Drugs on Specialty Tiers in Part D

A study conducted by staff from NORC at the University of Chicago and from Georgetown University for the Medicare Payment Advisory Commission

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FINAL REPORT

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Background

Medicare Part D requires plans to establish a formulary that lists the drugs that the plan agrees to cover and at what level of cost sharing. Although the original legislation set forth a "defined standard" benefit package with 25 percent cost sharing for all drugs, plans also have the flexibility to offer a benefit with tiered cost sharing. Plans typically use this flexibility to offer different levels of cost sharing for generic, preferred, and non-preferred drugs. A growing number of plans include an additional "specialty" tier for very high cost drugs. Most plans use flat copayments for most of their tiers (*e.g.*, $5 for generics, $30 for preferred brands), but variable coinsurance for specialty tiers (*e.g.*, 25 percent of the drug's cost).

Specialty drugs are, by definition, very expensive drugs. As it became clear that many plans were using specialty tiers, CMS established a minimum cost threshold drugs must meet before plans can place them on a specialty tier: in 2007, the minimum monthly cost was $500, and in 2008 and 2009, the minimum was $600. Many drugs placed on specialty tiers actually cost much more. Thus, the placement of a drug on a coinsurance-based specialty tier, rather than a tier with a flat copay, can have serious implications for both beneficiary and plan costs. That impact on beneficiaries is constrained, however, because many long-term users of these drugs reach the out-of-pocket limit and qualify for catastrophic coverage. Furthermore, federal reinsurance limits the impact on plan costs by paying 80 percent of costs once plan enrollees qualify for catastrophic coverage.

Part D enrollees have the right to request an exception to a plan's designation of a drug as non-preferred, but not for drugs on the specialty tier. In general, if an enrollee can establish that a non-preferred drug is medically necessary and no preferred drug would be as effective, the enrollee can pay the lower cost sharing that applies to the preferred drug. Plans are not required to grant tier exceptions requests for drugs on the specialty tier, even if no other drug is available to treat the beneficiary's condition. Thus, beneficiaries must in all cases pay the full cost-sharing amount for these high-cost drugs. CMS cites this as a policy that helps make plans' costs for expensive drugs more predictable. Because data are not available on the use of the tiering exceptions process for drugs on other tiers (such as high-cost non-preferred tiers), it is unclear how many beneficiaries might seek a tiering exception if that option were available for specialty drugs.

Summary Findings

- A substantial majority of all Part D plans use specialty tiers in 2008. The percentage of plans using specialty tiers has increased since 2006: from 63 to 76 percent of PDPs, and from 67 to 90 percent of MA-PDs.
- Most PDPs and MA-PDS with specialty tiers employ either 25 percent or 33 percent coinsurance, with a gradual trend toward higher coinsurance levels.
- About one in five drugs are placed on a specialty tier by at least one plan, but there is not much consensus among plans about which drugs belong on specialty tiers. Drugs that are on

a specialty tier for at least one plan are not typically listed on the specialty tier of all plans – in fact, fewer than one-fifth of specialty drugs are on a specialty tier in almost all plans. About 40 percent of specialty drugs ever listed on a specialty tier are on such a tier in fewer than half of all plans.

- When not listed on a specialty tier, specialty drugs are most often listed as preferred brand drugs or listed on a plan's only brand tier.
- Specialty drugs face utilization management restrictions in over one-third of plans – twice as much as other drugs – regardless of whether they are placed by the plan on a specialty tier. They are over five times as likely as other drugs to be subject to prior authorization.
- Brand-only drugs are much more likely to be placed on specialty tiers, compared to those with generic alternatives, and injectible drugs are much more likely than oral solids to be on specialty tiers.
- Drugs in just four classes (antineoplastics, immunologics, antivirals, and antibacterials) account for nearly two-thirds of specialty drugs.

Methodology

This report includes two types of analyses: changes over time (from 2006 to 2008) in the use of specialty tiers in Part D plans, and an in-depth look at specialty tiers in 2008. We used publicly available CMS files of Part D formularies to analyze plan tier structures and placement of drugs onto specialty tiers. However, these files do not clearly label specialty tiers. Thus, in 2006, 2007, and 2008, we labeled as an "apparent" specialty tier any tier that had all of the following characteristics:

- The plan's highest tier (or, in a very few cases where a plan uses a tier with cost sharing over 33 percent, second-highest tier);
- Cost sharing of from 25 percent to 33 percent; and
- A small number of drugs assigned to the tier.

This process yielded a count of 1,443 PDPs with "apparent" specialty tiers in 2008 (of 1,824 PDPs), but it likely resulted in some mis-labeling of tiers. For example, in situations where additional information is available, that information shows that some plans have tiers for non-specialty injectible drugs that would have been classified as specialty tiers under this process. Conversely, specialty tiers in a small number of MA plans have flat copays that would have caused us to label the tier as non-specialty.

In 2008, we obtained from CMS additional information about the plans' labeling of each tier. Thus, for the 2008 plans, we were able to identify true specialty tiers and eliminate tiers for non-specialty injectibles or other non-specialty drugs when those plans provided labels. However, many plans did

