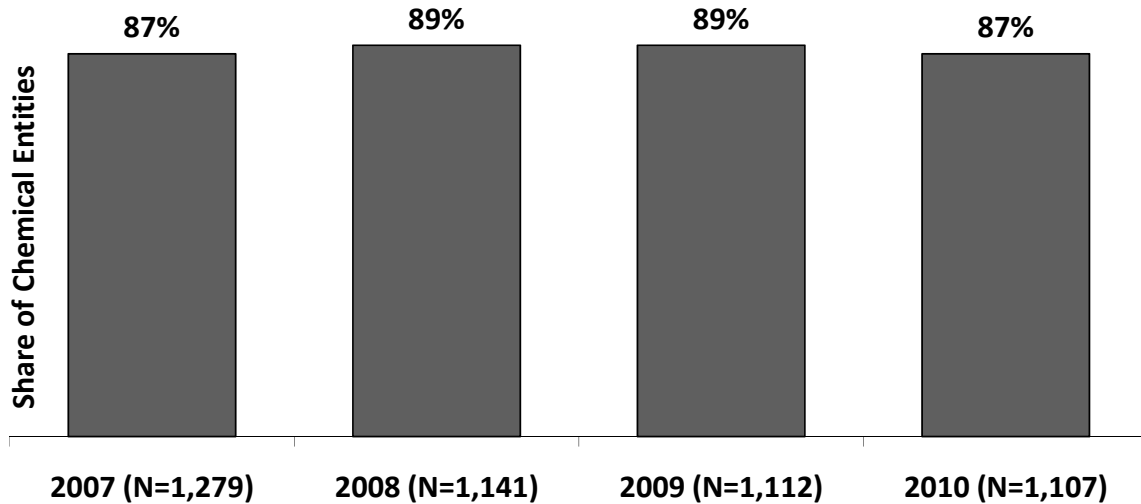
The brand or generic status of a drug is assigned based on indicators in the CMS formulary reference file. When any one of the component reference NDCs that makes up a drug (chemical entity) is classified as generic, we classify the drug as generic. In effect, this coding means that a generic drug is one that is an off-patent multi-source drug. It is thus available in generic form, although the original manufacturer may still sell the brand-name version.

Plan formularies often do not list all forms and strengths of a chemical entity. For example, a plan formulary might list generic paroxetine but not the brand-name versions, or it might omit the extended release versions. We consider a drug listed on formulary when at least one of the component reference NDCs is on formulary.

In many charts we present results that express the drugs for a particular formulary as a share of total chemical entities. The total set of chemical entities on the CMS formulary reference file – which are on at least one formulary – serves as the denominator for our calculations. The reference file is updated each year to reflect new drugs and drugs that have been taken off the market, so the denominator varies somewhat for each year. Although there have been changes in the structure of the formulary reference file over the four years it has been used, our testing suggests that the changes have little significance on the results we present.



**Chart 2.1. Share of Chemical Entities Listed by PDPs, 2007-2010**

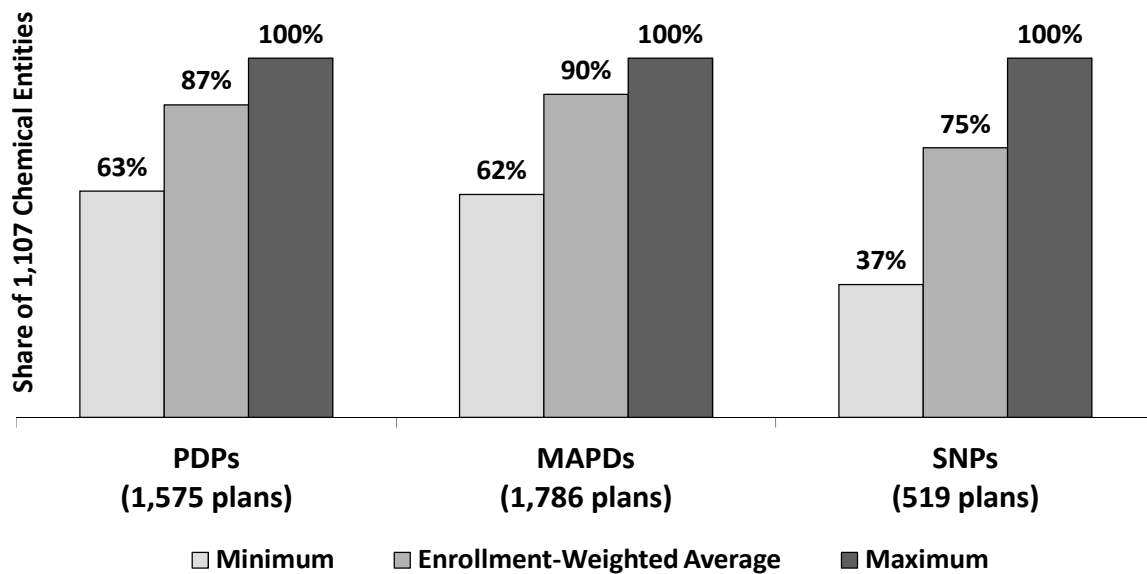


NOTE: Calculations are average shares of all chemical entities, weighted by enrollment. Ns are numbers of chemical entities based on the analysis of the CMS reference files for this project (defined on page 3 of this chartbook).

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Each Part D plan is required to maintain a formulary that meets certain criteria established by law and guidelines from the Centers for Medicare & Medicaid Services. Typically, Part D plan formularies include far more drugs than minimum standards require, but formulary size varies across plans.
- Collectively, the share of drugs listed among the Part D PDPs has been stable over time. Each year the PDPs have included almost 90 percent of the chemical entities for which CMS requires plans to report coverage (based on the CMS formulary reference files).

**Chart 2.2. Minimum, Average, and Maximum Share of Chemical Entities on Formulary, by Plan Type, 2010**

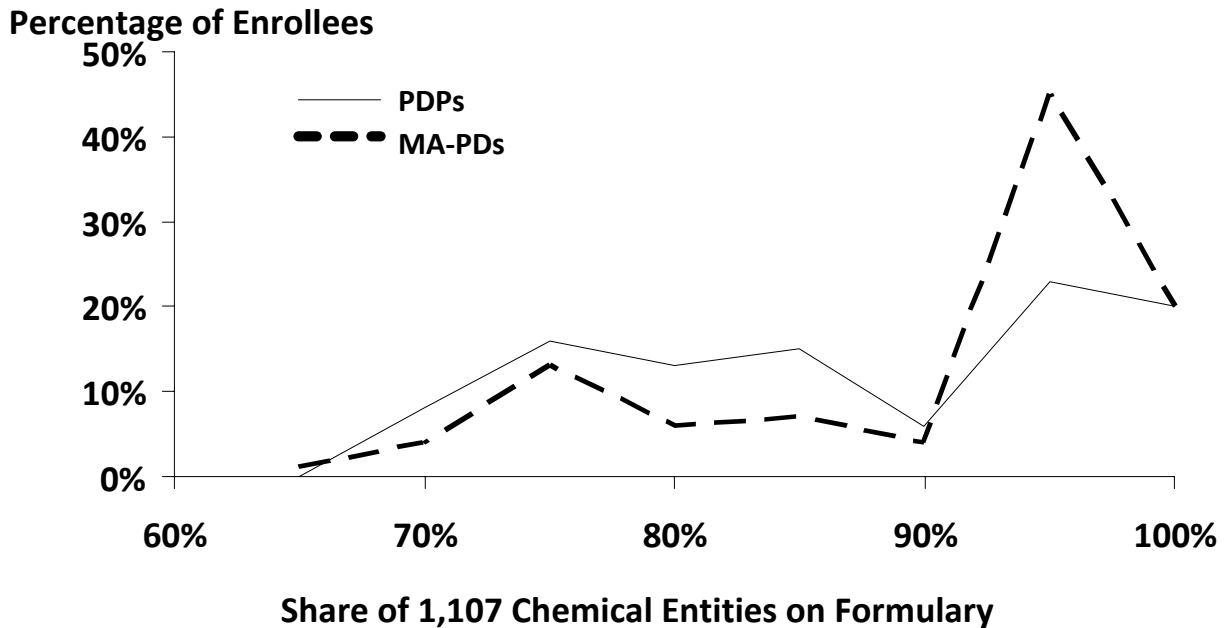


NOTE: Calculations are shares of all chemical entities on the CMS reference file, weighted by enrollment. Ns are numbers of plans.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Within each type of drug plan, the share of drugs listed on formularies varies widely. For both PDPs and MA-PDs, the plans listing the fewest drugs on formulary list under two-thirds of all drugs, while other plans list all drugs on formulary. SNPs are the type of plans with the widest coverage range in 2010, with a minimum share of 37 percent of drugs and a maximum of 100 percent. Because about 80 percent of SNP enrollees qualify for the low-income subsidy (LIS) benefit, sponsors of SNPs may offer tighter formularies in part because cost sharing for LIS beneficiaries is set by statute and thus tiered cost sharing cannot be used as part of a formulary management strategy.
- The number of chemical entities listed on formulary is fairly similar for the average PDP enrollee and the average MA-PD enrollee, with PDPs slightly lower than MA-PDs (87 percent vs. 90 percent). The average for SNP enrollees is considerably lower, at 75 percent.

**Chart 2.3. Distribution of Enrollees, by Share of Drugs Listed and Plan Type, 2010**

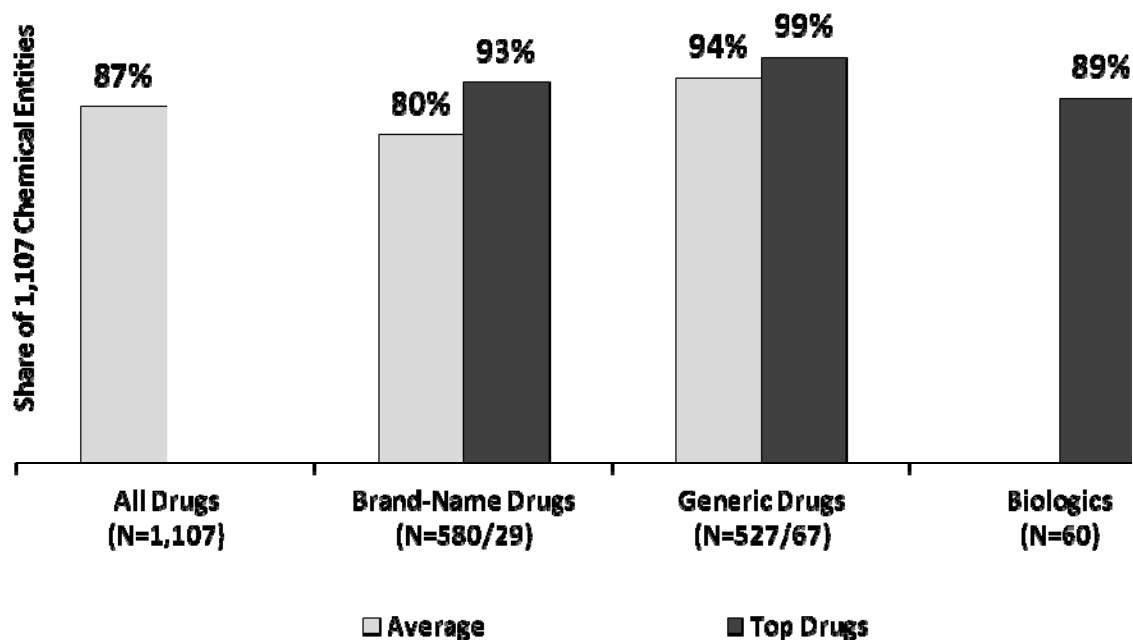


NOTE: Calculations are distributions of enrollments. Share of chemical entities is rounded to the nearest multiple of 5%.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Beneficiaries enrolled in both PDPs and MA-PDs are in plans that vary considerably in the share of drugs on formulary.
- Although the smallest formularies list fewer than two-thirds of drugs, most beneficiaries are enrolled in plans that have more than 75 percent of drugs on formulary.
- The proportion of beneficiaries enrolled in plans that list more than 90 percent of drugs is higher for MA-PDs than for PDPs, but a similar number (about one-fifth) of enrollees in both types of plans are enrolled in a plan that lists nearly all drugs on its formulary.

**Chart 2.4. Share of Chemical Entities on Formulary for Different Groups of Drugs, PDPs, 2010**

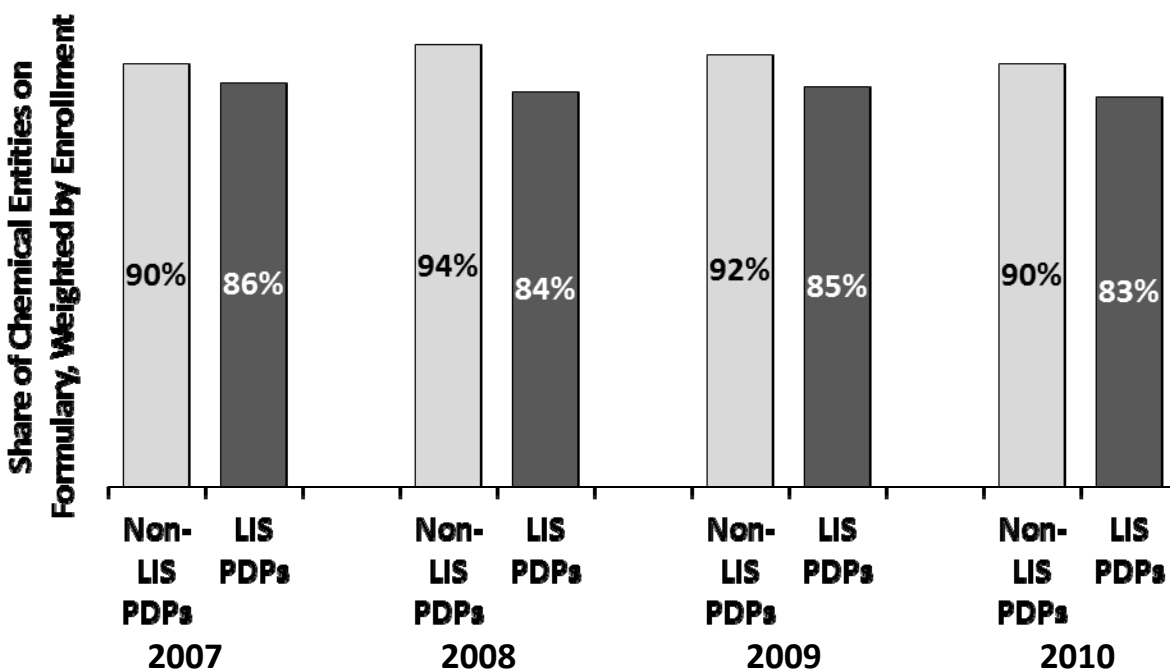


NOTE: Calculations are average shares of chemical entities for the particular group of drugs, weighted by enrollment.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- For the average PDP enrollee, generic drugs are considerably more likely to be on plan formularies than brand-name drugs. The average generic drug is on 94 percent of plan formularies, compared to 80 percent for the average brand-name drug.
- The most commonly prescribed drugs (those among the top 100 drugs based on total fills for Part D beneficiaries based on 2008 Part D claims) are more likely to be on formulary than the average drug. This difference could be both cause and effect.
  - Drugs are likely to be prescribed more often when on formulary. Furthermore, drugs purchased off formulary do not show up in Part D claims.
  - Plans may be more likely to place popular drugs on formulary either because the clinical indications for appropriate use are strong or because they want to attract enrollment by keeping the drugs people commonly use on formulary.
- The most commonly prescribed biologics (also based on 2008 Part D claims), nearly all of which are brand-name drugs, are on formulary about as often as the top brand-name drugs.

**Chart 2.5. Share of Chemical Entities on Formulary, by LIS (Benchmark) and Non-LIS PDPs, 2007-2010**



NOTE: Plans that qualified to keep LIS enrollees based on the waiver for 2007 and 2008 are excluded from this chart.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- The Medicare Part D program provides premium and cost-sharing assistance to beneficiaries who qualify for the program’s Low-Income Subsidy (LIS). LIS enrollees may choose to enroll in any Part D plan, but the LIS program will cover their premiums only up to a benchmark amount calculated for each region based on the average premium bid for the basic benefit by stand-alone PDPs and MA-PDs. Plans that qualify for zero-premium LIS enrollment are known as “benchmark” or “LIS” plans.
- Every year, benchmark PDPs have had somewhat smaller formularies than non-benchmark PDPs, with the largest difference – 10 percentage points – occurring in 2008. The difference in 2010 is seven percentage points. Because sponsors of benchmark plans cannot apply tiered cost sharing to their LIS enrollees, they may leave some drugs off formulary to influence their drug use for these beneficiaries.
- In 2010, the most commonly prescribed brand-name drug, Lipitor, is off formulary for 16 percent of benchmark plans enrollees, compared to 6 percent of non-benchmark plan enrollees (not shown). Larger differences exist for several other commonly prescribed drugs: Actonel (49 percent versus 14 percent), Vytorin (44 percent versus 16 percent), and Cozaar (26 percent versus 10 percent). Little, if any, difference exists for many other common drugs (especially generics), but there are substantial differences for some of the less commonly prescribed brand-name drugs in drug classes used to treat common conditions such as hypertension and diabetes.

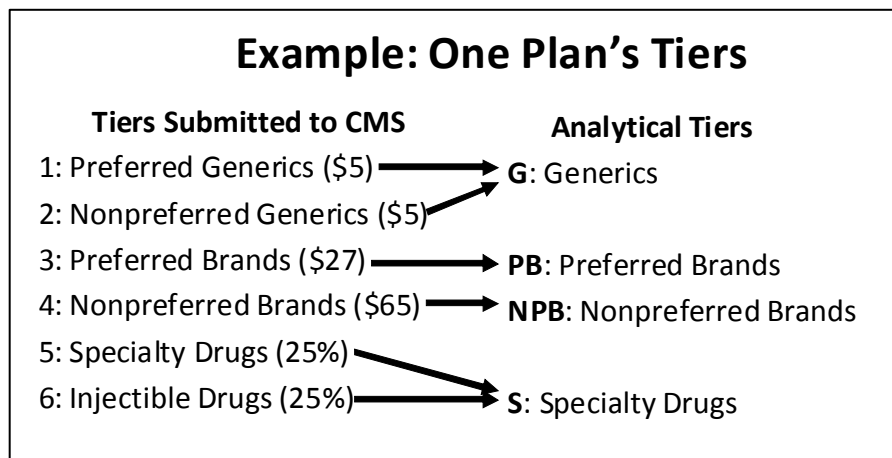
### 3. Plan Tier Designs and Cost Sharing

Although the “standard” Part D benefit uses 25 percent coinsurance for all drugs, most plans have varied from that uniform coinsurance. Instead, they place drugs on a variety of tiers with different coinsurance or copayment amounts, in an effort to steer utilization to lower-cost drugs.

In 2011, CMS will require plans to submit their formularies in a format that includes standardized tier labels. From 2006 to 2010, however, plans used a variety of tier designations that make it difficult to make an apples-to-apples comparison between plans without further standardization. For example, consider two plans with very different tier structures. Plan A has a single generic tier, a brand tier, and a specialty tier. Plan A’s specialty tier could be labeled “tier 3”, or any variety of specialty-related names such as “specialty drugs”, “high-cost specialty drugs,” specialty and injectible drugs” and so on. Meanwhile, Plan B has two generic tiers and three brand tiers. In that structure, “tier 3” might be used to designate a “value brand” tier with very different characteristics from the specialty tier labeled “tier 3” in Plan A.

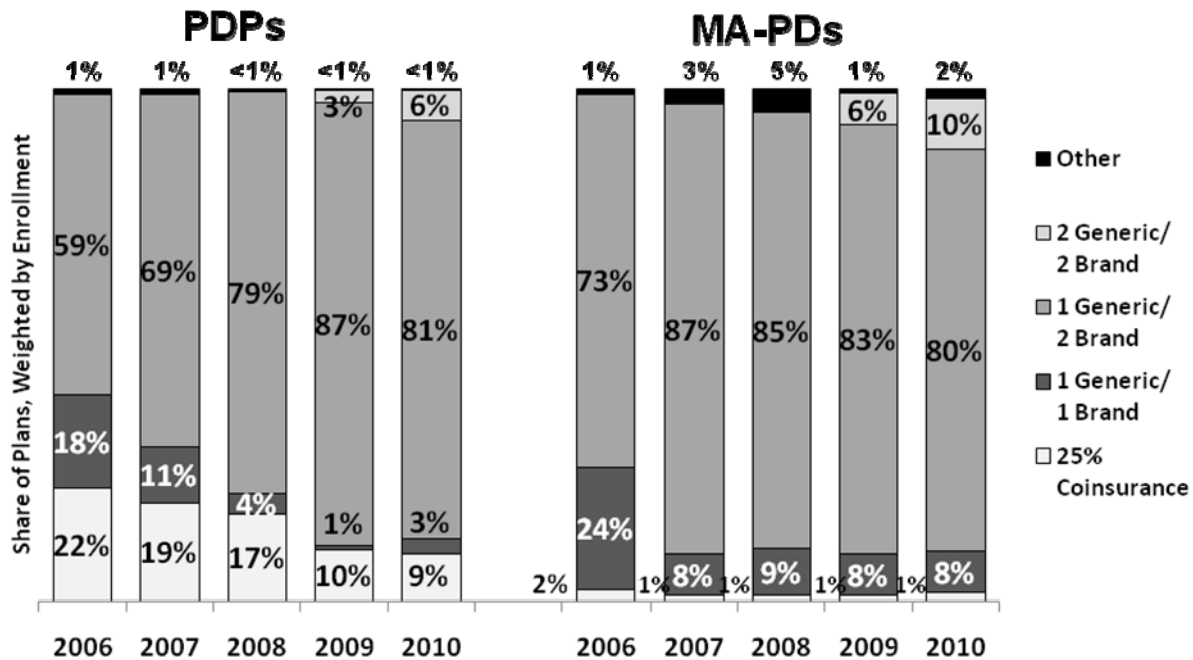
As part of our analysis, we assigned standardized tier labels to each plan’s tiers. We did this based on labels submitted by the plans when possible, and based on our research and our best judgment when the only available labels were numbered tiers. These standardized tiers allow us to summarize across all tiers of a similar type, regardless of what a plan called the tier in its formulary submission.

In some cases, we also collapsed tiers together. Some plan sponsors use the same formulary file for multiple plans with different tier structures, but the cost sharing in one of their plans may effectively cancel out some of the differentiation between tiers. As illustrated in the accompanying chart, when two similar tiers (such as preferred and non-preferred generics) have the same cost sharing, we treat them as a single tier in this analysis.



Plan formularies may assign different NDCs among those we consider to be a single drug (chemical entity) to different tiers. For example generic paroxetine may be assigned to the generic tier while Paxil, the brand-name form of the chemical entity, may be on the NPB tier in a particular formulary. When a situation like this occurs, we assign the drug to the “lowest” or least restrictive tier (thus a generic tier over a brand tier, a preferred over a non-preferred tier, and any tier over a specialty tier).

**Chart 3.1. Plan Use of Standard Benefit vs. Multiple Tiers, Excluding Specialty Tiers, 2006-2010**



NOTE: Calculations are share of plans, weighted by enrollment. Most non-standard plans also use specialty tiers, shown in a separate chart. Tracking of 2 generic/2 brand formularies began in 2009; some “other” plans before 2009 had that structure. SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

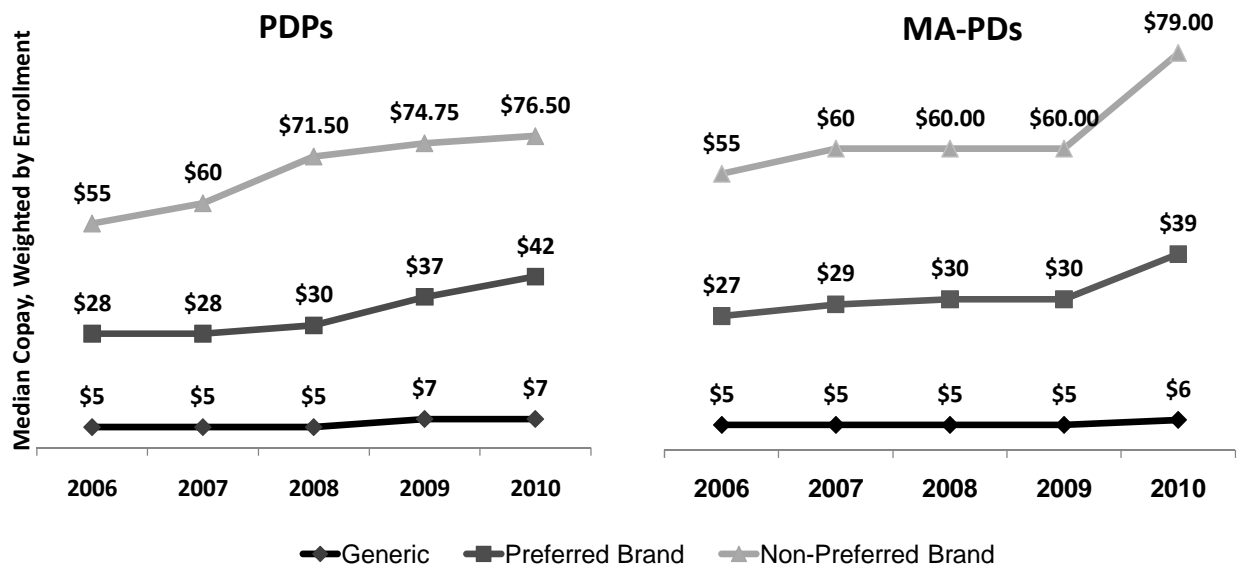
- The legislation creating Part D established a “standard” benefit in which beneficiaries are charged 25 percent coinsurance for all drugs on formulary. Use of this standard benefit design has declined over time: it is now used by PDPs with less than 10 percent of all enrollees. Use of this model has dropped from 22 percent of PDP enrollees to 9 percent; there has been almost no use of the standard benefit by MA-PDs going back to 2006.
- Throughout the life of the Part D program, the most common tier structure has been a single tier for generic drugs, two tiers for brand-name drugs (preferred and non-preferred), and a specialty tier for expensive drugs (not shown). Four-fifths of Part D enrollees (81 percent in PDPs and 80 percent in MA-PDs) are in such a plan (most of which also include a specialty tier).
  - In the first year of Part D, about a fifth of PDP enrollees and a quarter of MA-PD enrollees were in plans that did not differentiate between preferred and non-preferred brands. This share has declined, as more plans have added a second brand tier. Many of the plans using this tier structure in 2010 are the MA-PDs offered by Kaiser Permanente.
  - Most generics have low prices, but some are considerably more expensive. Perhaps for this reason, the use of a second generic tier is also growing. Several plan sponsors have

a “value” generic tier with lower cost sharing than most generics, while others have a “non-preferred” generic tier with higher cost sharing than most generics. (A second generic tier is included as “other” until 2009, when we began to track this tier design separately.)

- A few plans have started to include a third “value” brand tier (included under “other” in this chart). CVS Caremark Plus is the lone PDP to introduce this tier structure in 2010.
- This chart does not include use of specialty and injectible tiers; Chart 3.4 shows the prevalence of these tiers.



**Chart 3.2. Median Copayment for a Month's Supply, Most Common Tier Types, 2006-2010**

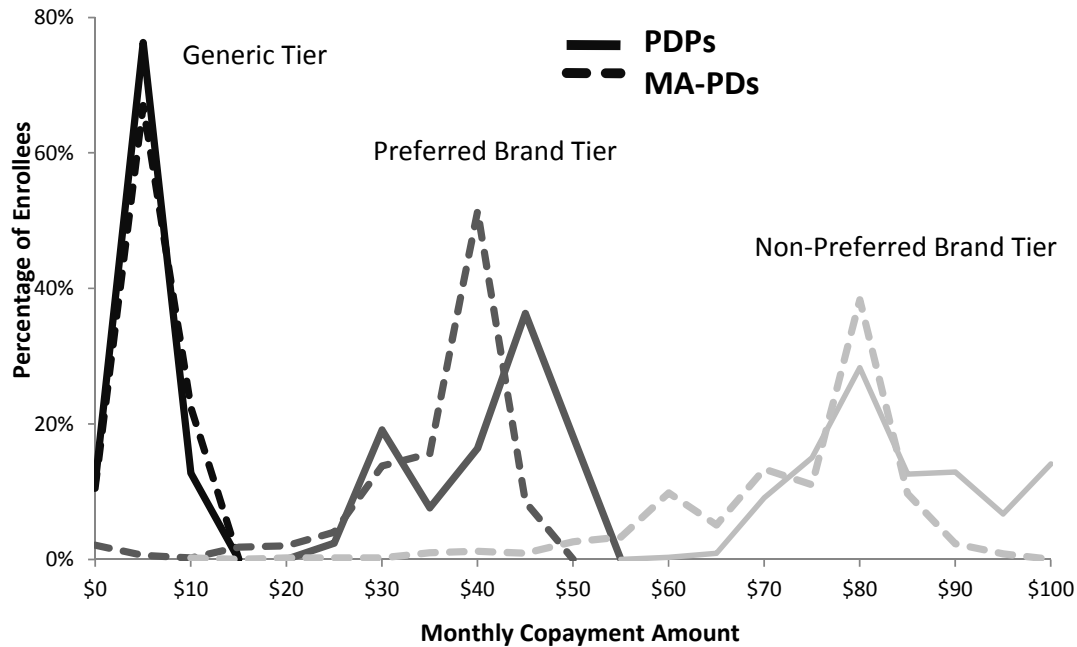


NOTE: Medians are calculated among plans that use copayments for each tier and are weighted by enrollment. Plans using coinsurance are not included.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Cost sharing for each of the most common drug tiers has risen over the first five years of the program. For example, among PDPs, cost sharing for preferred brands for the median enrollee rose a total of 50 percent (from \$28 per prescription in 2006 to \$42 in 2010).
- Plans are required to keep cost sharing actuarially equivalent to the standard benefit and its 25 percent coinsurance. Therefore, it is likely that increases in cost sharing are being driven in part by increases in the retail prices of prescription drugs. For example, if brand-name drug prices rise 10 percent from one year to the next, a plan might increase a \$40 copayment to \$44 just to keep up with the price increases and continue paying 25 percent of drug costs on average.
- For plans that introduced use of two generic tiers, the median cost sharing in 2010 (not shown) is \$2.50 for preferred generic tiers and \$25 for non-preferred generic tiers.
- In recent years, more PDPs (but almost no MA-PDs) are using cost-sharing tiers that apply different rates of coinsurance or combine coinsurance for some tiers with flat copayments for other tiers. In 2010, nearly one-third of PDPs with a tiered design used percentage coinsurance for at least one of its non-specialty tiers. Median coinsurance levels for 2010 (not shown) are 15 percent (generic tiers), 25 percent (preferred brand tiers), and 50 percent (non-preferred brand tiers).

**Chart 3.3. Distribution of Median Monthly Copayments for Common Tiers, PDPs and MA-PDs, 2010**

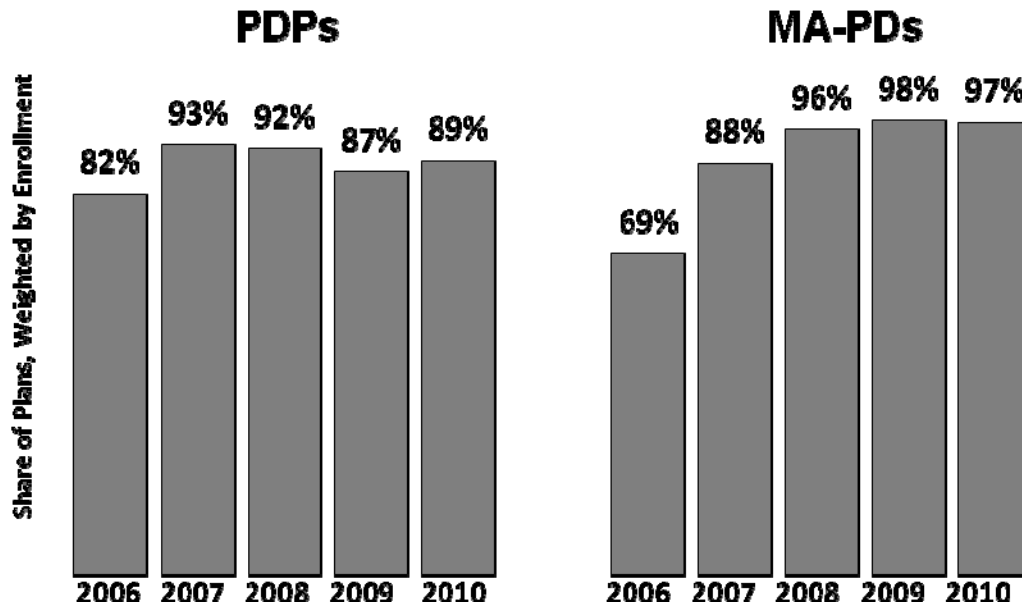


NOTE: Calculations are distributions of enrollees, excluding those in plans with only one brand tier or two generic tiers and plans with coinsurance for a particular tier. Monthly copayment amounts are rounded to the nearest multiple of \$5.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Cost sharing amounts vary around the medians shown in Chart 3.2.
  - For example, while the median PDP beneficiary faces a \$42 copayment for a preferred brand drug, the distribution is skewed, with few beneficiaries enrolled in plans charging over \$45 for preferred brands and many more in plans charging \$35 or less.
  - The most common PDP cost sharing for non-preferred brands is about \$80, reflected in the median of \$76.50. Similar shares of beneficiaries are in plans charging \$90 or more and those charging \$70 or less for non-preferred brands.
  - A substantial majority of beneficiaries in either PDPs or MA-PDs have copayments of more than \$4 for generic drugs – higher than the discount price for a generic drug offered by many retail pharmacy chains.
- The distribution of copayment amounts is slightly different in PDPs compared to MA-PDs
  - **Preferred brands:** the median enrollee in a MA-PD generally faces lower cost sharing for preferred brands, as shown in Chart 3.2. Enrollees in MA-PDs are more likely than enrollees in PDPs to have a copayment for preferred brands that is less than \$30. Enrollees in PDPs are more likely to have copayments of \$45 and higher.
  - **Non-preferred brands:** Compared to PDP enrollees, the median MA-PD enrollee faces a modestly higher copayment for non-preferred drugs. But more enrollees in PDPs have a copay of over \$85, and more MA-PD enrollees have copays of \$70 or less.

**Chart 3.4. Share of Non-Standard Plans Using Specialty or Injectable Tiers for Some Expensive Drugs, 2006-2010**

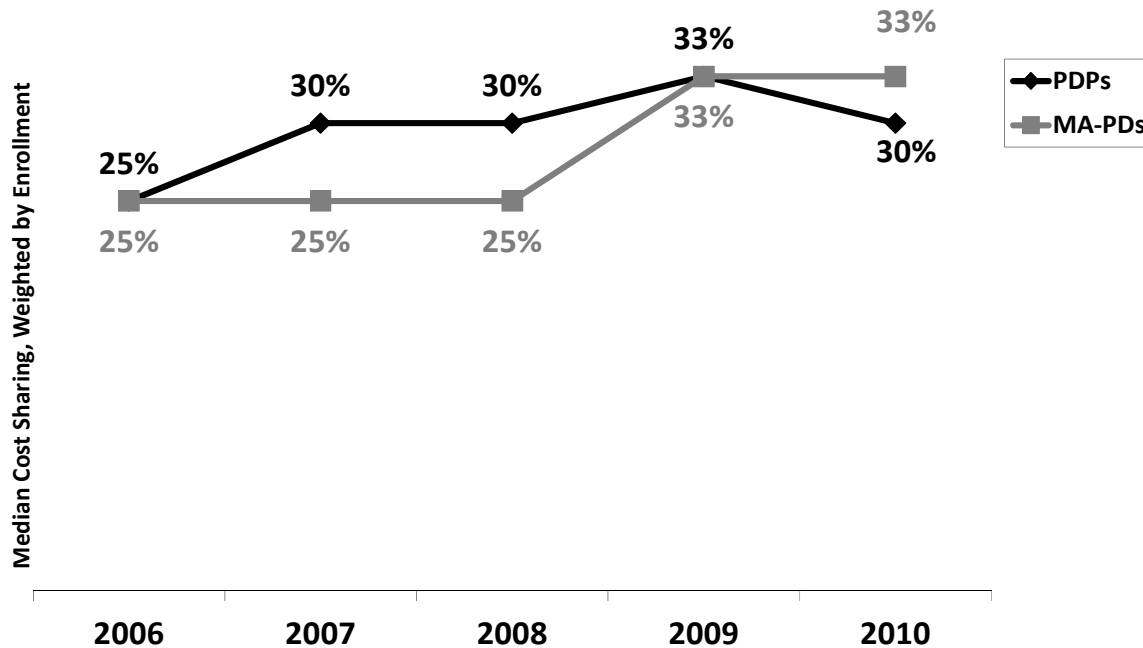


NOTE: Excludes standard-benefit plans.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Most Part D plans use a specialty tier for high-cost drugs (drugs must cost at least \$600 per month to be placed on a specialty tier in 2010). These tiers typically have cost sharing of 25 percent to 33 percent (see following chart), and beneficiaries are not allowed to request cost-sharing exceptions for these drugs.
  - Available data do not allow us to distinguish between true specialty tiers that meet the CMS standards and similar tiers used by some plans for non-specialty injectible drugs. It appears that in most cases, plans with such a tier also have a designated specialty tier. Some plans label two tiers as specialty and non-specialty injectible, but apply the same cost sharing. These tiers are combined in our analysis.
- The share of beneficiaries enrolled in plans using a specialty tier increased rapidly in the first few years of the program, but has remained fairly stable since then.
- Most plans that do not have an explicit specialty tier (other than those with a standard benefit design) have other brand tiers for which they already charge coinsurance of at least 25 percent. Some charge coinsurance higher than 33 percent for drugs on a non-preferred tier.
  - Plans with a standard benefit design (excluded from the denominator in this chart) charge 25 percent coinsurance for all drugs.
- MA-PDs are less likely to use coinsurance in their cost-sharing tiers. As a result, they must use a specialty tier in order to ask enrollees to pay a higher share of the cost of these expensive drugs.