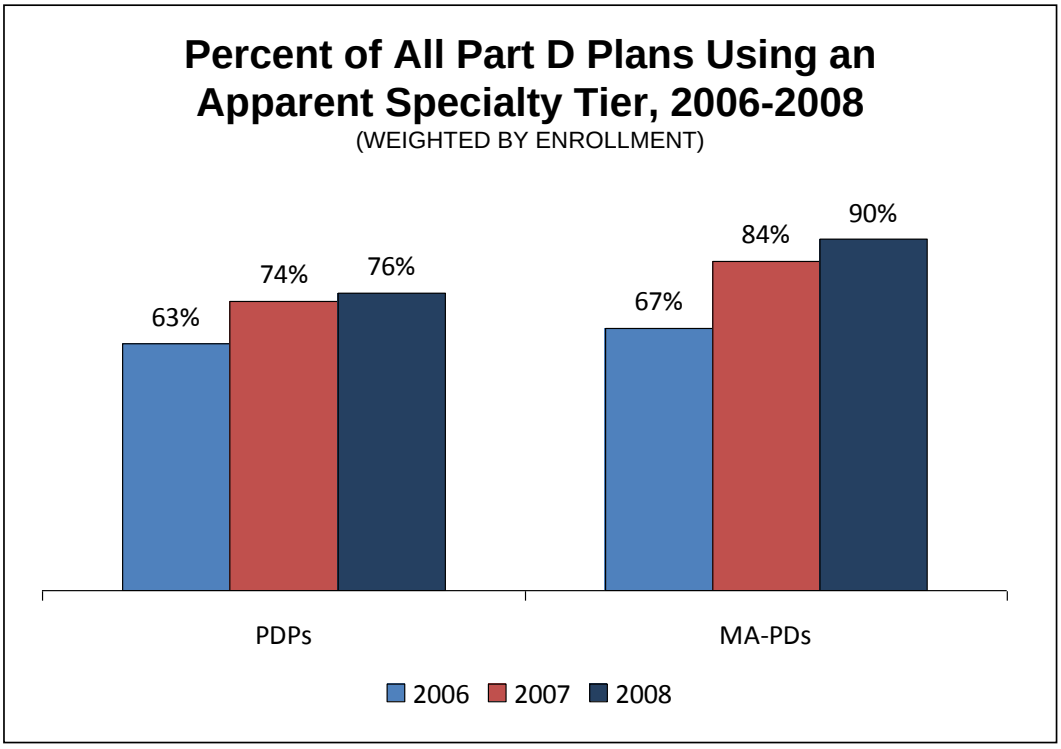
not provide labels and we were not able to determine whether or not their apparent specialty tiers were truly specialty tiers. As reported below, this information yielded a count of 1,262 PDPs with specialty tiers – or 181 fewer than the count of "apparent" specialty tiers. This group includes some for which no information was provided in the labeling information as well as some tiers that are not "true" specialty tiers.

For the purposes of comparing the use of specialty tiers from 2006 to 2008, we have used our more general measure of "apparent" specialty tiers. For our descriptions of which drugs are on specialty tiers in 2008, we used the more precise definition of a specialty tier based on plans' own labels and eliminated from the analysis plans that did not provide labels for their tiers.

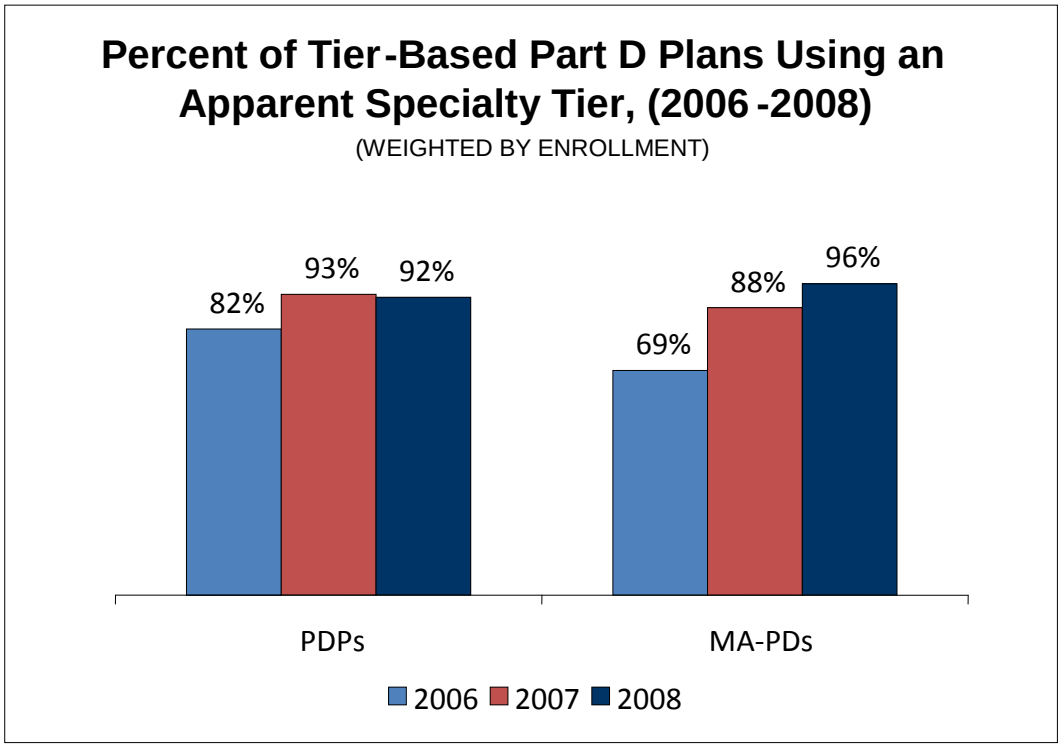
2006-2008 Comparisons

Use of Specialty Tiers

Since 2006, there have been notable increases in the use of what appear to be specialty tiers. Three-fourths of PDP enrollees, and nine-tenths of all MA-PD enrollees, are in a plan that uses an apparent specialty tier – up from about two-thirds of enrollees in 2006. As noted above, the count for 2008 relies on our definition of "apparent" specialty tiers, resulting in a larger count than reliance on labels supplied to CMS (but not available for all plans).



Most of the plans without a specialty tier have a structure in which a separate tier for drugs listed by other plans on a specialty tier would be redundant – such as the standard benefit in law of 25 percent coinsurance for all drugs. When defined standard plans and other plans that did not fit into a clear tier structure are set aside, over nine in ten beneficiaries enrolled in tier-based plans are in plans that have a specialty tier in 2008 (92 percent of PDPs and 96 percent of MAPDs). By 2008, many of the small set of tier-based plans without specialty tiers used percentage coinsurance for most or all tiers. In these cases, specialty-tier drugs were likely to be on tiers with a similar level of coinsurance to that found in specialty tiers. But these plans differ in that there is no limitation on requests for tiering exceptions.