**Chart 3.5. Median Copayment for Specialty and Injectable Tiers, 2006-2010**

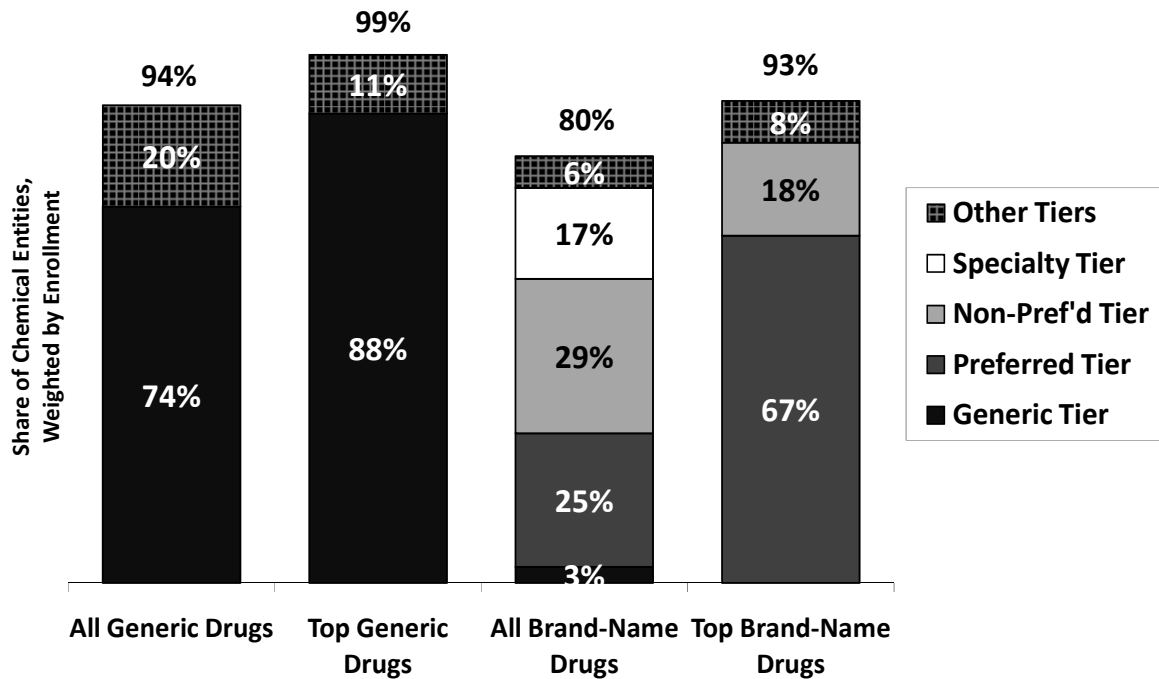


NOTE: Medians are calculated among plans that have a specialty tier, weighted by enrollment.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Under current CMS rules, the default cost sharing for specialty tiers is coinsurance of 25 percent. However, plans are permitted to increase coinsurance for specialty tiers to as high as 33 percent if they eliminate or lower the standard deductible enough to offset the higher coinsurance. Almost no plans use flat copayments for their specialty tiers.
- For the median beneficiary, cost sharing for specialty tiers began at 25 percent in 2006. Since then, plans have used the flexibility allowed in the benefit to increase this cost sharing.
  - In PDPs, median cost sharing for specialty tiers rose to 30 percent in 2007 and to 33 percent in 2009. However, the median fell back to 30 percent in 2010. Whereas 59 percent of PDP enrollees faced 33 percent coinsurance in 2009, the share dropped to 47 percent in 2010 (data not shown). Seven national PDPs with no deductible in 2009 added a partial deductible for 2010 and lowered specialty tier coinsurance rate from 33 percent to 30 percent or less.
  - In MA-PDs, median coinsurance for specialty tiers rose more slowly than it did in PDPs, but remains at 33 percent in 2010. The share of MA-PD enrollees facing 33 percent coinsurance has increased from 48 percent in 2008 to 75 percent in 2010. The share with 25 percent coinsurance has dropped from 39 percent to 19 percent in that same period.

**Chart 3.6. Distribution of Brand and Generic Drugs by Tier in PDPs, 2010**

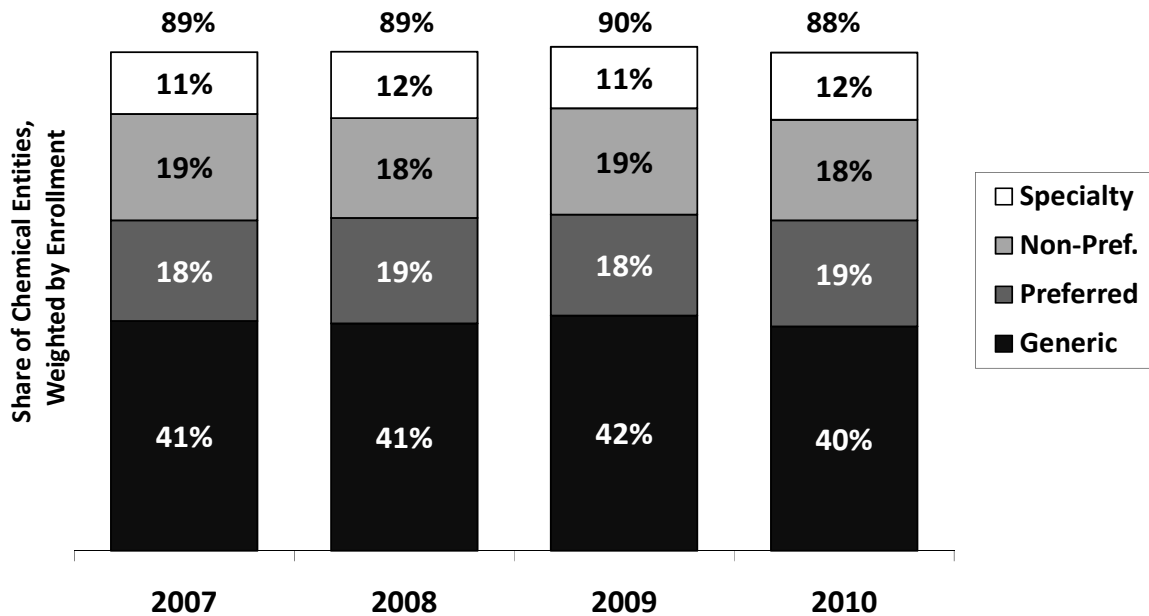


NOTE: Some plans do not use specialty tiers. Totals atop bars refer to total share of chemical entities on formulary; difference from 100 percent is for drugs off formulary. The “other” category includes standard benefit designs. For generic drugs, the “other” category also includes any drugs placed in brand or specialty tiers.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Generic drugs are mostly, but not exclusively, placed on generic tiers. The average generic drug is placed in a tier other than a generic tier (including standard benefit designs) for 20 percent of beneficiaries; the average generic is on a brand or specialty tier about 12 percent of the time (not shown). The drugs placed on these other tiers are expensive off-patent drugs. Examples include paclitaxel (an intravenous cancer treatment), streptomycin (an antibiotic that must be injected), several vaccines, and various forms of penicillin.
- The most commonly prescribed generic drugs are even more likely to be on generic tiers than the average generic drug, appearing on brand tiers for only about 2 percent of beneficiaries and almost never on specialty tiers (not shown). The common drugs are typically lower-cost drugs.
- Brand-name drugs (those still on patents) commonly appear on preferred, non-preferred, and specialty tiers, but are listed on preferred tiers only about one-fourth of the time on average. Brand drugs are placed on a generic tier only 3 percent of the time. An example is niacin, which is only listed under brand-names Niaspan or Niacor, but is mostly placed on a generic tier.
- The most commonly prescribed brand-name drugs are far more likely to be on preferred tiers than the average brand-name drug (65 percent compared to 25 percent). As with formulary placement, this could be both cause and effect. Drugs are more likely to be used when on a preferred tier, and plans may be more likely to place popular drugs on preferred tiers. None of the most common brand-name drugs are listed on specialty tiers.

**Chart 3.7. Distribution of Drugs by Tier in PDPs with Most Common Tier Structure, 2007-2010**



NOTE: Some plans do not use specialty tiers. Totals atop bars refer to total share of chemical entities on formulary; difference from 100 percent is for drugs off formulary.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- The most common tier structure used by PDPs is a four-tier structure comprising generic, preferred, non-preferred, and specialty drugs. For plans with this tier structure, the share of drugs in each of the four tiers commonly designated by PDPs has remained constant over the life of the Part D program.
- The distribution is in part a reflection of the overall distribution of brand-name and generic drugs in the universe of drugs.

## 4. Utilization Management

Utilization management (UM) tools also help plans control the extent to which lower and higher cost drugs are used by enrollees. The three utilization management tools that plans must report to CMS are:

- Prior authorization (PA), a requirement that an enrollee obtain permission from the plan to obtain a drug. The criteria for these requirements may include specific clinical stipulations, administrative concerns such as distinguishing between coverage under Part B or Part D, or cost-based considerations.
- Step therapy (ST), a requirement that certain drugs (either less expensive or clinically preferred alternatives) be tried before other drugs can be prescribed. For example, a plan might require that a less expensive H2 blocker be tried for gastrointestinal problems before approving a proton pump inhibitor or that a preferred drug on its formulary be tried before approving a non-preferred drug.
- Quantity limits (QL), which affect the amount of a drug that can be prescribed over a defined period of time. These requirements may be imposed for administrative reasons, such as limiting a drug to a 30-day supply (no 90-day prescriptions). They may also be used for safety or fraud reasons, for example, limiting a drug for migraines to 9 pills per month or a strong pain medication to 90 pills per month.

An examination of the use of UM tools for particular drugs suggests that beneficiaries' access to specific drugs is influenced by UM policies as well as formulary size.

The UM rules may vary within a formulary for different forms and strengths of a drug. To date, we have used a "flag" indicator for a particular drug (chemical entity) if the particular UM flag is associated with any component NDC. Thus, if any form or strength of a drug requires prior authorization, we classify the drug (chemical entity) as requiring prior authorization. We also create an "Any UM" measure to show when any one of the three types of UM is used for a particular drug.

Our original measure has the downside of attaching a particular UM flag to the drug in situations where that flag might only be associated with a form or strength that is not commonly prescribed. For example, prior authorization might be required for a more expensive high-strength version of the drug or a liquid formulation. Or a UM restriction might be placed on the brand version of a drug that is off patent to ensure it is only used where the generic version is ineffective for a particular patient.

We have tested several alternative measures of UM and introduce here one of those alternatives. Whereas our original measure assigned the UM flag if any of the component NDCs for a particular drug, the new measure assigns the UM flag if the utilization management is applied when the drug is on the lowest (least restrictive) cost-sharing tier (specifically if any of the NDCs on that lowest tier have the flag). For example, if the generic version of a drug is on a G (generic) tier and does not require prior authorization, but the brand version of the same drug is on a non-preferred brand tier and requires prior authorization, then the new measure would not classify the drug with a PA flag whereas it would have received that classification under the original measure. However, if both the low-strength and high-

strength version are on the G tier, but only the high-strength version requires PA, then under both measures we would classify the drug with a PA flag.

The impact of the alternative measure is modest as shown in the accompany table. For each of the three types of UM and the measure of any UM, the prevalence of their use is reduced by about 10 percent under the new measure compared to the original measure.

Utilization Management PDPs, 2010 Percent of covered drugs, weighted by enrollment	Original Measure	New Measure
Any Utilization Management	30.6%	28.4%
Prior Authorization	15.2%	14.5%
Step Therapy	3.6%	3.1%
Quantity Limits	17.8%	16.1%

In this section, Charts 4.5 and 4.6 present results using the new measure and correspond to Charts 4.3 and 4.4, which use the original measure.



## Chart 4.1. Plan Use of Utilization Management Tools, 2007-2010

### *Comparing Types of Plans, 2010*

<b>2010</b>	<b>Ever Use Prior Authorization?</b>	<b>Ever Use Step Therapy?</b>	<b>Ever Use Quantity Limits?</b>
<b>PDPs</b>	100%	94%	100%
<b>MA-PDs, excluding SNPs</b>	100%	88%	98%
<b>SNPs</b>	100%	91%	99%

NOTE: Applies original UM measure (see section introduction). Entries are shares of plans, not weighted by enrollment.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

### *Comparing PDPs Over Time, 2007-2010*

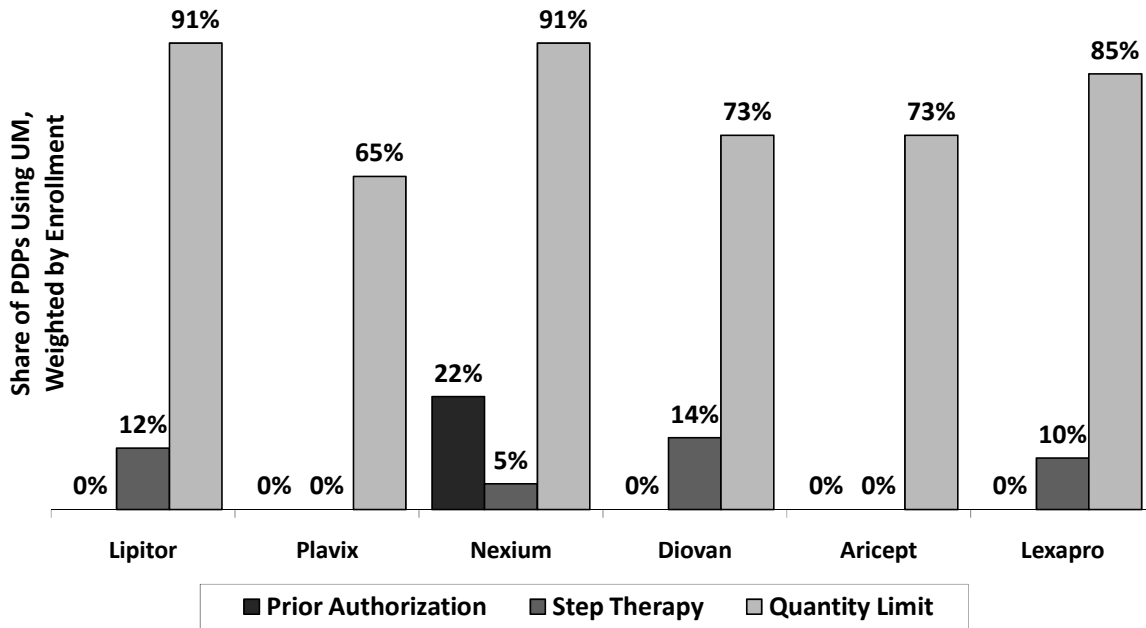
<b>PDPs</b>	<b>Ever Use Prior Authorization?</b>	<b>Ever Use Step Therapy?</b>	<b>Ever Use Quantity Limits?</b>
<b>2007</b>	100%	77%	100%
<b>2008</b>	100%	88%	100%
<b>2009</b>	100%	94%	100%
<b>2010</b>	100%	94%	100%

NOTE: Applies original UM measure (see section introduction). Entries are shares of plans, not weighted by enrollment.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- All plans, regardless of type, employ utilization management tools. All use prior authorization to some extent. Quantity limits are used by all PDPs and nearly all SNPs (99 percent) and MA-PDs (98 percent). Although also used by most plans, step therapy is used least often of the three tools, with 12 percent of MA-PDs never using step therapy.
- The use of step therapy has increased over time. Just over three-fourths of all PDPs used step therapy in 2007, but that share had increased to 94 percent of all PDPs by 2010.

**Chart 4.2. Share of PDPs Using Utilization Management for Top Drugs, 2010**

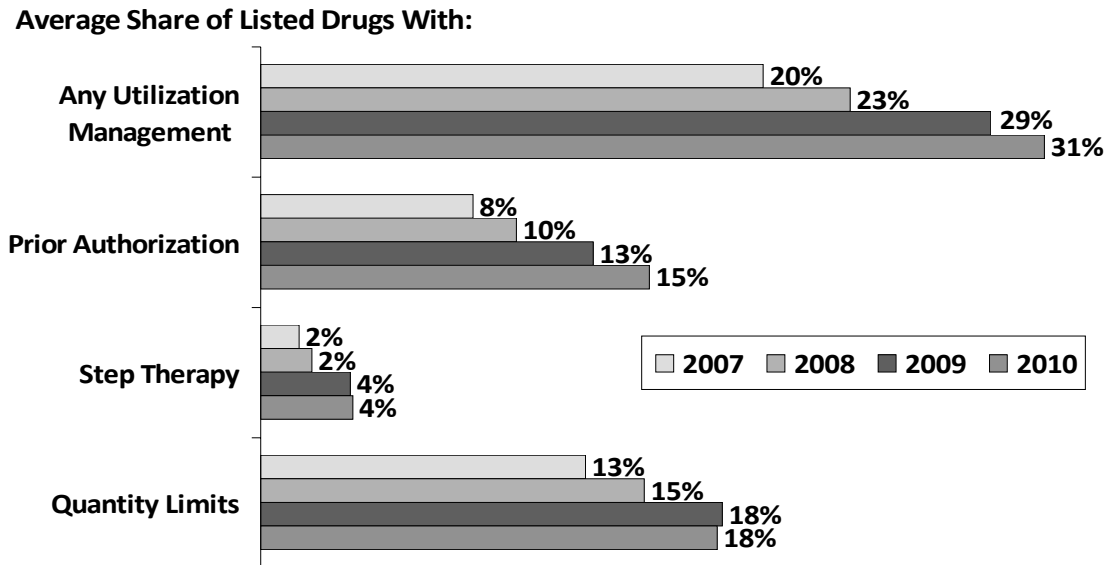


NOTE: Applies original UM measure (see section introduction). Values represent the share, weighted by enrollment, of use of the particular UM tool, out of the cases where the drug is listed on formulary.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- For the six brand-name drugs that CMS reports were most filled in 2008 (among those still on patent in 2010), quantity limits are the most common utilization management tool. For three of the drugs, 80 percent or more of the plans impose quantity limits. For many commonly prescribed brand-name drugs, it seems that quantity limits are used to limit patients to a 30-day supply.
- Step therapy is much less common. It is most likely to be used for drugs that have therapeutic alternatives in the same drug class or a closely related class. For example, before approving a prescription for brand-name Diovan, some plans may request that the enrollee try a generic angiotensin-converting enzyme (ACE) inhibitor (a closely related drug class for treating hypertension).
- Nexium is the only drug in this sample for which some plans require prior authorization. In its class of drugs, there are both generic and over-the-counter alternatives. In addition, there is some clinical literature that suggests the potential for over-use of drugs in this class.
- Plavix and Aricept, which have no generic or closely related therapeutic equivalents, are not subject to prior authorization or step therapy requirements in any of the PDPs.

**Chart 4.3. Share of Drugs with Utilization Management Requirements, PDPs, 2007-2010 (Previous Definition)**

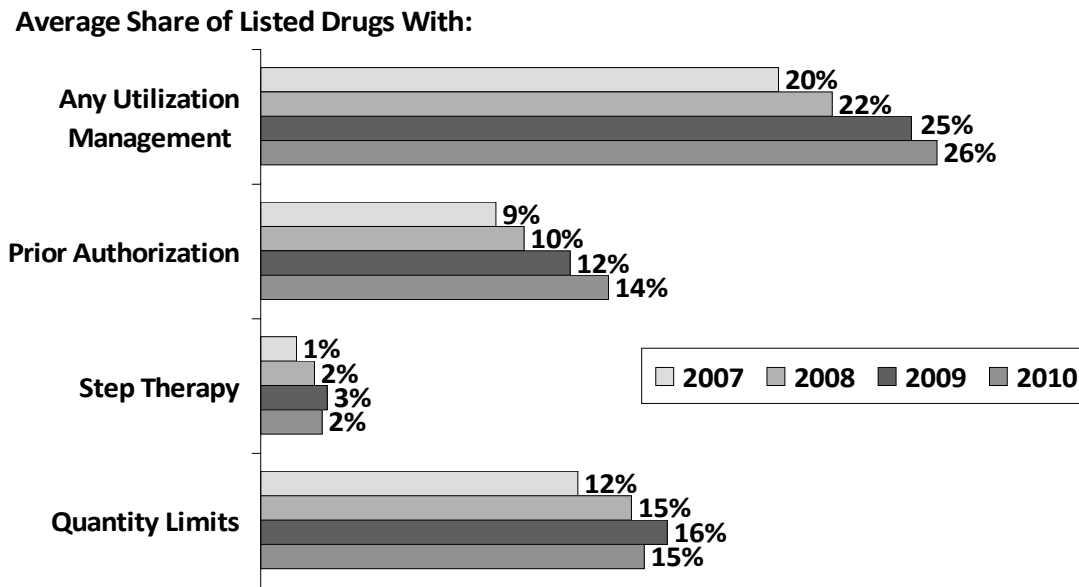


NOTE: Applies original UM measure (see section introduction). Calculations are share of listed chemical entities, weighted by enrollment.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- The extent to which PDPs use UM tools has increased over the course of the Part D program. In 2010 for the average PDP enrollee, almost one-third (31 percent) of drugs listed on PDP formularies were subject to utilization management, up from 18 percent in 2007.
  - The largest increase occurred in requirements for prior authorization. Quantity limits, which have consistently been the most common tool in use, also increased substantially from 12 to 18 percent of listed drugs.
  - Although step therapy is not a common UM tool, its use increased more than doubled between 2007 and 2010.
- There is variation among PDPs in the use of UM. For example, the HIP and GHI plans in New York State place restrictions on more than half of all on-formulary drugs. By contrast, two plans offered in nearly all regions by EnvisionRxPlus have restrictions on only 7 percent of the drugs on their formulary.

**Chart 4.4. Share of Drugs with Utilization Management Requirements, MA-PDs, 2007-2010 (Previous Definition)**

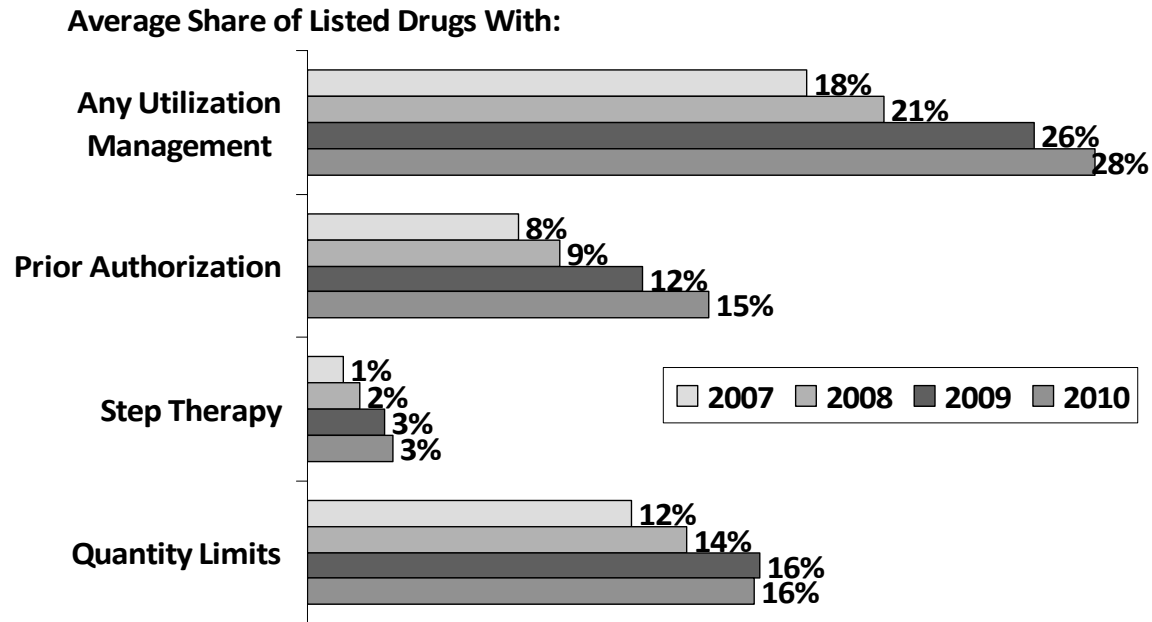


NOTE: Applies original UM measure (see section introduction). Calculations are share of listed chemical entities, weighted by enrollment.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- The use of UM tools among MA-PDs has also increased over the course of the Part D program, but to a lesser extent than among PDPs. The share of listed drugs with any utilization management increased among the average MA-PD enrollee from 20 percent in 2007 to 26 percent in 2010. Since MA-PDs seek to manage other aspects of health care including provider practices, they may have other means of controlling utilization as well.
- As with PDPs, the largest increase among types of utilization management occurred in requirements for prior authorization, increasing from 9 to 14 percent of drugs over a four-year period.
- Use of UM tools varies considerably among MA-PDs. Plans offered by Kaiser Permanente, for example, apply restrictions on only 3 percent of their on-formulary drugs. By contrast, several large HMOs in California, Florida, Nevada, and New York have restrictions on over half of the drugs on their formularies.

**Chart 4.5. Share of Drugs with Utilization Management Requirements, PDPs, 2007-2010 (New Tier-Based Definition)**

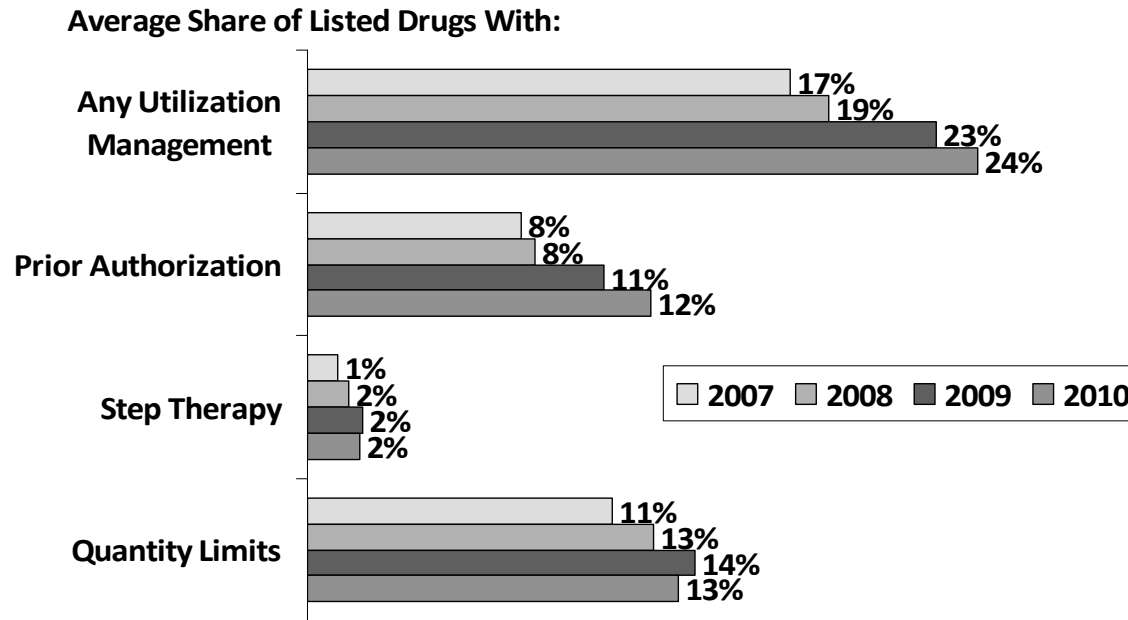


NOTE: Applies new tier-based UM measure (see section introduction). Calculations are share of listed chemical entities, weighted by enrollment.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- The new tier-based measure of utilization management lowers the level of use for each measure by an average of about one-tenth. For example, the average PDP enrollee saw an increase in the use of any UM from 20 percent to 31 percent based on the original measure (Chart 4.3). With the new measure, the increase is from 18 percent to 28 percent.
- Substitution of the new measure does not modify the trend of increased UM use over time.

**Chart 4.6. Share of Drugs with Utilization Management Requirements, MA-PDs, 2007-2010 (New Tier-Based Definition)**



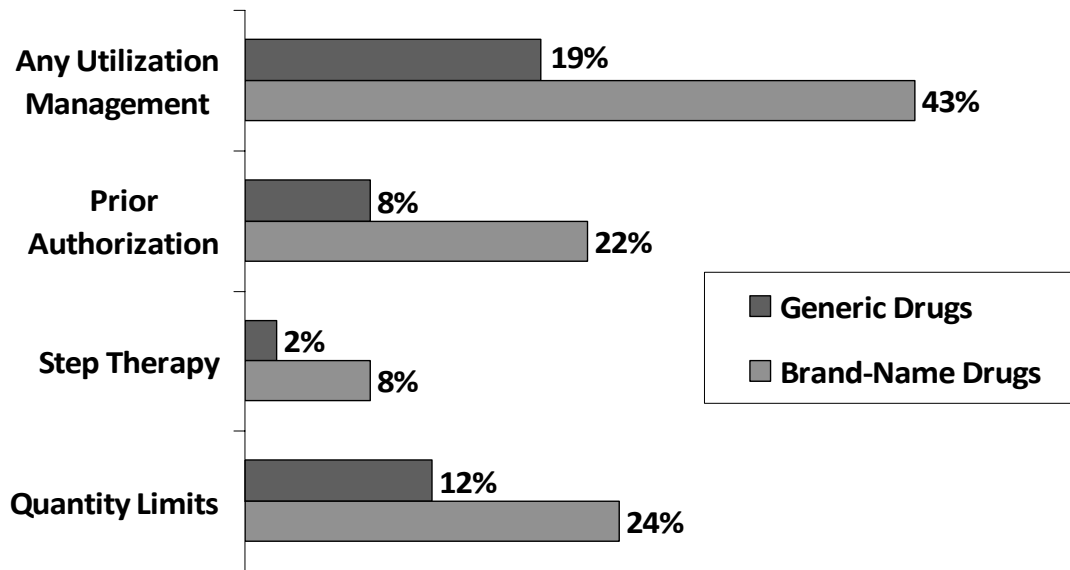
NOTE: Applies new tier-based UM measure (see section introduction). Calculations are share of listed chemical entities, weighted by enrollment.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- The new tier-based measure of utilization management lowers the level of use for each measure by an average of about one-tenth. For example, the average MA-PD enrollee saw an increase in the use of any UM from 20 percent to 26 percent based on the original measure (Chart 4.4). With the new measure, the increase is from 17 percent to 24 percent.
- Substitution of the new measure does not modify the trend of increased UM use over time.

## Chart 4.7. Share of Brands and Generics with Utilization Management Requirements, PDPs, 2010

Average Share of Listed Drugs With:



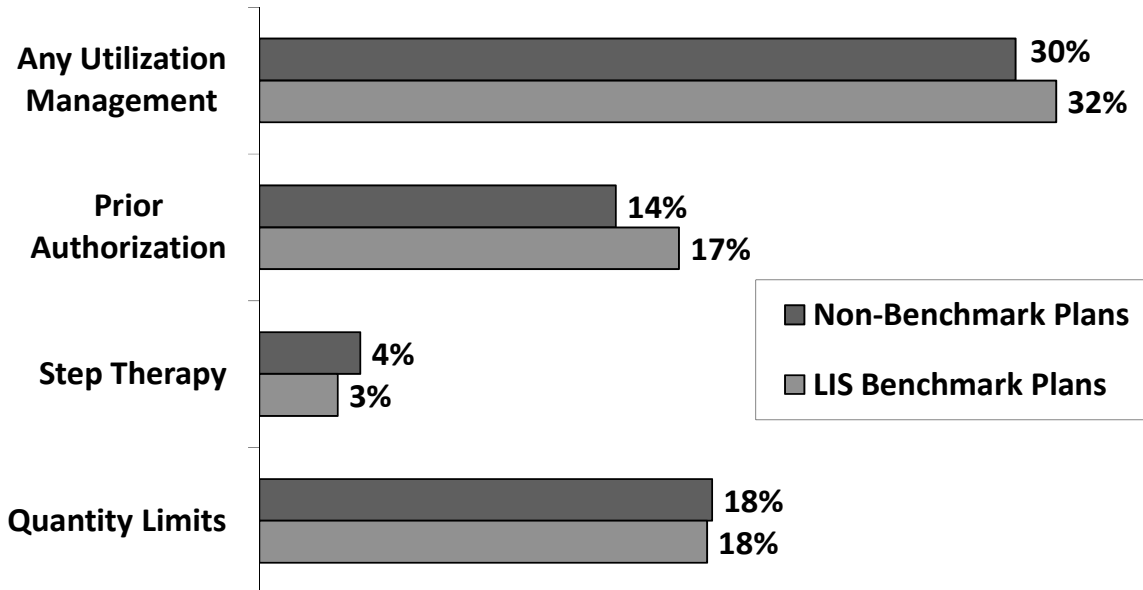
NOTE: Applies original UM measure (see section introduction). Calculations are share of listed chemical entities, weighted by enrollment.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- In 2010, brand-name drugs are more than twice as likely to be subject to utilization management for PDPs as generic drugs.
- Prior authorization is nearly three times as likely to be used for brands as opposed to generics, and step therapy is used four times as often. By contrast, the use of quantity limits for brands is only double that for generics. A possible difference is that quantity limits are often used to restrict purchases to a 30-day supply, a restriction that might be as relevant to generics as to brands.
- The most commonly prescribed brand-name drugs (not shown) are much more likely to have quantity limits than other brand-name drugs and slightly more likely to require step therapy. But these common drugs are less likely to require prior authorization.
- The most prescribed biologics (not shown) are considerably more likely to require prior authorization (on average, for 58 percent of enrollees).

## Chart 4.8. Share of Drugs with Utilization Management Requirements, PDPs by LIS Status, 2010

Average Share of Listed Drugs With:



NOTE: Applies original UM measure (see section introduction). Calculations are share of listed chemical entities, weighted by total enrollment.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- The differences in utilization management rules for benchmark and non-benchmark plans are not large.
- Beneficiaries enrolled in benchmark plans are slightly more likely to have utilization management requirements, primarily because of the more common use of prior authorization.
- Beneficiaries in these plans are marginally less likely, however, to have quantity limits or step therapy requirements.



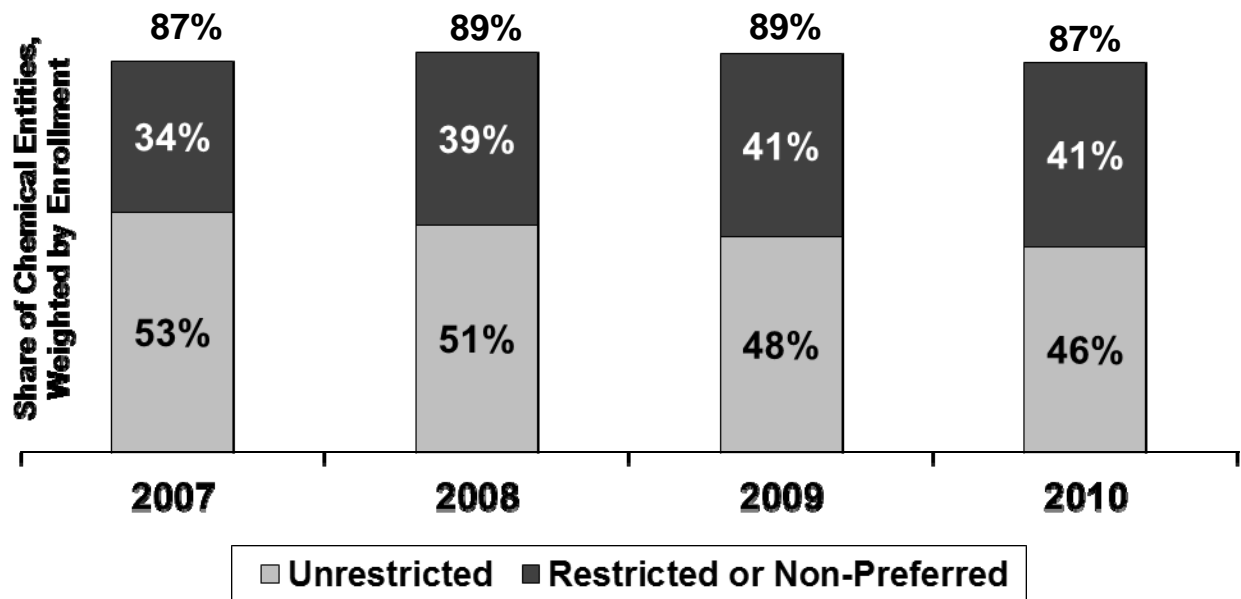
## 5. Restricted vs. Unrestricted Drugs

In previous sections, we reviewed the use of tier placement and utilization management as separate phenomena. In this section, we consider how the use of these two tools combines within formularies, as another important indicator of how easily beneficiaries may obtain drugs across plans.