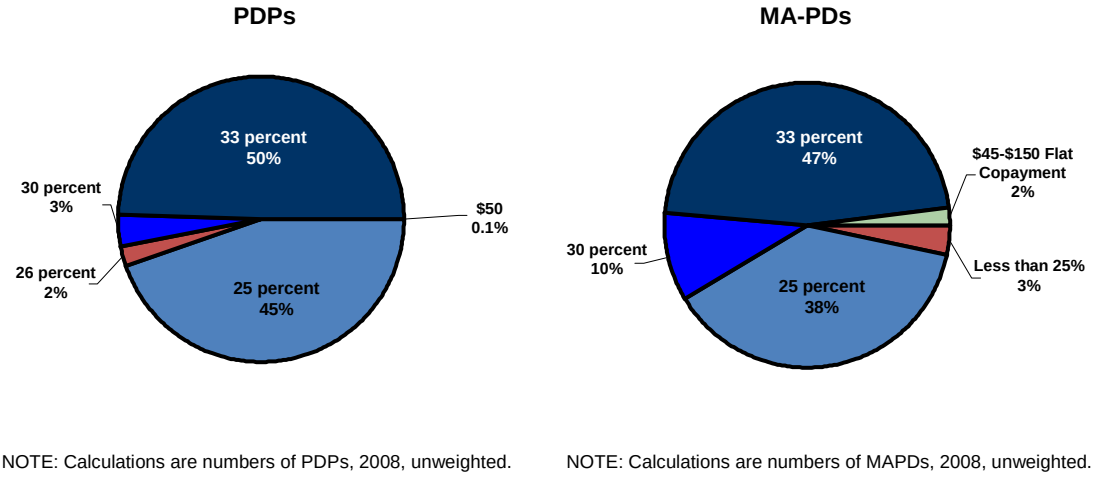


Cost Sharing

CMS limits cost sharing for specialty tiers to 25 percent, but allows plans to charge higher coinsurance if offset with other plan features, such as a lower deductible. Fewer than half of plans charge 25 percent coinsurance. Instead, half of PDPs, and slightly less than half of MA-PDs, take advantage of the flexibility offered by CMS to charge the maximum of 33 percent coinsurance for specialty-tier drugs.

Percent of Plans With Various Levels of Cost Sharing for Apparent Specialty Tiers, 2008

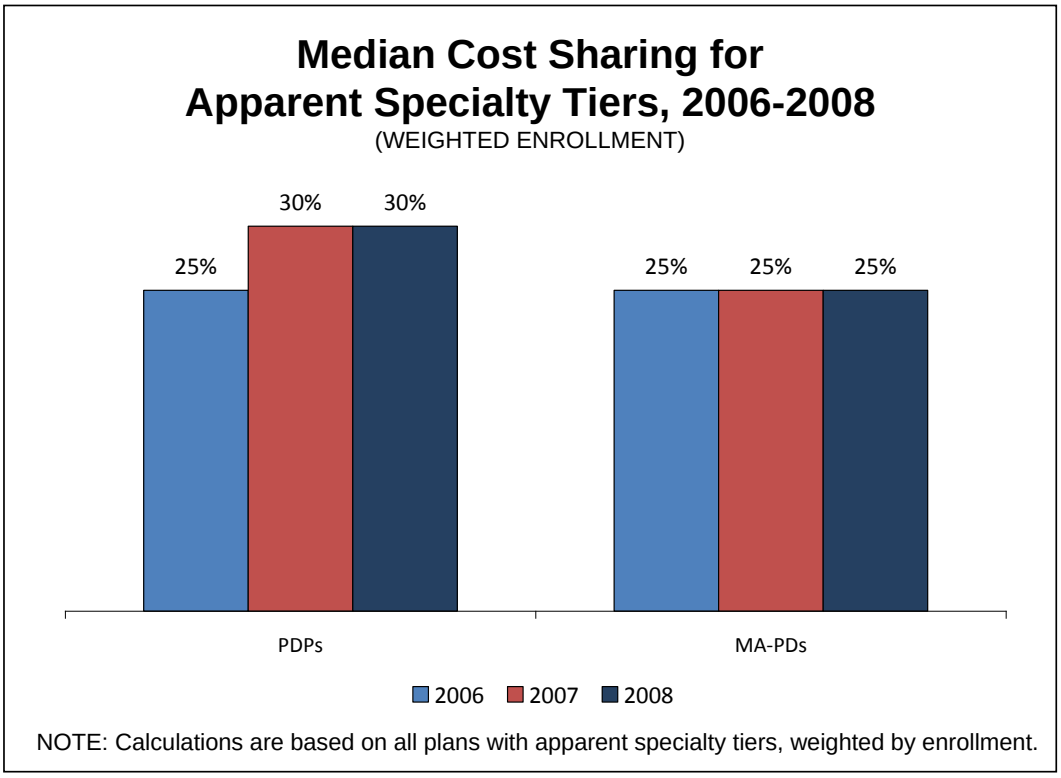
(NOT WEIGHTED BY ENROLLMENT)



NOTE: Calculations are numbers of PDPs, 2008, unweighted.

NOTE: Calculations are numbers of MAPDs, 2008, unweighted.

Despite these shifts, enrollment still favors plans with lower coinsurance for specialty-tier drugs. The enrollment-weighted median copay for specialty tiers has grown from 25 percent to 30 percent in PDPs, but it has remained at 25 percent for MA-PDs. MA-PDs are slightly more likely than PDPs to charge lower coinsurance for specialty tiers, including a small percentage of MA-PDs that charge less than 25 percent (including flat copays).



Because specialty-tier drugs are by definition very expensive, a beneficiary will reach both the coverage gap and catastrophic coverage during a full year of taking a specialty-tier drug. A beneficiary taking a $600 drug monthly for the entire year will reach the $2,510 initial coverage limit in just over four months and the catastrophic cap in about ten months; more quickly if she is taking additional drugs or a more expensive drug. Higher coinsurance during the initial coverage period will not change the timing of when the beneficiary reaches the coverage gap, because the initial coverage limit is based on total spending. If the beneficiary has paid more out of pocket before reaching the gap, however, she will reach catastrophic coverage somewhat earlier in the year – whenever she has paid $4,050 out of pocket.[1] Because the out-of-pocket threshold amount and catastrophic coverage do not vary by plan, plan cost sharing differences during the initial coverage period have little impact on total costs paid by beneficiaries by the end of the year. In four different examples (flat copayments of $25 and $50 and coinsurance of 25 percent and 33 percent) calculated

[1] Initial coverage limit and catastrophic threshold amounts are for 2008.

for a drug priced at $1,000 per month taken all year long, total out-of-pocket costs for the year ranged only from $4,340 to $4,373.

The cost sharing amount paid by the beneficiary in the initial coverage period will affect their pattern of out-of-pocket costs from month to month, so it could have an impact on affordability to the patient – her ability to continue taking the drug before or during the coverage gap. For example, a beneficiary who cannot afford the full $1,000 cost of the drug during the coverage gap may never reach catastrophic coverage. Likewise, a beneficiary who does not need to take a drug for the full year may not reach the catastrophic coverage threshold. These beneficiaries will experience larger differences in total out-of-pocket costs depending on whether they pay lower or higher cost sharing in the initial coverage period.