For this section, we have divided a plan's treatment of drugs into two categories: restricted and unrestricted. Restricted drugs include drugs that are either on a non-preferred brand tier, on a specialty tier, or subject to any of the three tracked utilization management restrictions (prior authorization, step therapy or quantity limits). Any one of these tiers or UM restrictions qualifies a drug as restricted. Those placed on generic, brand, or preferred brand tiers, and not subject to UM requirements, are classified as unrestricted.

Chart 5.2 shows the effect of incorporating the new UM measure into the definitions of restricted and unrestricted drugs (compared to Chart 5.1).

**Chart 5.1. Shares of Restricted and Unrestricted Drugs, PDPs, 2007-2010  
(Previous Definition)**



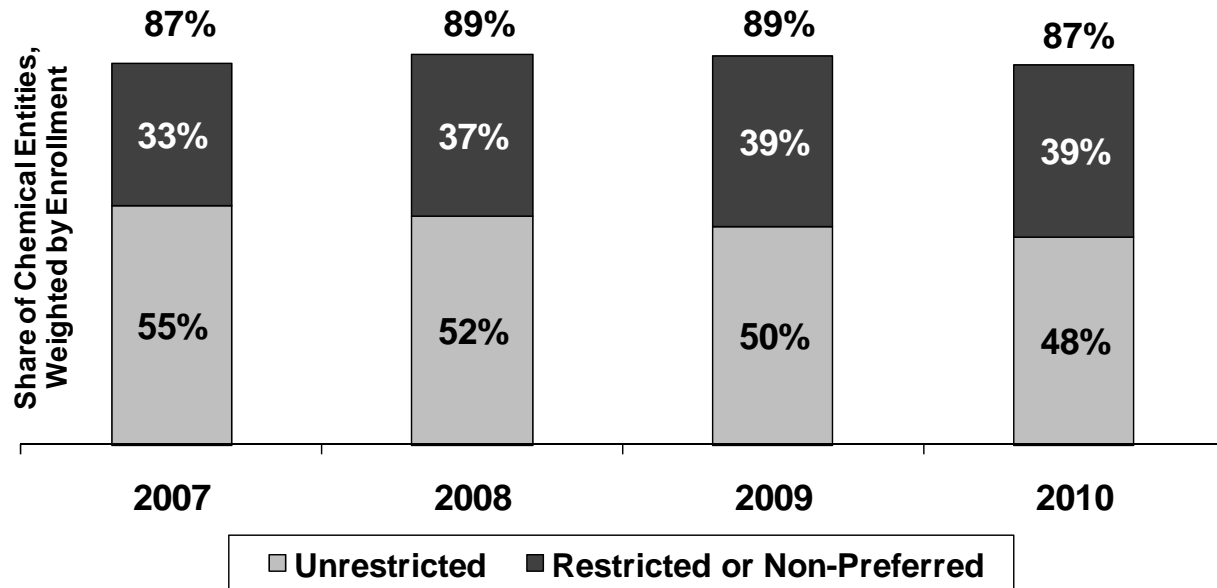
NOTE: Calculations are average shares, weighted by enrollment. Totals atop bars refer to total share of chemical entities on formulary; difference from 100 percent is for drugs off formulary.

“Unrestricted” = placement on certain tiers (generic, brand, preferred brand) and absence of utilization management restrictions (prior authorization, step therapy, quantity limits). Both apply the original UM measure (see section introduction).

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- For the average PDP enrollee, over half of drugs on formulary fall in the unrestricted category (46 percent of all drugs for the average enrollee in 2010, compared to 87 percent of drugs that are on formulary), meaning they are both on a preferred tier and have no utilization management restrictions.
- The relative share of unrestricted drugs has modestly decreased between 2007 and 2010, mostly as a result of the increasing use of utilization management.

**Chart 5.2. Shares of Restricted and Unrestricted Drugs, PDPs, 2007-2010  
(New Tier-Based Definition)**



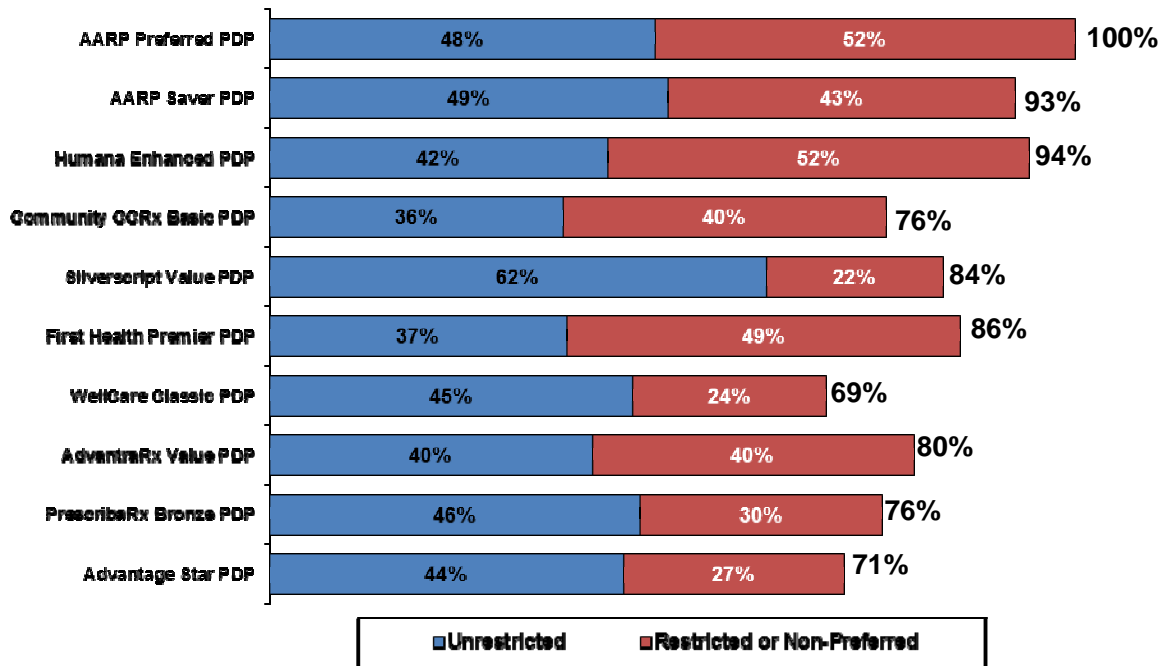
NOTE: Calculations are average shares, weighted by enrollment. Totals atop bars refer to total share of chemical entities on formulary; difference from 100 percent is for drugs off formulary.

“Unrestricted” = placement on certain tiers (generic, brand, preferred brand) and absence of utilization management restrictions (prior authorization, step therapy, quantity limits). Both apply the new tier-based UM measure (see section introduction).

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- The division of formulary drugs into unrestricted and restricted categories based on the new tier-based measure of utilization management raises the share of unrestricted drugs by one or two percentage points for each year. For example, in 2010 the average PDP enrollee had access to 46 percent of all drugs without restrictions based on the original measure (Chart 5.1). With the new measure, the share of unrestricted drugs is 48 percent.
- Substitution of the new measure does not modify the trend of a decreasing share of unrestricted drugs over time.

**Chart 5.3A. Share of Chemical Entities Listed on Formulary With and Without Restrictions, PDPs with Highest Enrollments, 2010**



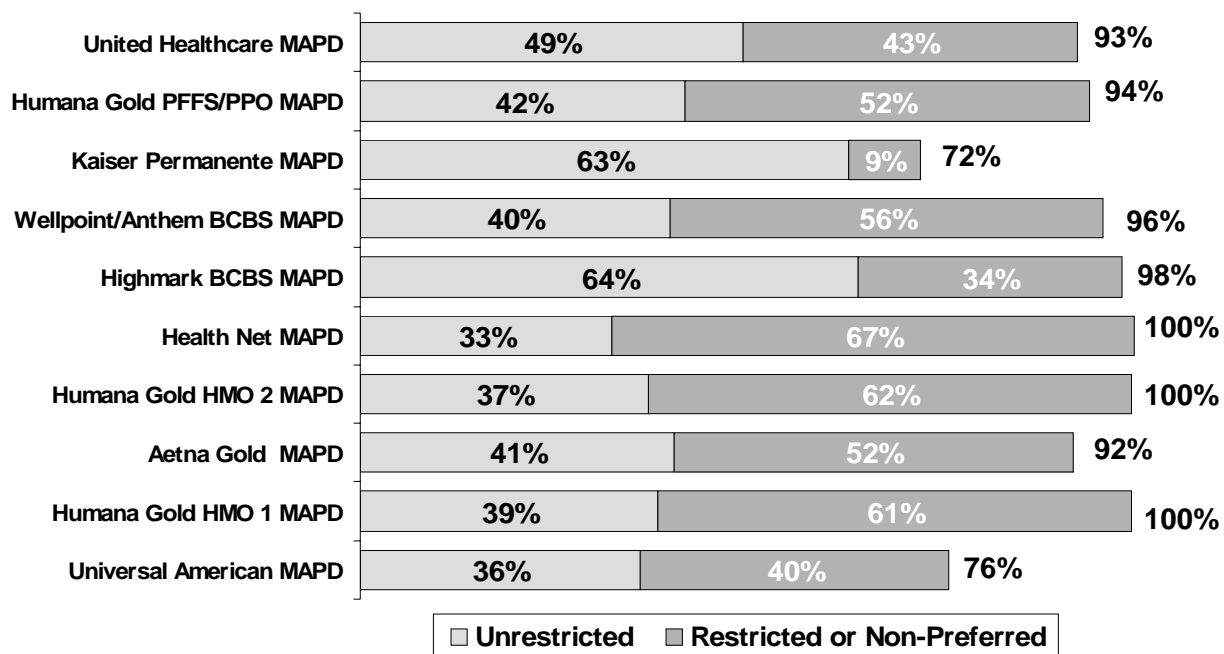
NOTE: Calculations are share of chemical entities. Totals to right of bars refer to total share of chemical entities on formulary; difference from 100 percent is for drugs off formulary. Totals may not add due to rounding. Plans are listed in order of enrollment.

“Unrestricted” = placement on certain tiers (generic, brand, preferred brand) and absence of utilization management restrictions (prior authorization, step therapy, quantity limits). Both apply the original UM measure (see section introduction).

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Formulary size among the ten PDPs with the greatest number of enrollees in 2010 ranges from 69 percent to 100 percent of the chemical entities for which CMS requires plans to report coverage (based on the CMS formulary reference files).
- The distribution of restricted and unrestricted drugs varies among plans with different formulary sizes. For example, AARP Preferred PDP, which includes all drugs, restricts almost half (48 percentage points) of them. By contrast, Silverscript Value PDP has a smaller formulary, listing 84 percent of chemical entities, but has a larger proportion of unrestricted drugs – 62 percentage points. First Health-Premier has a similar size formulary to Silverscript Value, but a much smaller share of unrestricted drugs.

**Chart 5.3B. Share of Chemical Entities Listed on Formulary With and Without Restrictions, MA-PDs with Highest Enrollments, 2010**



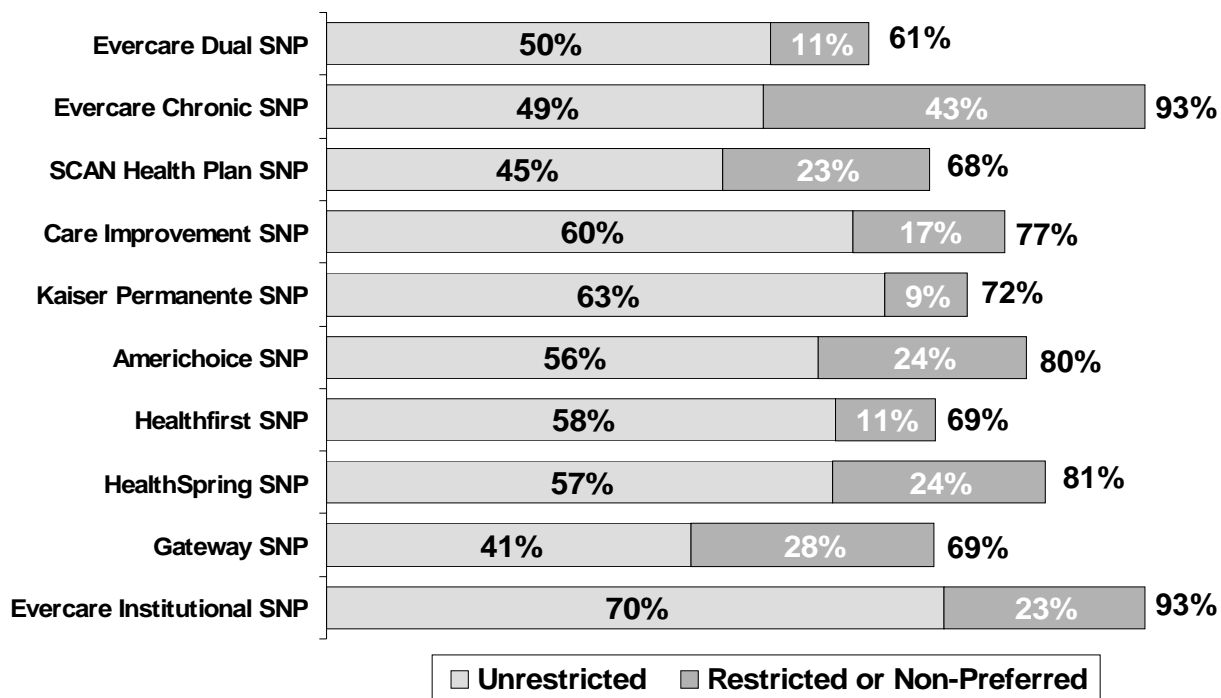
NOTE: Calculations are share of chemical entities. Totals to right of bars refer to total share of chemical entities on formulary; difference from 100 percent is for drugs off formulary. Totals may not add due to rounding. Plans are listed in order of enrollment.

“Unrestricted” = placement on certain tiers (generic, brand, preferred brand) and absence of utilization management restrictions (prior authorization, step therapy, quantity limits). Both apply the original UM measure (see section introduction).

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Formulary size among the ten MA-PDs with the greatest number of enrollees in 2010 (excluding SNPs) ranges from 72 percent to 100 percent of the chemical entities for which CMS requires plans to report coverage (based on the CMS formulary reference files).
- Kaiser Permanente stands out among the MA-PDs because of the small share of chemical entities listed on its formulary, but the great majority of drugs on formulary are unrestricted. The doctors associated with this closed-network plan all prescribe from an established formulary and are able to make their own substitutions. Kaiser Permanente also uses only a single brand tier, again presumably with less interest or need in offering financial incentives for its enrollees to use preferred drugs.

**Chart 5.3C. Share of Chemical Entities Listed on Formulary With and Without Restrictions, Special Needs Plans with Highest Enrollments, 2010**



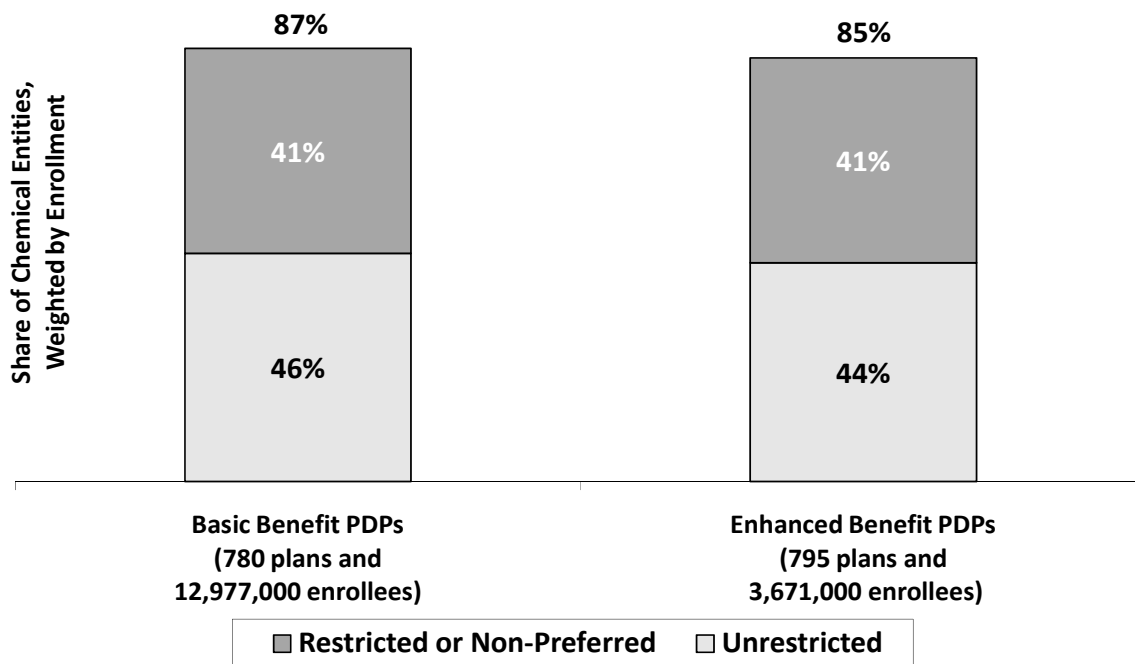
NOTE: Calculations are share of chemical entities. Totals to right of bars refer to total share of chemical entities on formulary; difference from 100 percent is for drugs off formulary. Totals may not add due to rounding. Plans are listed in order of enrollment.

“Unrestricted” = placement on certain tiers (generic, brand, preferred brand) and absence of utilization management restrictions (prior authorization, step therapy, quantity limits). Both apply the original UM measure (see section introduction).