2008 Analysis

Methodology

For this 2008 analysis, we examined data for both MA-PDs and PDPs, but saw no systematic differences between the two types of plans. Results are reported here for PDPs only. PDPs are included in this analysis only if they clearly labeled a tier as a specialty tier in 2008 (1,262 of 1,824 PDPs in 2008 – fewer than the 1,443 PDPs which we identified with "apparent" specialty tiers in the previous section). We excluded any plans that did not submit tier labels or that have unusual tier designs. Many of these plans use the defined standard benefit, but some may also have specialty tiers. For example, some plans number their tiers rather than providing labels, so there is no way to tell with publicly available information which tier is officially designated a specialty tier. We also excluded "apparent" specialty tiers that were labeled by the plan as being for injectibles or Part B drugs.

As in other analysis we completed recently for MedPAC, we define a drug as a unique chemical entity, for example, combining all brand-name and generic versions of the same chemical entity.[2] Normally in our analysis of plan formularies, we also combine all forms, strengths, and package sizes of the chemical entity. For this analysis of specialty drugs, we found that dosage form – but not strength or package size – affects the consideration of a drug as a specialty drug.

For many drugs, dosage form affects whether a drug is on the specialty tier (likely due to price). For example, Fentanyl (an opioid analgesic) is never a specialty drug as a patch, but it is often a specialty drug as an oral solid. Tobramycin (an antibiotic) is often a specialty drug in the inhaled form used for cystic fibrosis patients. In this analysis, we define "drugs" at the chemical entity x form level. Thus, Fentanyl counts as 4 "drugs":

Dosage Form for Fentanyl	Ever Specialty?
Oral Solid	Yes
Oral Other	Yes
Patch	No
Solution/Suspension/Powder	No

This strategy results in a universe of 1,493 form and chemical entity combinations, which we simply call "drugs" on the following pages. This universe represents an increase over the 1,141 separate chemical entities used in other analysis of formularies for 2008.

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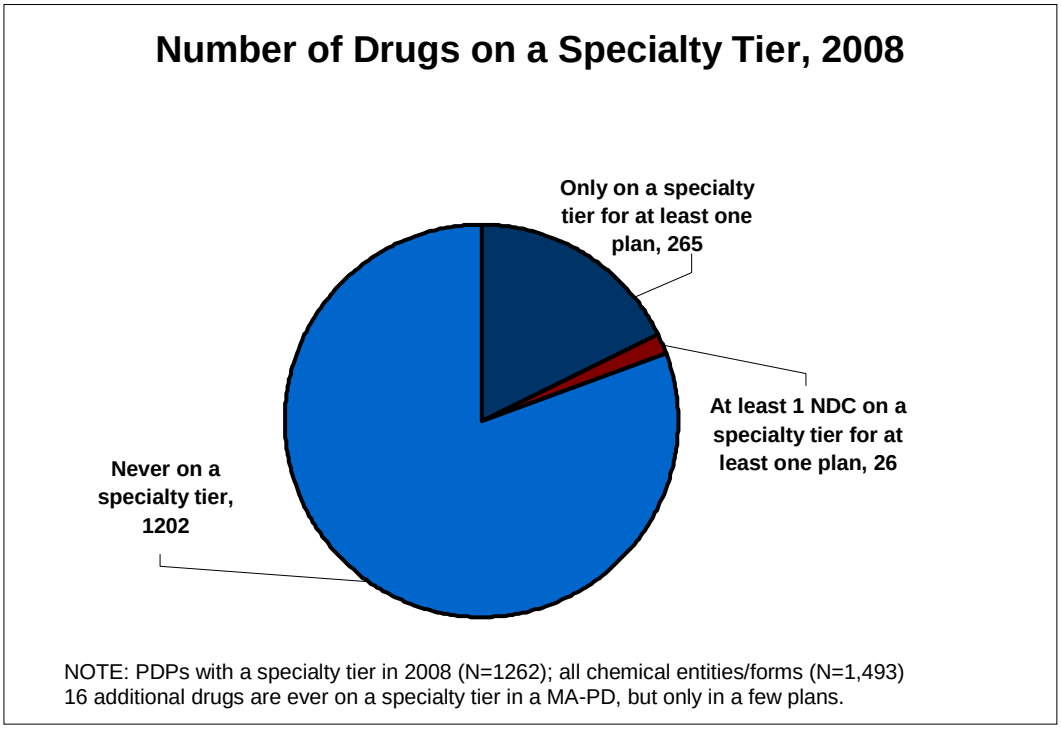
[2] Jack Hoadley, Elizabeth Hargrave, Katie Merrell and Lan Zhao, "Medicare Part D Benefit Designs and Formularies, 2006-2009," presentation to MedPAC, December 5, 2008.

Number of Drugs Ever on a Specialty Tier

Most drugs (81 percent of all possible combinations of chemical entities and forms) are never placed on a specialty tier by any Part D plan. Nearly one in five drugs (291 drugs, or 19 percent) are on a specialty tier in at least one plan. However, as will be shown in a later chart, this does not mean that a fifth of all drugs are *frequently* on a specialty tier.