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Formulary size among the ten SNPs with the greatest number of enrollees in 2010 ranges from 61 percent to 93 percent of the chemical entities for which CMS requires plans to report coverage (based on the CMS formulary reference files).
- Three SNPs operated by Evercare (a subsidiary of United Healthcare) – each representing a different category of SNP – show a contrast in formulary strategies.
  - The dual-eligibles SNP has a much smaller formulary than its two corporate companions.
  - In general, dual-eligible and institutional SNPs do not use a tiered cost-sharing structure since most enrollees pay only subsidized cost-sharing amounts (most enrollees in institutional SNPs face no cost sharing). As a result, the share of unrestricted drugs is larger for these plans.
- It may be that SNPs with higher LIS enrollments have smaller formularies because LIS cost sharing is limited by law, so plans may use smaller formularies to manage utilization.

**Chart 5.4. Share of Chemical Entities on Formulary, Restricted and Unrestricted, Basic Benefit PDPs vs. Enhanced Benefit PDPs, 2010**

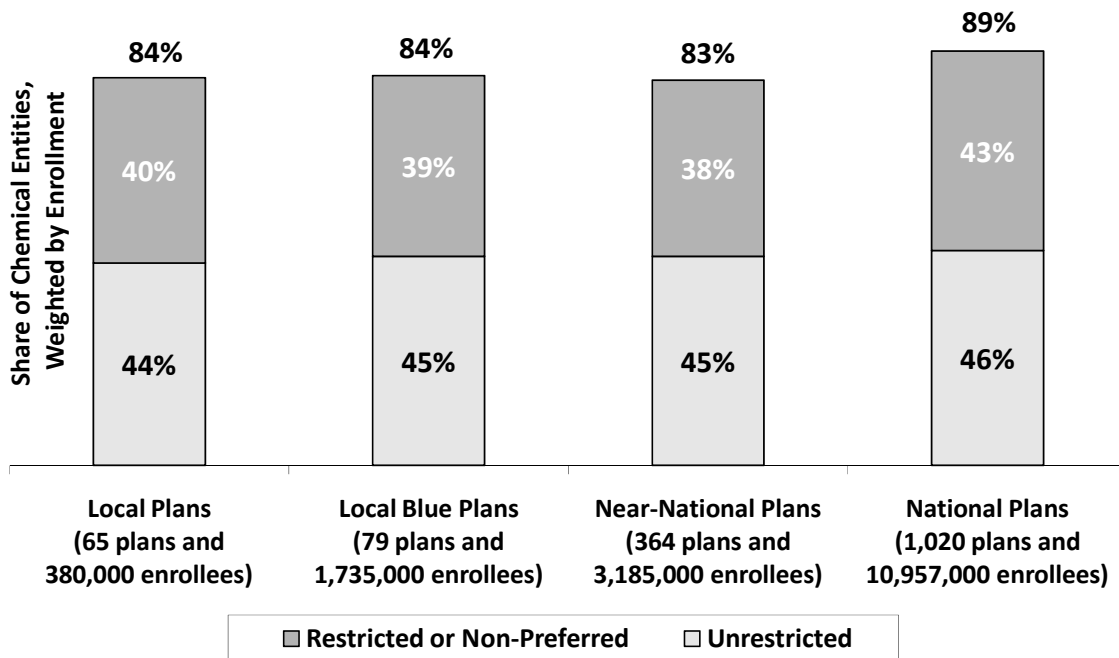


NOTE: Calculations are share of chemical entities. Totals atop bars refer to total share of chemical entities on formulary; difference from 100 percent is for drugs off formulary. “Unrestricted” = placement on certain tiers (generic, brand, preferred brand) and absence of utilization management restrictions (prior authorization, step therapy, quantity limits). Both apply the original UM measure (see section introduction).

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Medicare Part D plan sponsors are required to offer a basic benefit, either the standard Part D benefit defined by law or an actuarially equivalent benefit design. They may also offer plans with enhanced drug benefits. Enhanced plans must have a greater actuarial value than basic plans, but plans vary in how they achieve this. Enhanced plans may reduce or eliminate the deductible, charge less (on average) than the standard 25 percent coinsurance, pay for drugs in the coverage gap, or use a combination of these approaches. Enhanced plans may also cover additional drugs that are not otherwise eligible for coverage under Part D (any such drugs on formulary are not included in this analysis).
- Even though enhanced plans have a higher actuarial value, the total share of chemical entities offered and the share of those drugs offered on an unrestricted basis is slightly lower for the enhanced benefit PDPs.
  - There is no difference in the proportion of restricted drugs offered by basic and enhanced plans.

**Chart 5.5. Share of Chemical Entities on Formulary, Restricted and Unrestricted, National vs. Local PDPs, 2010**



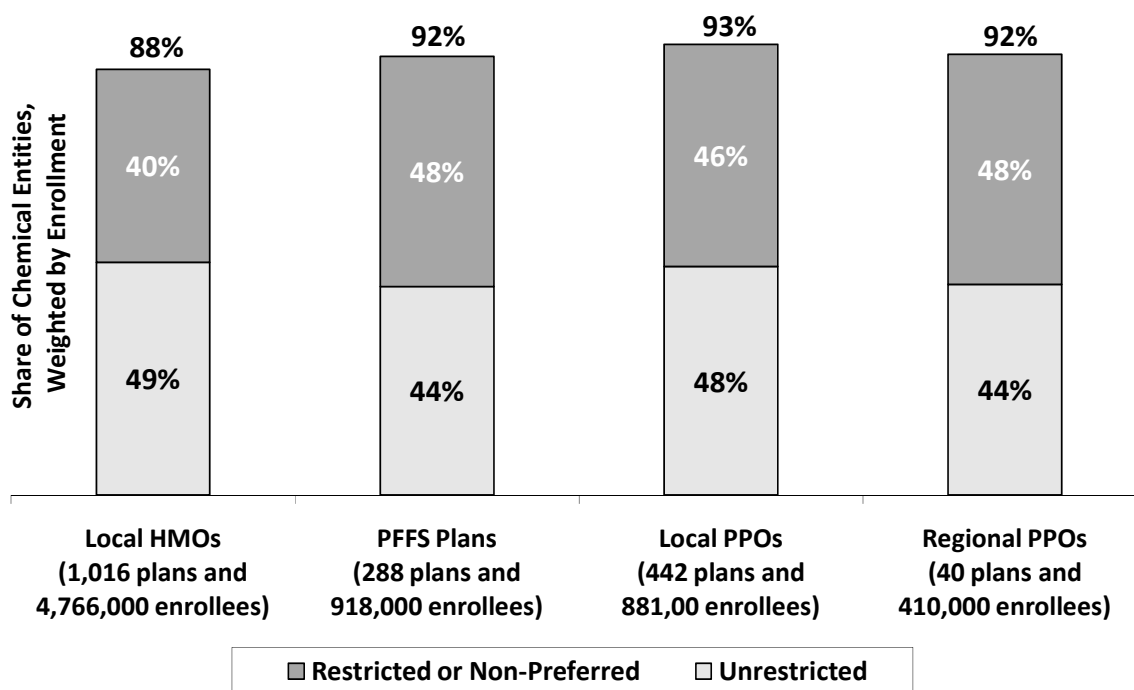
NOTE: Calculations are share of chemical entities. Totals atop bars refer to total share of chemical entities on formulary; difference from 100 percent is for drugs off formulary. “Unrestricted” = placement on certain tiers (generic, brand, preferred brand) and absence of utilization management restrictions (prior authorization, step therapy, quantity limits). Both apply the original UM measure (see section introduction).

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- National plans are offered in all 34 of the regions established across the country for the Part D plan. Near-national plans are available in most, but not all, of the regions (and include certain smaller plans offered by plan sponsors that offer at least some plans in all regions). Local plans are offered in a small number or in just one of the regions. Local plans are divided between those sponsored by Blue Cross or Blue Shield companies and all other local plans.
- Formularies offered by national plans include a somewhat higher share of chemical entities than other types of plans.
- The proportion of unrestricted drugs in each type of plan is similar. Thus the share of “extra” drugs included on national plans’ formularies tends to fall into the restricted or non-preferred category.



**Chart 5.6. Share of Chemical Entities on Formulary, Restricted and Unrestricted, by Type of MA-PD, 2010**

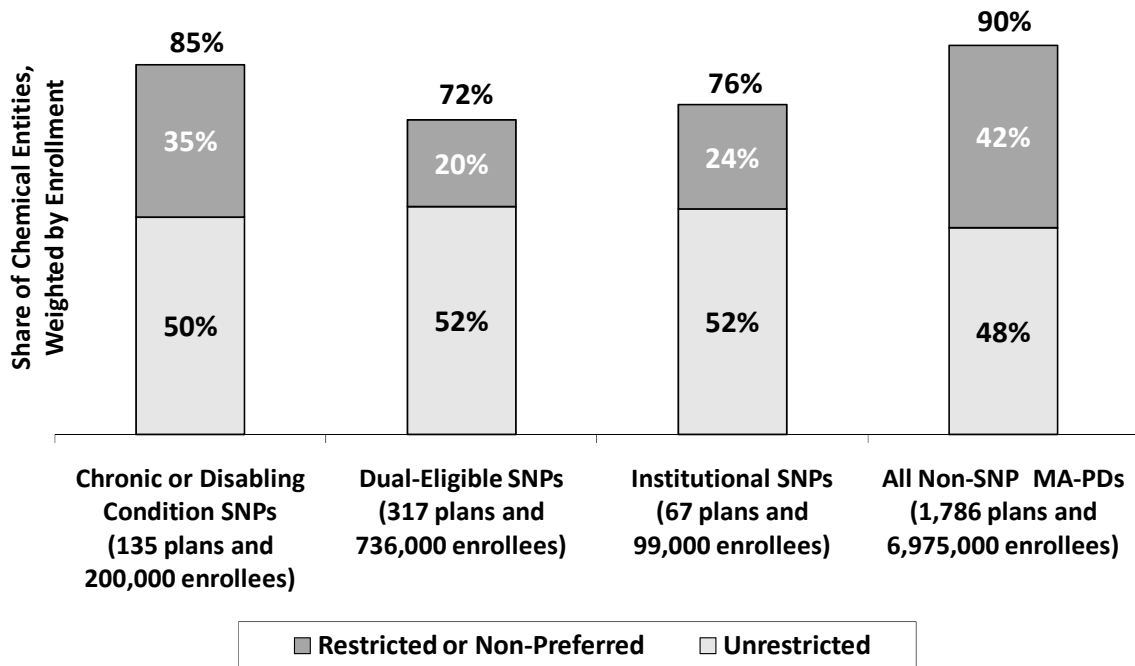


NOTE: Calculations are share of chemical entities. Totals atop bars refer to total share of chemical entities on formulary; difference from 100 percent is for drugs off formulary. “Unrestricted” = placement on certain tiers (generic, brand, preferred brand) and absence of utilization management restrictions (prior authorization, step therapy, quantity limits). Both apply the original UM measure (see section introduction).

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Several types of Medicare Advantage plan sponsors offer Part D benefits. Local health maintenance organizations (HMOs) comprise the largest share of MA-PDs followed by local Preferred Provider Organizations (PPOs). These plans are typically within a specified service area. Service areas are typically limited to a portion of a single state, but sometimes cut across state boundaries. Regional PPOs, by law, must be available to beneficiaries who reside in established Medicare Advantage regions. (Medicare Advantage and Part D regions differ). Some sponsors also offer Private Fee-for-Service (PFFS) plans, another category of MA-PD. PFFS plans are often available across broader geographic areas than local HMOs or PPOs.
- Among MA-PDs, local HMOs list the smallest share of chemical entities (88 percent) and local PPOs include the largest share on formulary (93 percent).
- Local HMOs and PPOs have somewhat less restrictive formularies than private fee-for-service plans or regional PPOs.

**Chart 5.7. Share of Chemical Entities on Formulary, Restricted and Unrestricted, SNPs vs. MA-PDs, 2010**



NOTE: Calculations are share of chemical entities. Totals atop bars refer to total share of chemical entities on formulary; difference from 100 percent is for drugs off formulary. “Unrestricted” = placement on certain tiers (generic, brand, preferred brand) and absence of utilization management restrictions (prior authorization, step therapy, quantity limits). Both apply the original UM measure (see section introduction).

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Special Needs Plans, the MA-PDs that are allowed to limit membership to beneficiaries with specific diseases or characteristics, have fewer total drugs on formulary than non-SNP MA-PDs, but offer somewhat higher proportions of unrestricted drugs (in part because some SNPs, especially those restricted to dual eligibles, do not maintain tiered formularies).
- Among the SNPs, those that serve dual-eligible beneficiaries have the smallest formularies, covering just 72 percent of drugs, but they also have the smallest proportion of restricted or non-preferred drugs.

## 6. Drug Classes

In previous sections, we present results broadly across all drugs that are potentially covered under Medicare Part D (separated for a few charts between brands and generics or the most commonly prescribed drugs). In this section, we consider how drug coverage may differ across different drug classes. We consider several selected drug classes that include drugs used to treat common health conditions. The drug classes themselves were identified from the United States Pharmacopeia (USP) classification that is recognized by Medicare as a default classification system (although some plan sponsors may choose to use other classification systems). We use the list of drugs published on the USP website that assigns drugs to particular drug classes and subclasses. In doing so, we follow USP's lead and exclude combination drugs from the drug classes (though we show some combination drugs in drug-level charts). Formulary treatment of drug classes is influenced by the brand-generic mix of drugs in the class, so we show the share of brand-name drugs in most tables.

Because CMS guidelines designate some drug classes as protected classes, we identify these in the charts of this section. With a few exceptions, plans are required to list on formulary all drugs in protected classes. Plans may assign these drugs to different tiers and in most cases may apply utilization management restrictions (but not for drugs used to treat HIV or AIDS).

In addition to tables showing a selection of drug classes, this section includes charts with examples of individual drugs in a few drug classes to provide more detail on the variations in how the drugs in a particular class are treated.

**Chart 6.1. Formulary Tier Placement of Key Drug Classes, 2010**

Drug Class ( <i>Protected – Italics</i> )	N	N Brand	Off Formulary	Standard 25%	Generic or Pref. Generic Tier	Brand or Pref. Brand Tier	Non-Pref. Brand Tier	Specialty Tier
<i>Antineoplastics (Cancer)</i>	28	23	1%	9%	13%	20%	15%	41%
<i>Atypical Antipsychotics</i>	7	5	0%	9%	20%	36%	33%	0%
<i>Reuptake Inhibitors (Antidepressants)</i>	8	2	1%	9%	64%	18%	6%	0%
Antidiabetic Agents	16	8	9%	8%	42%	23%	17%	0%
ACE Inhibitors (Hypertension)	10	1	7%	8%	79%	0%	4%	0%
ARBs (Hypertension)	7	7	35%	3%	0%	28%	34%	0%
Beta Blockers (Hypertension)	14	2	6%	8%	75%	6%	4%	0%
Calcium Channel Blockers (Hypertension)	9	0	4%	9%	70%	5%	3%	6%
Cholesterol Drugs	13	6	8%	8%	52%	24%	7%	0%
Nonsteroidal Anti-inflammatory Drugs (Pain)	19	2	9%	9%	74%	5%	2%	0%
Opioids (Pain)	14	2	16%	7%	53%	14%	7%	2%
H2 Blockers (Gastrointestinal)	4	0	7%	8%	82%	0%	1%	0%
Proton Pump Inhibitors (Gastrointestinal)	5	3	33%	5%	20%	25%	15%	1%

NOTE: The percentage for the drug class is the unweighted average for the drugs in that class. The percentage for each drug represents the share of PDPs, weighted by enrollment, for which the drug is on a particular tier or off formulary. ARBs are angiotensin II receptor blockers; ACE inhibitors are angiotensin-converting enzyme inhibitors.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- There is considerable variation among drug classes in the frequency of off-formulary drugs and in placement of drugs into tiers.
- As expected, the protected classes have very few cases of off-formulary drugs. CMS allows plans to exclude from their formularies Iressa (gefitinib), an antineoplastic drug used for cancer and either Lexapro (escitalopram) or citalopram, chemically similar antidepressants; these represents the few exceptions shown in this table. These classes are generally as likely as other classes to have drugs on non-preferred tiers.

- Many of the characteristics of the classes seem to have idiosyncratic explanations.
  - A brand-dominated class, such as the angiotensin II receptor blockers (ARBs), used to treat hypertension, is far more likely to have drugs off formulary. The class of proton pump inhibitors (PPIs) used to treat gastrointestinal conditions is also likely to have off-formulary drugs, perhaps because PPIs are often viewed by physicians as interchangeable and because over-the-counter versions are available.
  - Generic-dominated classes, such as antidepressants, angiotensin-converting enzyme (ACE) inhibitors, beta blockers, and nonsteroidal anti-inflammatory drugs, are mostly on formulary (the handful of brands in these classes represent most of the off-formulary cases). They are also much less likely to have any products on brand tiers, except of course where there are some brand-name alternatives on formulary (e.g., antidepressants).
  - Of the classes listed in this chart, only the antineoplastics used to treat cancer are commonly on specialty tiers.

**Chart 6.2. Formulary Tier Placement of Key Drug Classes, 2007**

Drug Class ( <i>Protected - Italics</i> )	N	N Brand	Off Formulary	Standard 25%	Generic or Pref. Generic Tier	Brand or Pref. Brand Tier	Non-Pref. Brand Tier	Specialty Tier
<i>Antineoplastics (Cancer)</i>	24	20	3%	19%	14%	29%	9%	26%
<i>Atypical Antipsychotics</i>	6	5	0%	19%	13%	49%	18%	0%
<i>Reuptake Inhibitors (Antidepressants)</i>	8	2	2%	19%	59%	15%	6%	0%
Antidiabetic Agents	15	8	5%	19%	35%	31%	9%	0%
ACE Inhibitors (Hypertension)	10	4	10%	17%	48%	12%	13%	0%
ARBs (Hypertension)	7	7	19%	16%	0%	27%	37%	0%
Beta Blockers (Hypertension)	13	2	3%	18%	67%	7%	4%	0%
Calcium Channel Blockers (Hypertension)	9	3	6%	18%	50%	11%	9%	5%
Cholesterol Drugs	13	7	7%	18%	39%	23%	12%	0%
Nonsteroidal Anti-inflammatory Drugs (Pain)	19	2	5%	18%	66%	3%	7%	0%
Opioids (Pain)	14	2	11%	18%	57%	4%	8%	2%
H2 Blockers (Gastrointestinal)	4	0	4%	19%	75%	0%	2%	0%
Proton Pump Inhibitors (Gastrointestinal)	5	4	12%	17%	15%	36%	17%	2%

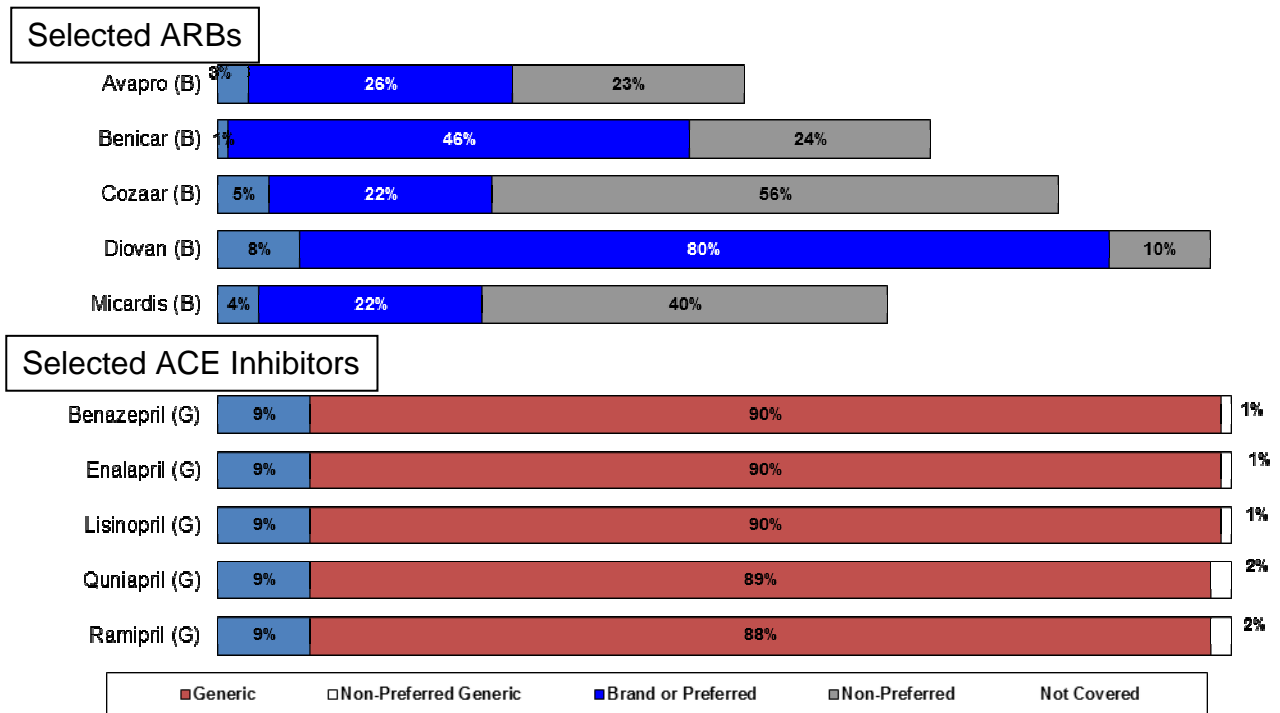
NOTE: The percentage for the drug class is the unweighted average for the drugs in that class. The percentage for each drug represents the share of PDPs, weighted by enrollment, for which the drug is on a particular tier or off formulary. ARBs are angiotensin II receptor blockers; ACE inhibitors are angiotensin-converting enzyme inhibitors.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- The overall pattern of formulary treatment was similar in 2007 to that for 2010 (the higher use of the standard benefit without tiers has the effect of somewhat lowering the absolute shares in other tiers).
- Most 2007-2010 differences seem to reflect changes in patent status for drugs in the class.
  - Proton pump inhibitors were less likely to be off formulary in 2007. Perhaps the availability of generic and over-the-counter options has increased the willingness of plans to omit the remaining brand options.
  - The loss of patent status for some important ACE inhibitors and calcium channel blockers appears to be reflected in the near-disappearance of these classes on brand tiers from 2007 to 2010.

- Some other differences between 2007 and 2010 may result from different factors.
  - For example, ARBs are more likely to be off formulary in 2010, despite no changes (yet) in patent status. This could reflect plans moving drugs off formulary in preparation for upcoming generic availability of some products. But it could also reflect more aggressive negotiating with manufacturers.
  - Antineoplastics (cancer drugs) are more often on specialty tiers in 2010, perhaps reflecting a growing consensus among plans on the importance of specialty tiers.

**Chart 6.3. Formulary Tier Placement for Selected Hypertension Drugs, 2010**



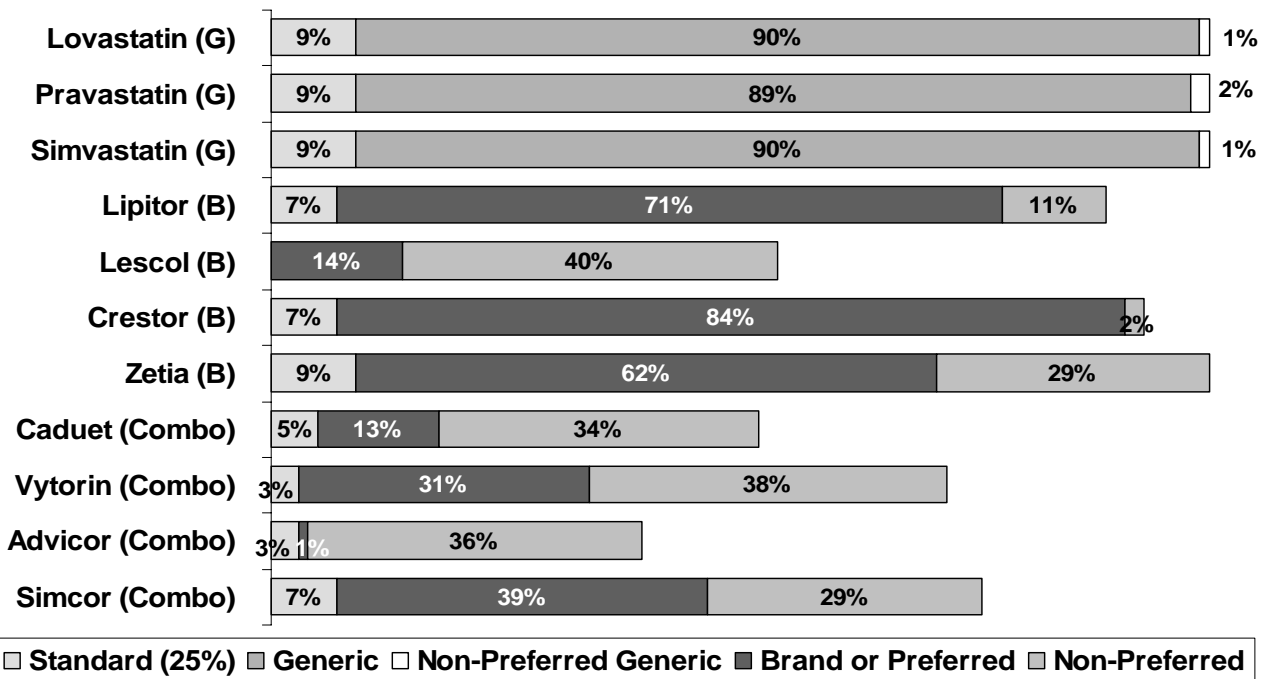
NOTE: Calculations are share of all PDPs, weighted by enrollment. Length of bar represents share on formulary; difference from 100 percent is for drugs off formulary. ARBs are angiotensin II receptor blockers; ACE inhibitors are angiotensin-converting enzyme inhibitors.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Angiotensin II receptor blockers (ARBs) and angiotensin-converting enzyme (ACE) inhibitors are two closely related classes of drugs used to treat hypertension. All ARBs remained on patent at the end of 2009, whereas most ACE inhibitors are available as generics.
- Accordingly, the ACE inhibitors are almost uniformly available on generic tiers.
- The ARBs are on brand tiers, but the five drugs displayed here are treated differently. Diovan, the best-selling drug in this group, is mostly likely to be on formulary and most likely to be on a preferred tier. Cozaar, while the second most likely to be on formulary, is typically listed on a non-preferred tier.



**Chart 6.4. Formulary Tier Placement for Cholesterol Drugs, 2010**

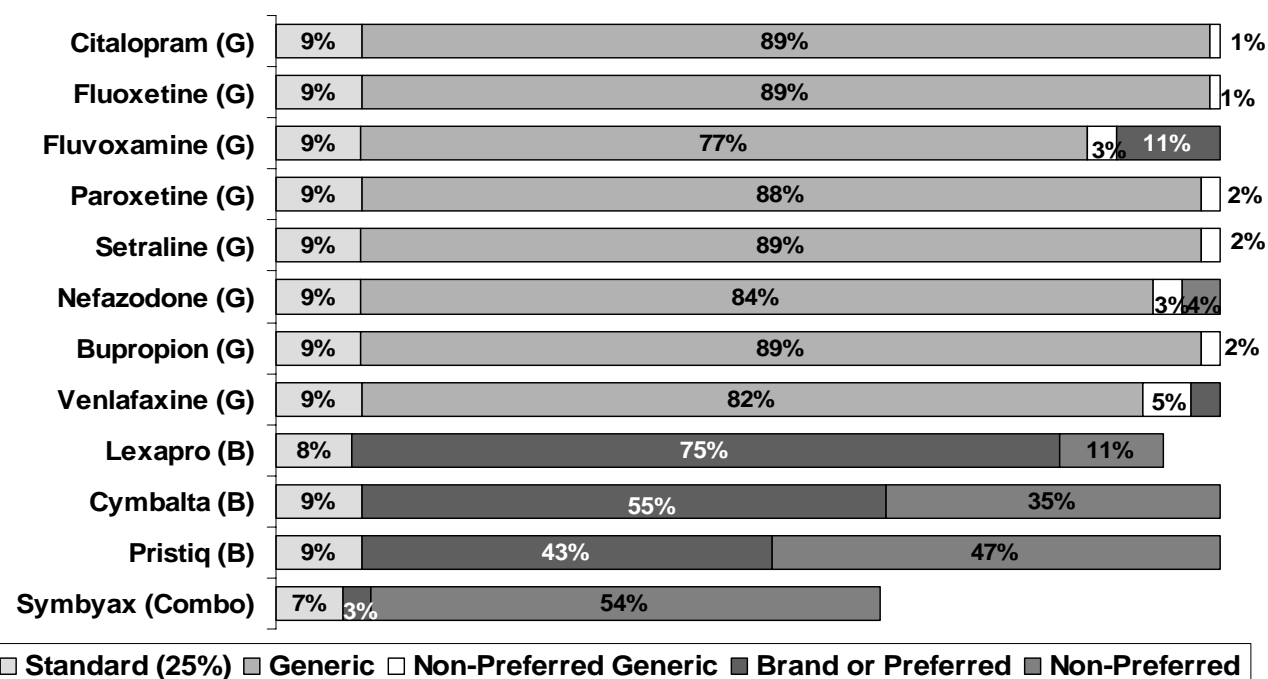


NOTE: Calculations are share of all PDPs, weighted by enrollment. Length of bar represents share on formulary; difference from 100 percent is for drugs off formulary.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- The class of cholesterol drugs includes a mix of brand-name and generic drugs. For comparison purposes, this chart also displays four combination drugs that are not included in the averages shown in Charts 6.1 and 6.2. Caduet is a combination of a cholesterol drug and a hypertension drug, while Vytorin, Advicor, and Simcor each combine two different types of cholesterol medications.
- The three cholesterol drugs available as generics are on nearly all plan formularies and nearly always on generic tiers. Among the four brand-name drugs displayed in this chart, Lipitor, Crestor, and Zetia are generally on plan formularies and most often on preferred tiers. Zetia, because it constitutes its own formulary key drug type in the classification system, is required to be on formulary, perhaps explaining the somewhat more frequent appearance on non-preferred tiers. By contrast, Lescol is much less often on formulary and mostly on the non-preferred tier when listed.
- The combination drugs displayed here are regularly either omitted from plan formularies or placed on non-preferred tiers when on formulary. Although sometimes viewed as a convenience for patients thus increasing adherence, these drugs tend to be more expensive than the individual components, especially when the component drugs are available as generics.

**Chart 6.5. Formulary Tier Placement for Antidepressants, 2010**

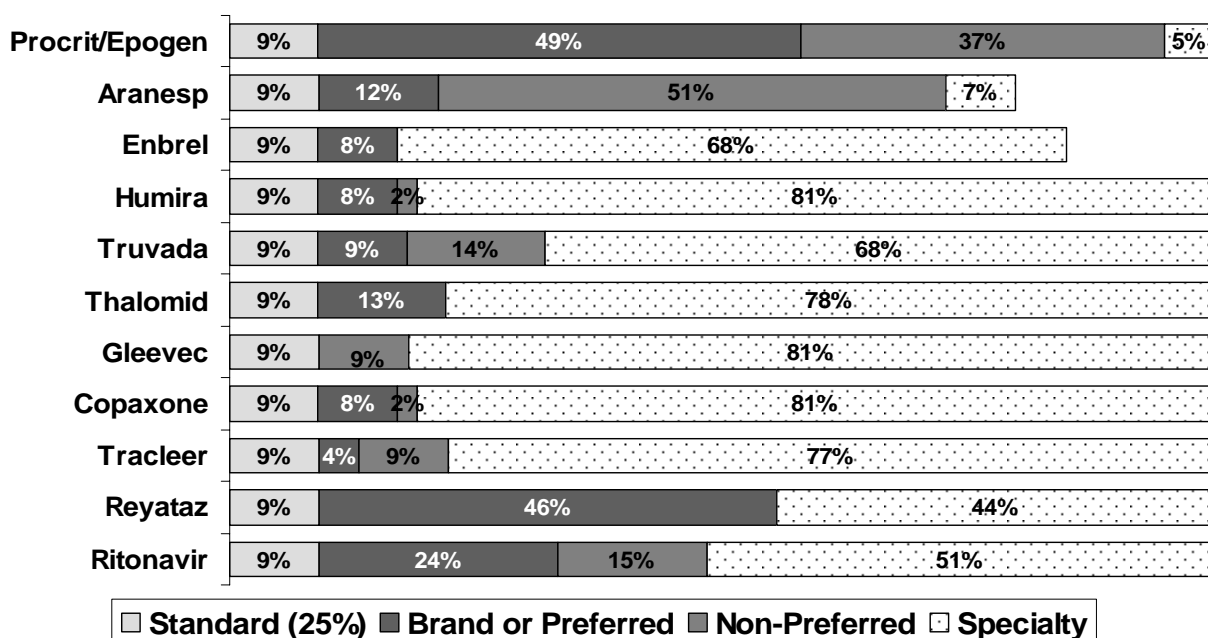


NOTE: Calculations are share of all PDPs, weighted by enrollment. Length of bar represents share on formulary; difference from 100 percent is for drugs off formulary.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- The antidepressants displayed here are mostly reuptake inhibitors, but include a few drugs from other classes of antidepressants. One combination drug, which puts together an antidepressant with an antipsychotic drug, is displayed. A growing number of antidepressants are available as generics.
- Because antidepressants are one of the protected classes according to CMS guidelines, plans are typically required to list on formulary all drugs in this class.
- One exception is Lexapro; plans have the option of covering either Lexapro or citalopram. About 6 percent of beneficiaries are in plans that opt not to list Lexapro.
- In addition, plans are not required to list on formulary the combination drug Symbyax. Over one-third of all beneficiaries are in plans that opt not to list this drug on formulary. Most that do list it place it on a non-preferred tier.
- Pristiq is the newest drug in this set of drugs, a fact that may help to explain why it is the most likely of the required drugs to be placed on a non-preferred tier.

**Chart 6.6. Formulary Tier Placement for Expensive Specialty Drugs, 2010**



NOTE: Calculations are share of all PDPs, weighted by enrollment. Length of bar represents share on formulary; difference from 100 percent is for drugs off formulary.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- The drugs in this chart were selected because they are among the top 100 drugs according to costs in the CMS analysis of prescription drug events (claims) for 2008 and they appear in some form on specialty tiers. Most drugs displayed here are unique treatments for a particular health condition, such as HIV/AIDS, cancer, rheumatoid arthritis, or multiple sclerosis. As such, they either belong to one of the protected classes or are otherwise viewed as essential drugs on a formulary. Thus, they are infrequently if ever left off plan formularies.
- The only drugs in this group left off formulary by some plans are Enbrel and Aranesp. Both have competing drugs that may be regarded as therapeutic options (Humira and Procrit/Epogen, respectively). It appears that a few plans have a preference for one of the competing products and thus leave the alternative off formulary. By the same logic, a majority of beneficiaries are in plans where Aranesp is treated as a non-preferred drug. Procrit and Epogen, although marketed by different companies, are treated as a single chemical entity in our analysis.
- Most drugs in this chart are on specialty tiers in most cases where plans use specialty tiers. Procrit/Epogen and Aranesp are exceptions. Available in several strengths, these drugs do not meet the cost threshold for a specialty tier in the lowest strength. Because our system assigns a drug to the least restrictive tier among all forms and strengths that make up a single chemical entity, we generally see these drugs in tiers other than specialty tiers. Patients needing higher strengths may find their version on the specialty tier. Reyataz and Ritonavir are also exceptions, possibly reflecting the desire to make these HIV/AIDS drugs available at lower costs.