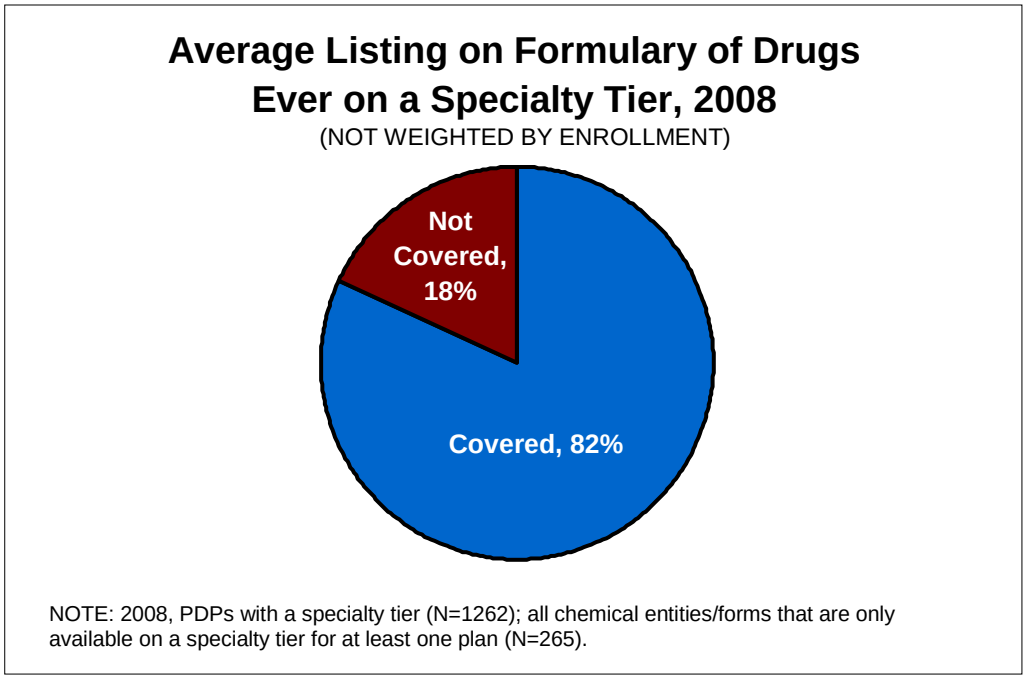
For most of these drugs (265), each plan's formulary treats all NDC codes for a drug as one unit, either placing them all on a specialty tier, all on a different tier, or all off the formulary. For just a small fraction of drugs (26 drugs, or fewer than 2 percent), a plan placed at least one NDC code on a specialty tier, but also placed an NDC code for that drug on a non-specialty tier. For example, there are a few drugs for which a certain strength of a drug is on a specialty tier while other strengths are not. For the purposes of the following analyses, we do not include these 26 drugs as "specialty drugs" because they are always available in a non-specialty version when they are listed by a plan.



The following charts provide more detail on the 265 drugs that at least one plan places only on a specialty tier. We call these drugs "specialty drugs."

Listing of Specialty Tier Drugs

The average specialty drug is listed on formulary by 82 percent of PDPs in 2008. This is slightly lower than the average for non-specialty drugs, which are on formulary for an average of 86 percent of PDPs.



Variation in Placement of Specialty Drugs on Specialty Tier

There is considerable variation in whether plans put a given drug on a specialty tier. Although we have identified 265 drugs as "specialty drugs," no one plan places all of these drugs on a specialty tier, and very few of these drugs are on a specialty tier in every plan. As discussed in the next section, these differences in tier placement can have important implications for beneficiary cost sharing.

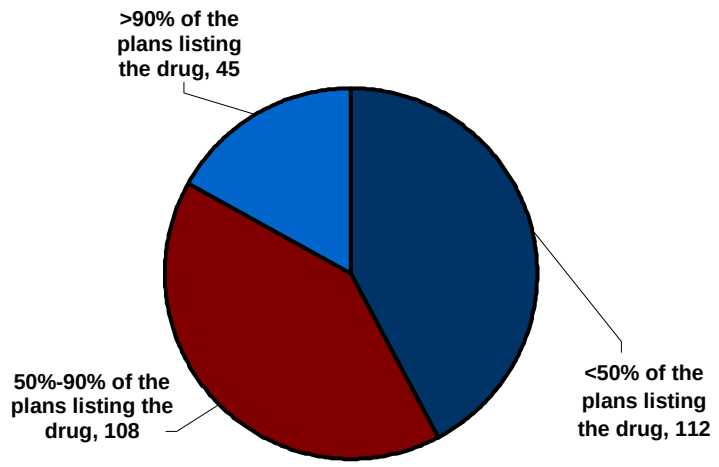
Of the 265 specialty drugs we identified, fewer than one in five (45 drugs, or 17 percent) are placed on a specialty tier in almost all cases, that is, by more than 90 percent of plans that list them on formulary. Even among these drugs, only three (glatiramer/Copaxone, imatinib/Gleevec, and lanreotide/Somatuline) are always on the specialty tier when listed by a plan with a specialty tier. A full list of the drugs that are placed on the specialty tier in more than 90 percent of plans appears on the following page. The list is dominated by cancer therapies and drugs for auto-immune disorders, but also includes drugs to treat AIDS, hepatitis C, and a variety of other conditions.

For other specialty drugs, there is even more variation in whether they are placed on a specialty tier when they are listed. About two in five specialty drugs (108, or 41 percent) are placed on a specialty tier by a majority of plans, but fewer than 90 percent of plans. The remaining two-fifths of specialty drugs (112 drugs, or 42 percent) are placed on a specialty tier in fewer than half of plans.

We did not collect pricing information for this project, so we are not able to determine how often proximity to the $600/month threshold may be causing this lack of uniformity in plan decisions about whether to include a drug on the specialty tier.

Frequency of Placement on Specialty Tier, Specialty Drugs, 2008

(NOT WEIGHTED BY ENROLLMENT)



NOTE: 2008, PDPs with a specialty tier (N=1262); all chemical entities/forms that are EVER available on a specialty tier for any NDC for at least one plan (N=291).

Drugs on Specialty Tier for at Least 90 Percent of Plans Listing Them

Cancer Therapy	Auto-Immune Diseases	Other Conditions
Imatinib	Infliximab (RA, psoriasis)	Cidofovir (AIDS)
Sunitinib	Abatacept (RA)	Enfuvirtide (AIDS)
Temsirolimus	Etanercept (RA, psoriasis)	Botulinum toxin A (Various)
Dasatinib	Adalimumab (RA,psoriasis)	Agalsidase (Fabry disease)
Sorafenib	Alefacept (psoriasis)	Imiglucerase (Gauchers disease)
Erlotinib	Efalizumab (psoriasis)	Immune globulin (immunodeficiency)
Aldesleukin	Natalizumab (MS, Crohns)	Pegademase (immunodeficiency)
Arsenic	Glatiramer (MS)	Interferon gamma (granulomatous disease)
Vorinostat	Interferon beta (MS)	Interferon alfacon (hepatitis C)
Sargramostim	Lenalidomide (multiple myeolma)	Interferon Alfa (HPV)
Filgrastim		Palivizumab (premature infants)
Palifermin		Ziconotide (chronic pain)
Lanreotide Acetate		Tobramycin (antibiotic)
Palonosetron		Somatropin (pituitary stimulant)
Oprelvekin		Treprostinil (pulmonary hypertension)
		Bosentan (pulmonary hypertension)
		Basiliximab (anti-rejection)

Tier Placement of Specialty Drugs When Not on a Specialty Tier

As shown in the previous exhibit, most drugs that appear on specialty tiers are not universally placed there by the plans that list them on formulary. For each of the 265 drugs that are placed on at least one PDP's specialty tier, we determined the share of plans assigning the drug to various different tier.