**Chart 6.7. Utilization Management Requirements for Key Drug Classes, 2007-2010**

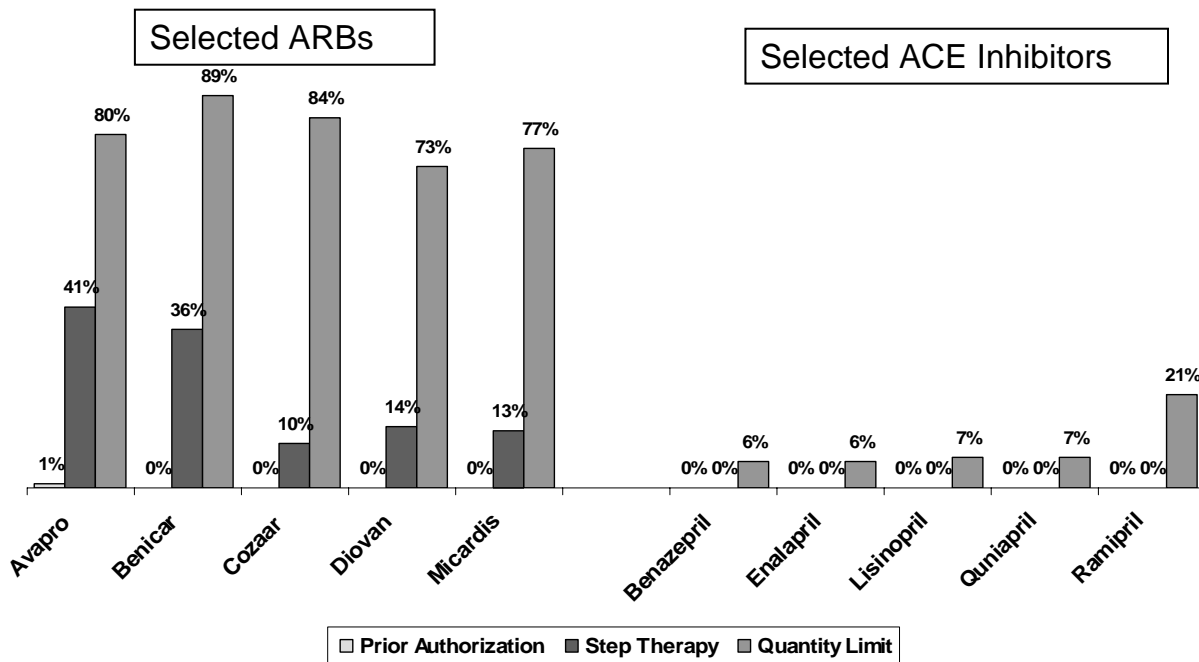
Drug Class ( <i>Protected - Italics</i> )	Prior Authorization		Step Therapy		Quantity Limits	
	2007	2010	2007	2010	2007	2010
<i>Antineoplastics (Cancer)</i>	20%	39%	0%	2%	9%	18%
<i>Atypical Antipsychotics</i>	9%	17%	3%	26%	43%	66%
<i>Reuptake Inhibitors (Antidepressants)</i>	1%	2%	10%	13%	55%	67%
Antidiabetic Agents	8%	7%	4%	24%	24%	26%
ACE Inhibitors (Hypertension)	0%	0%	4%	0%	8%	12%
ARBs (Hypertension)	1%	0%	47%	40%	72%	81%
Beta Blockers (Hypertension)	1%	1%	1%	2%	4%	17%
Calcium Channel Blockers (Hypertension)	1%	1%	0%	3%	35%	33%
Cholesterol Drugs	1%	2%	2%	9%	36%	49%
Nonsteroidal Anti-inflammatory Drugs (Pain)	4%	2%	4%	3%	12%	13%
Opioids (Pain)	11%	15%	1%	4%	30%	41%
H2 Blockers (Gastrointestinal)	3%	2%	1%	0%	1%	0%
Proton Pump Inhibitors (Gastro)	17%	10%	24%	41%	87%	87%

NOTE: The percentage for the drug class is the unweighted average for the drugs in that class. The percentage for each drug represents the share of PDPs, weighted by enrollment, for which the drug has a particular UM requirement (using the original UM measures, as described in the Section 5 introduction), out of all PDPs where the drug is on formulary. ARBs are angiotensin II receptor blockers; ACE inhibitors are angiotensin-converting enzyme inhibitors.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Like tier placement, the use of UM requirements varies considerably across drug classes in both 2007 and 2010. To some degree, the changes between 2007 and 2010 reflect the overall increase in use of UM restrictions over time.
- Increased use of prior authorization (PA) from 2007 to 2010 is concentrated in two classes: cancer drugs and atypical antipsychotics. PA is common in these classes for administrative reasons (cancer drugs where Part B coverage is an option) or clinical reasons (antipsychotics, which have been subject to considerable scrutiny in recent years). PA is common, but not increasing, for antidiabetic drugs and opioids for pain. The use of PA for proton pump inhibitors has decreased somewhat (perhaps because of increased generic availability in this class).
- Step therapy is common (both years) for ARBs. Clinical studies and cost factors both suggest that therapeutic alternatives (especially ACEs) can be considered. Step therapy has become more common for PPIs, which have therapeutic alternatives. The use of this restriction has grown for antipsychotics and antidiabetic agents, probably reflecting new studies on clinical safety and appropriateness of certain drugs. Step therapy remains rare for classes dominated by generics and for cancer drugs (where PA seems the preferred management approach).
- Use of quantity limits is widespread for PPIs and ARBs. For PPIs in particular, overuse is a clinical concern. Use of quantity limits has grown somewhat for the two mental health classes.

**Chart 6.8. Utilization Management Restrictions for Selected Hypertension Drugs, 2010**

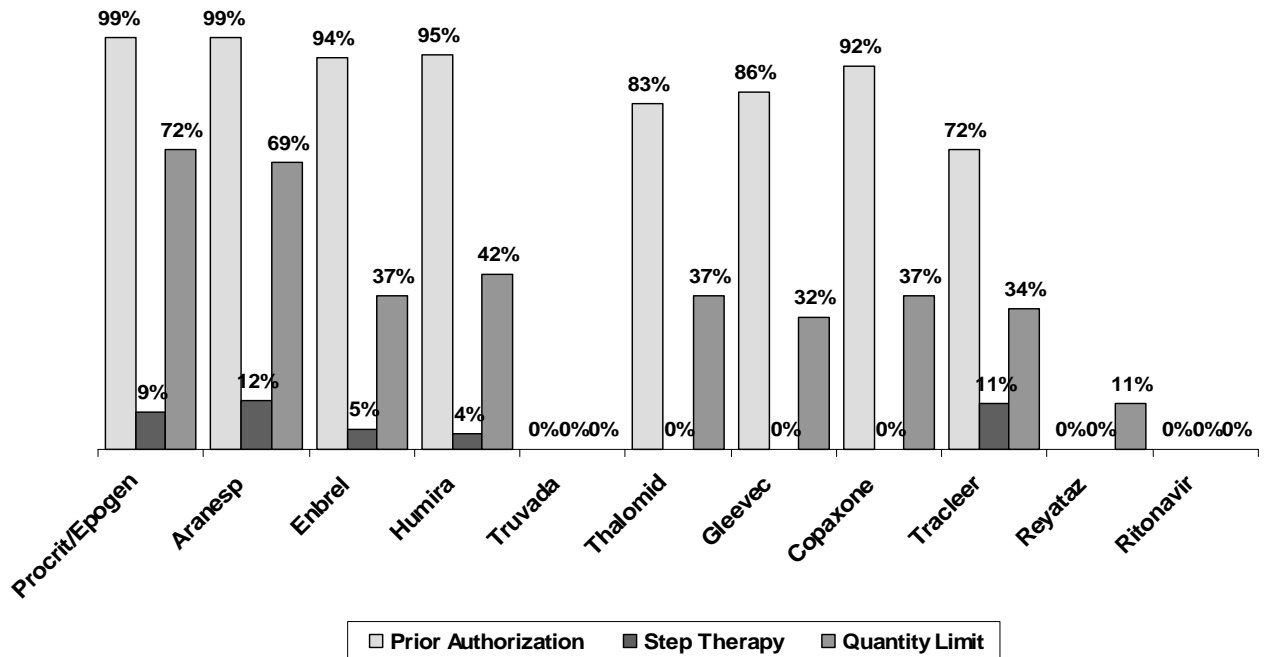


NOTE: Calculations are share of all PDPs listing drug on formulary, weighted by enrollment and based on the original UM measures, as described in the Section 5 introduction. ARBs are angiotensin II receptor blockers; ACE inhibitors are angiotensin-converting enzyme inhibitors.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Angiotensin-converting enzyme (ACE) inhibitors are mostly generics; as a result, plans are much less likely to apply any utilization management restrictions to them.
- All angiotension II receptor blockers (ARBs) are on-patent brand-name drugs. About eight in ten beneficiaries are in PDPs with quantity limits for ARBs, and 40 percent of beneficiaries are in PDPs that use step therapy for ARBs (Chart 6.7). Step therapy is more commonly used for some ARBs than others. Prior authorization is not used for any of these drugs except for Avapro (plans enrolling 1 percent of beneficiaries).

**Chart 6.9. Utilization Management Restrictions for Expensive Specialty Drugs, 2010**



NOTE: Calculations are share of all PDPs listing drug on formulary, weighted by enrollment and based on the original UM measures, as described in the Section 5 introduction.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Prior authorization is commonly used for these expensive specialty drugs. The major exception is for the HIV/AIDS drugs (Truvada, Reyataz, and Ritonavir), where CMS guidelines generally require that UM restrictions are not applicable to those currently taking a drug.
- Prior authorization may be used for some of these drugs both to ensure that expensive drugs are used for the correct patients as well as to help ensure that the drugs are correctly paid under Part D versus Part B.
- Step therapy is not commonly used for most of these expensive specialty drugs, in part because there are no therapeutic alternatives in many cases.
- Quantity limits are relatively common for these drugs.

## 7. Commonly Prescribed Drugs

The formulary treatment of the most commonly prescribed drugs offers another way to illustrate the variations in how plan sponsors structure their Part D benefits. Differences between these commonly prescribed drugs and all other drugs may be both cause and effect. Drugs may be prescribed more often when they are on preferred tiers or not subject to restrictions, or plans may decide to treat popular drugs differently.

The charts in this section feature the most commonly prescribed drugs as defined from rankings of the top 100 drugs. We use rankings based on the total number of prescriptions filled in 2008, calculated and published by CMS from prescription drug events (claims) data.

Because formulary treatment differs so fundamentally by drugs' patent status, we separate that list into separate lists of brand-name and generic drugs, using their patent status as of late 2009. In some cases, we note changes in patent status between 2007 and the present.

**Chart 7.1. Formulary Treatment of Commonly Prescribed Brand Drugs, 2007-2010**

Drug	Off Formulary		Brand or Preferred Brand Tiers		Non-Preferred Brand Tier	
	2007	2010	2007	2010	2007	2010
Lipitor	6%	11%	59%	71%	15%	11%
Plavix	0%	0%	74%	77%	7%	14%
Nexium	8%	6%	62%	78%	4%	5%
Diovan	0%	2%	75%	80%	5%	10%
Aricept	0%	0%	75%	81%	6%	10%
Lexapro	12%	6%	50%	75%	20%	11%
Flomax	2%	3%	71%	74%	7%	14%
Seroquel	0%	0%	80%	90%	1%	1%
Advair Diskus	1%	4%	69%	88%	11%	1%
Prevacid	7%	62%	60%	4%	12%	33%
Actos	6%	0%	74%	77%	0%	13%
Lantus	0%	1%	79%	81%	1%	9%
Actonel	0%	30%	74%	35%	6%	29%
Vytorin	21%	28%	55%	31%	7%	38%
Crestor	15%	7%	58%	84%	8%	2%

NOTE: The percentage for each drug represents the share of PDPs, weighted by enrollment, for which the drug is on a particular tier or off formulary.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- The most likely drugs on this list to be off formulary in 2010 are Prevacid, Actonel, and Vytorin. The first generic version of Prevacid went on the market late in 2009, after the date of the formulary files used in this analysis.
- Actonel (used for osteoporosis) is the one example of a drug much more likely to be off formulary in 2010 compared to 2007, presumably because of new competition from generic Fosamax.
- The most likely drugs on this list to be on a non-preferred tier in 2010 are also Vytorin, Prevacid, and Actonel. This tier placement represents a less extreme step than leaving them off the formulary, but a step presumably taken by plan sponsors for the same reasons.



**Chart 7.2. Utilization Management Status of Commonly Prescribed Brand Drugs, 2007-2010**

Drug	Prior Authorization		Step Therapy		Quantity Limits	
	2007	2010	2007	2010	2007	2010
Lipitor	2%	0%	2%	12%	59%	91%
Plavix	6%	0%	0%	0%	35%	65%
Nexium	25%	22%	9%	5%	84%	91%
Diovan	1%	0%	41%	14%	69%	73%
Aricept	12%	0%	0%	0%	38%	79%
Lexapro	0%	0%	12%	10%	44%	85%
Flomax	2%	0%	15%	7%	59%	71%
Seroquel	1%	2%	1%	0%	46%	65%
Advair Diskus	2%	0%	2%	0%	54%	91%
Prevacid	15%	9%	8%	73%	89%	92%
Actos	3%	0%	9%	54%	71%	45%
Lantus	2%	0%	0%	0%	2%	7%
Actonel	4%	8%	6%	29%	83%	91%
Vytorin	0%	1%	0%	6%	51%	81%
Crestor	1%	0%	10%	1%	55%	86%

NOTE: The percentage for each drug represents the share of PDPs, weighted by enrollment, for which the drug has a particular UM requirement, out of all PDPs where the drug is on formulary.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Prior authorization is most common for Nexium, Prevacid, and Actonel and nearly nonexistent for other drugs on this list.
- The most common use of step therapy in 2007 was for Diovan, but this use had dropped considerably by 2010. Since the ARB class of hypertension drugs uses step therapy a lot, this is surprising but could reflect a preference for Diovan over some alternatives in the ARB class.
- Step therapy use has grown dramatically for Prevacid from 2007 to 2010, probably a further reflection of its imminent move off patent. But Nexium, which competes with both over-the-counter and generic therapeutic alternatives, rarely has step therapy applied. Step therapy use has also grown considerably for Actos, which competes with Avandia. Actonel has experienced an increase in step therapy use, possibly reflecting the new availability of generic Fosamax between 2007 and 2010.
- Quantity limits are applied frequently for most of these commonly prescribed drugs, and their use has grown for many of them. One of the few exceptions in Lantus (a form of insulin).

**Chart 7.3. Formulary Treatment of Commonly Prescribed Generic Drugs, 2007-2010**

Drug	Off Formulary		Generic or Preferred Generic Tier		Non-Preferred Generic Tier	Brand/Preferred Brand Tier	Non-Preferred Brand Tier
	2007	2010	2007	2010	2010	2007	2007
Lisinopril	0%	0%	81%	90%	1%	0%	0%
Simvastatin	1%	0%	80%	90%	1%	0%	0%
Furosemide	0%	0%	80%	91%	0%	0%	0%
Hydrocodone/ Acetaminophen	0%	0%	80%	89%	2%	0%	0%
Thyroxine	0%	0%	80%	90%	1%	0%	0%
Amlodipine (Norvasc in 2007)	1%	0%	0%	89%	2%	64%	15%
Omeprazole	3%	0%	77%	90%	1%	0%	1%
Hydrochlorothiazide	0%	0%	81%	91%	0%	0%	0%
Atenolol	0%	0%	81%	91%	0%	0%	0%
Metformin	0%	0%	81%	90%	1%	0%	0%
Metoprolol	0%	0%	81%	91%	0%	0%	0%
Warfarin	0%	0%	81%	89%	1%	0%	0%
Potassium	0%	0%	81%	90%	0%	0%	0%
Gabapentin	0%	0%	80%	88%	3%	0%	0%
Lovastatin	0%	0%	81%	90%	1%	0%	0%
Glipizide	0%	0%	81%	91%	0%	0%	0%
Sertraline	0%	0%	77%	89%	2%	3%	1%
Alendronate (Fosamax in '07)	1%	0%	0%	88%	3%	80%	0%
Zolpidem (Ambien in 2007)	0%	0%	0%	89%	2%	71%	10%
Carvedilol (Coreg in 2007)	0%	0%	0%	89%	2%	78%	2%

NOTE: The percentage for each drug represents the share of PDPs, weighted by enrollment, for which the drug is on a particular tier or off formulary. Values are based on the original UM measures, as described in the Section 5 introduction.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Most generic drugs have not seen a change in coverage over this time period. The exceptions reflect four drugs experiencing a shift in patent status between 2007 and 2010 (brand tiers are not shown for 2010, since values are nearly all zero). These four drugs were on brand tiers in 2007, most often preferred brand tiers. Otherwise, drugs in this group are universally on formulary and nearly universally on the generic or preferred generic tiers in both 2007 and 2010.
- Use of the non-preferred generic tier (not identified as a distinct tier type in 2007) is most common for the recently off-patent drugs and for gabapentin. But levels of use for this tier are so small that this result must be regarded as only suggestive.

**Chart 7.4. Utilization Management Status of Commonly Prescribed Generic Drugs, 2007-2010**

Drug	Prior Authorization		Step Therapy		Quantity Limits	
	2007	2010	2007	2010	2007	2010
Lisinopril	0%	0%	4%	0%	5%	7%
Simvastatin	0%	0%	1%	1%	56%	52%
Furosemide	2%	4%	0%	0%	0%	0%
Hydrocodone/ Acetaminophen	0%	0%	2%	0%	46%	37%
Thyroxine	2%	0%	0%	0%	1%	0%
Amlodipine (Norvasc in 2007)	0%	0%	0%	3%	76%	33%
Omeprazole	7%	1%	27%	4%	79%	89%
Hydrochlorothiazide	0%	0%	0%	0%	0%	0%
Atenolol	4%	0%	0%	0%	0%	0%
Metformin	0%	0%	1%	0%	25%	17%
Metoprolol	3%	4%	0%	0%	14%	25%
Warfarin	3%	4%	0%	0%	0%	1%
Potassium	2%	7%	0%	0%	0%	0%
Gabapentin	2%	8%	0%	0%	27%	28%
Lovastatin	0%	0%	1%	31%	48%	80%
Glipizide	0%	0%	0%	0%	4%	6%
Sertraline	1%	0%	11%	1%	46%	45%
Alendronate (Fosamax in 2007)	3%	6%	0%	28%	84%	90%
Zolpidem (Ambien in 2007)	3%	2%	22%	30%	59%	77%
Carvedilol (Coreg in 2007)	0%	0%	0%	23%	8%	54%

NOTE: The percentage for each drug represents the share of PDPs, weighted by enrollment, for which the drug has a particular UM requirement, out of all PDPs where the drug is on formulary. Values are based on the original UM measures, as described in the Section 5 introduction.

SOURCE: NORC/Georgetown University/Social & Scientific Systems analysis for MedPAC.

- Prior authorization is rare for any of these generic drugs. Those for which prior authorization is most common include several where clinical safety issues have arisen (gabapentin, potassium, warfarin).
- Step therapy is relatively common for three of the drugs that went off patent recently (alendronate, zolpidem, and carvedilol). This could at least partially reflect use of step therapy for the branded version of these drugs and thus result from the way we define UM status. The only other drug in this set where step therapy is commonly used is lovastatin.
- Quantity limits are common for some of these drugs and not for others. For some, the clinical or safety reasons seem clear: hydrocodone (a pain medication that is subject to abuse), omeprazole (a gastrointestinal drug where this some clinical evidence of overuse), zolpidem (a sleep aid, subject to overuse), and alendronate (an osteoporosis drug, taken once a week). For others, the reasons are less obvious (simvastatin, lovastatin, carvedilol).