Because of variation in plan decisions about whether to place drugs on a specialty tier, PDPs place the average specialty drug on a specialty tier just over half the time (56 percent).[3] The most important implication of this variation in tier placements is the cost sharing faced by a beneficiary for these drugs.

When plans list these drugs on formulary but do not place them on a specialty tier, they most often place the drugs on a preferred brand tier or a single tier for brand drugs (18 percent). These tiers are likely to have a flat copay; in 2008, the median copay for a preferred brand tier was $30. This amount is considerably below the coinsurance on a specialty tier, which amounts to at least $150 (25 percent coinsurance for a drug at the minimum monthly cost of $600).

It is also somewhat likely that a plan will place a specialty drug on a non-preferred tier (14 percent). These tiers most commonly have flat copays typically about $70, but in a small number of plans they have coinsurance even higher than the 25 to 33 percent coinsurance typical of specialty tiers.

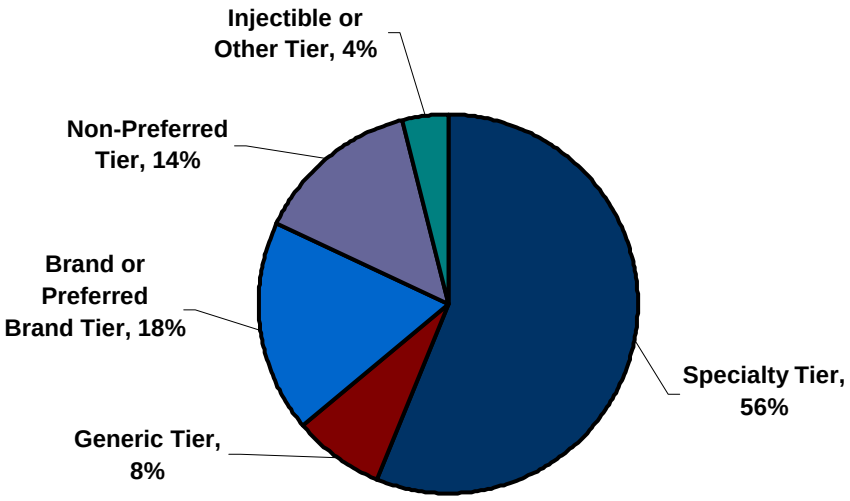
Most specialty drugs are branded drugs. Thus, it is not surprising that plans with specialty tiers rarely place specialty drugs on a generic tier, but it does happen 8 percent of the time – presumably for drugs that are costly even when sold as generics. In most plans, placement on a generic tier means a very low copay, typically about $5 in 2008.

A small number of plans have additional tiers specifically for injectible drugs, drugs that are usually covered by Part B, or other special cases. These tiers often have the same coinsurance as a plan's specialty tier. Plans place specialty drugs on these tiers only 4 percent of the time, in part because these tiers are less common.

[3] The numbers shown in the chart represent averages, calculated across the 265 drugs that are ever on a specialty tier, of the percentage of plans placing each drug on a particular tier. Averages are not weighted by enrollment.

Average Tier Placement of Specialty Drugs, 2008

(NOT WEIGHTED BY ENROLLMENT)



NOTE: PDPs with a specialty tier (N=1262); all chemical entities/forms that are only available on a specialty tier for at least one plan (N=265). If plans have multiple tier placements for one drug, we use the most favorable.

Utilization Management for Specialty Drugs

In addition to the high costs they face for specialty drugs, beneficiaries are also fairly likely to face utilization management hurdles that can delay or restrict their access to a given drug. Steps that create hurdles for beneficiaries and their physicians are viewed by plans as tools to ensure appropriate use of these expensive drugs. Specialty drugs are nearly twice as likely as other drugs to be subject to utilization management measures (37 to 38 percent vs. 20 percent). The measures flagged in CMS's formulary database are prior authorization, quantity limits, and step therapy.

The contrast is even more striking when looking specifically at the use of prior authorization. Non-specialty drugs are subject to prior authorization just 6 percent of the time when they are listed on formulary, but specialty drugs are subject to prior authorization 34 to 35 percent of the time. Because prior authorization is a labor intensive process, plans are more likely to use this tool for more expensive drugs such as those that are placed on specialty tiers.

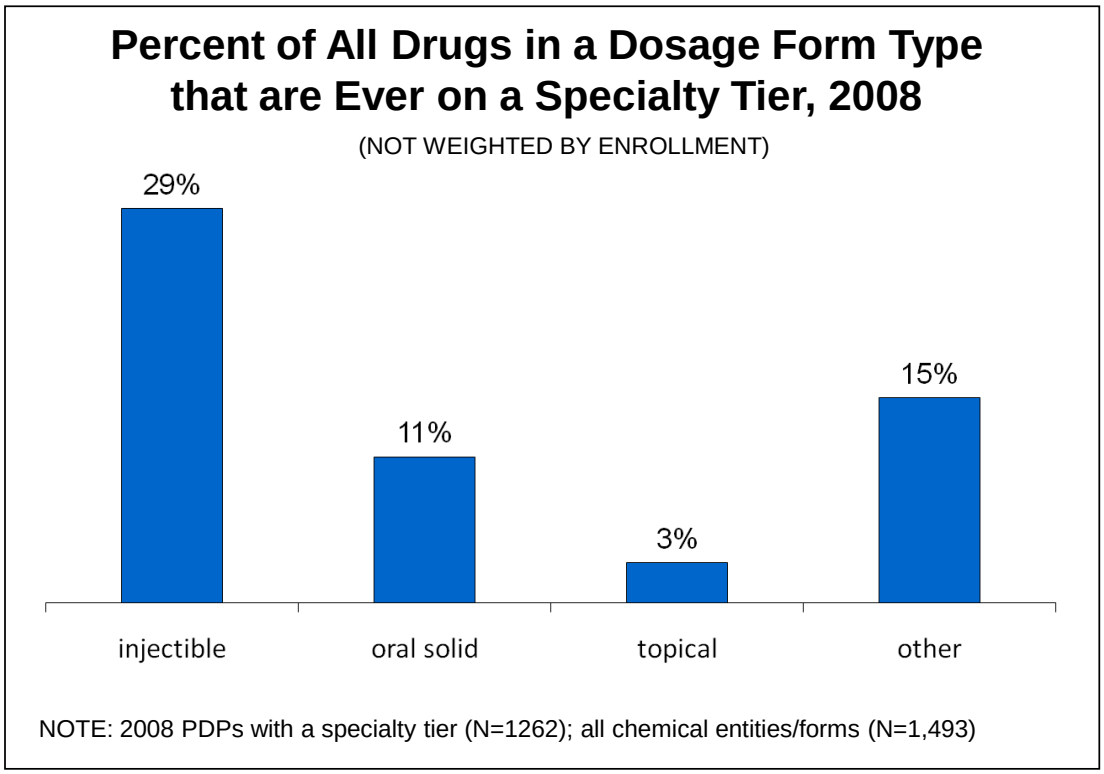
Interestingly, specialty drugs are about equally likely to be subject to these utilization management measures regardless of whether they are on a particular plan's specialty tier. In other words, the use of a specialty tier seems not to preclude a plan's reliance on prior authorization to help manage the appropriate use of these drugs.

	Drugs Never on Specialty Tier	Drugs Ever on Specialty Tier
Share of PDPs Applying Utilization Management, if Listed on Formulary:		
Not on Specialty Tier	20%	37%
On Specialty Tier		38%
Share of PDPs Applying Prior Authorization, if Listed on Formulary:		
Not on Specialty Tier	6%	34%
On Specialty Tier		35%

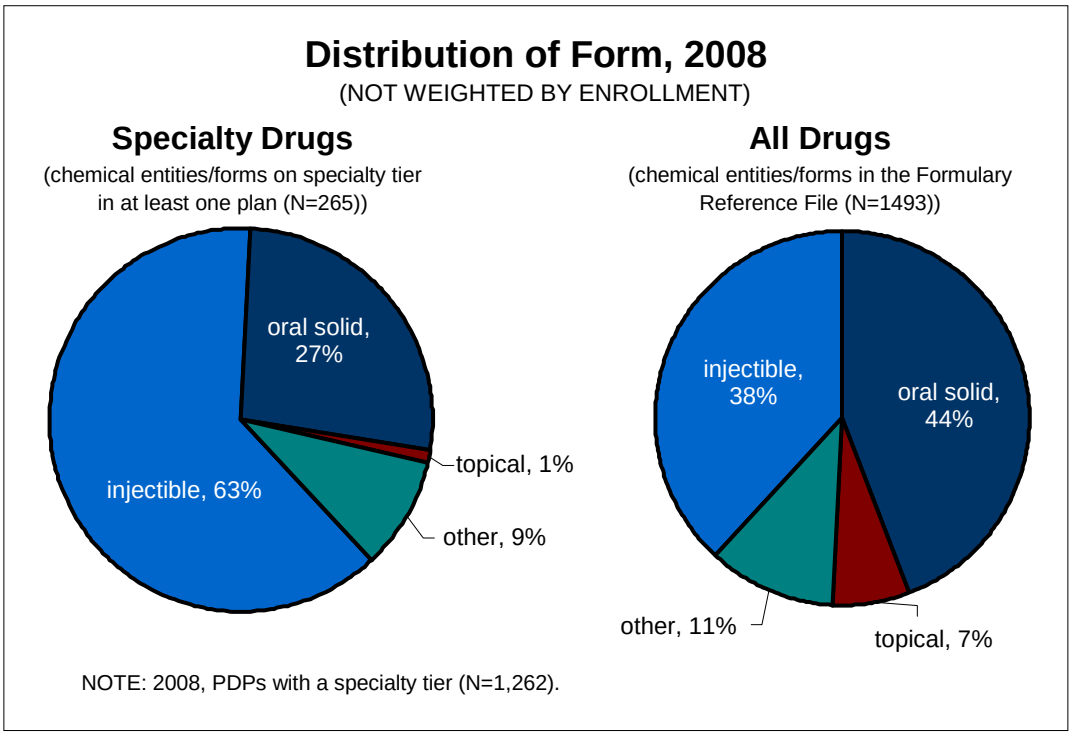
Characteristics of Specialty Drugs: Form

Injectible drugs are more likely than any other dosage form to be placed on a specialty tier, and the majority of specialty drugs are injectibles. Many injectibles are biologics that are costly to produce, pushing the monthly cost of these drugs over CMS's $600 minimum monthly price threshold.

Nearly a third of all injectible drugs are on a specialty tier in at least one plan, while only one in ten pills are ever placed on a specialty tier.



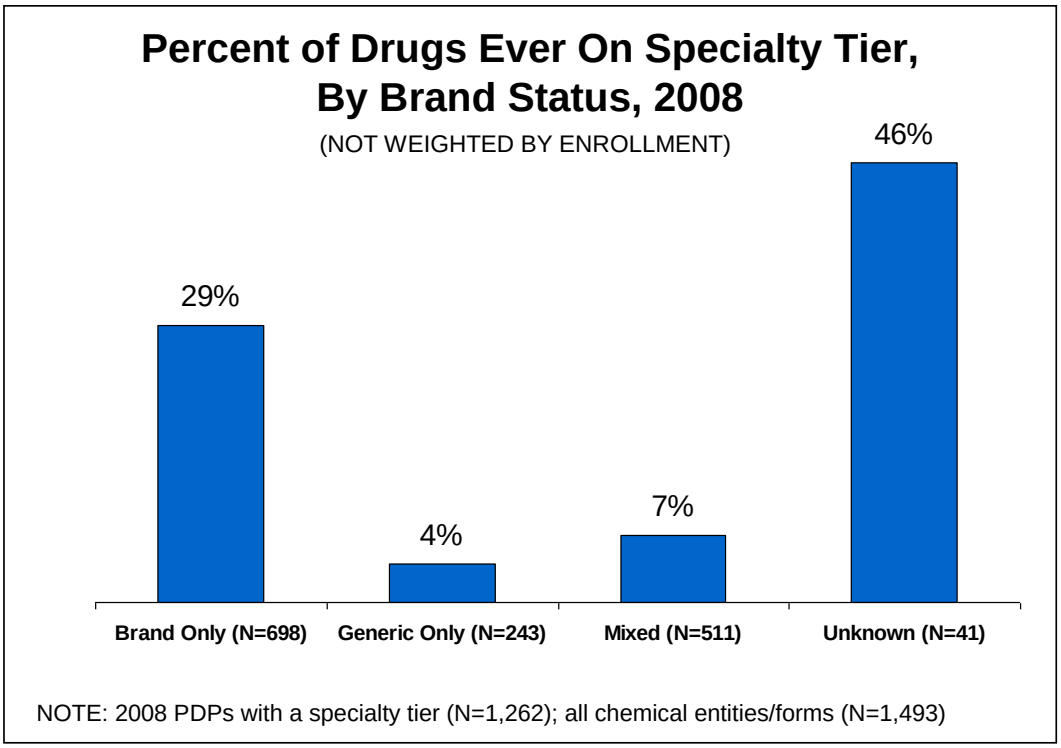
As a result of the likelihood that injectibles will be placed on a specialty tier, nearly two-thirds of specialty drugs are injectibles, even though injectibles make up closer to one-third of all drugs.



Characteristics of Specialty Drugs: Brand Status

Drugs available only as brands are much more likely than other drugs to be placed on a specialty tier, and the majority of specialty drugs are only available as brands. Drugs tend to be more expensive while they are still on patent, and many of the drugs listed on specialty tiers are fairly recent. In addition, many specialty drugs are biologics that have no pathway for direct generic competition.

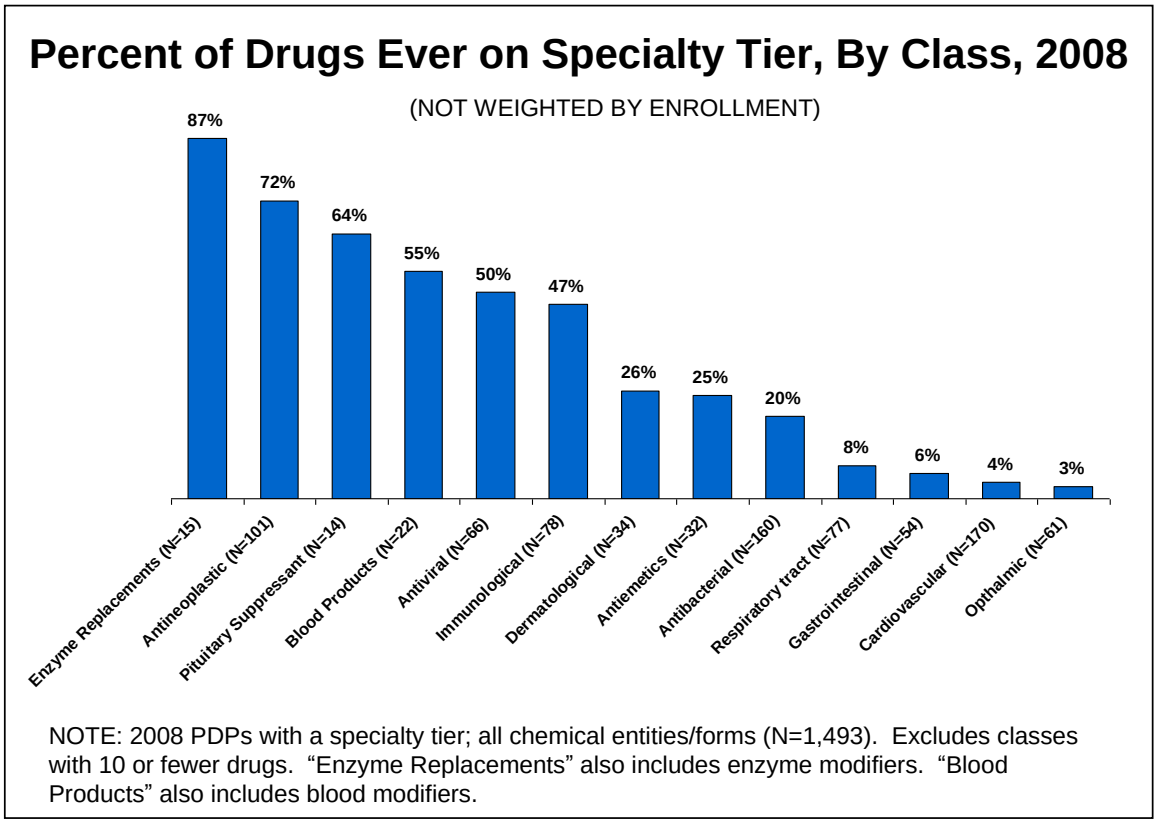
Drugs only available as brands are placed on a specialty tier almost a third of the time. (Drugs with "unknown" brand status are probably brands; those labeled "mixed" have both brand and generic versions or brand and "unknown" versions.)



Characteristics of Specialty Drugs: Therapeutic Class

Some classes are much more likely than others to be on a specialty tier; in six classes, drugs are on a specialty tier about half the time or more. Three of those classes are relatively small: enzyme replacements and modifiers, pituitary suppressants, and blood products and modifiers (including erythropoetins, or EPO). The others are large classes that are also "protected classes" under CMS rules: antineoplastics (cancer therapies such as Gleevec) and antivirals (including HIV drugs), as well as the class of immunological drugs that includes the protected immune suppressant drugs for transplant patients. Plans are required to list on formulary most or all of the protected drugs in these classes.

Classes with drugs for many common chronic conditions (Cardiovascular, Respiratory, Gastrointestinal) are mostly not on specialty tiers.



NOTE: 2008 PDPs with a specialty tier; all chemical entities/forms (N=1,493). Excludes classes with 10 or fewer drugs. "Enzyme Replacements" also includes enzyme modifiers. "Blood Products" also includes blood modifiers.

Drugs in just four classes account for nearly two-thirds of specialty drugs. These four classes include the three large classes with a high rate of placement on specialty tiers (Antineoplastics, Immunologics, and Antivirals), as well as Antibacterials, a very large class whose drugs are placed on a specialty tier about 20 percent of the time. Antineoplastics alone make up over a quarter of all specialty drugs.

Although they make up a large share of specialty drugs, these four classes make up only a fourth of all drugs.