Specialty Tiers: Benefit Design Considerations for Medicare Part D

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Executive Summary

Today's specialty drugs include the latest product innovations used to treat complex, chronic, rare, and life-threatening conditions and are used by thousands of patients. However, the costs of these medical treatments can range from several hundred to thousands of dollars. For people with health insurance, this cost may be split between the patient and the patient's prescription drug coverage. In the Medicare prescription drug program (Medicare Part D), most Part D sponsors have established benefit designs with coinsurance from 25% to as much as 33% for specialty drugs (as defined by the Centers for Medicare and Medicaid Services [CMS]). Part D plans normally include these drugs in a separate tier, known as the specialty tier.

This paper considers the following questions:

- How much do specialty-tier drugs add to costs for Medicare Part D plans (PDPs)?
- What are benefit design alternatives to covering specialty-tier drugs without utilizing specialty tiers?
- How will individuals' out-of-pocket costs vary with coverage design?
- What are the demographic characteristics of Part D users of specialty-tier drugs?
- What is the impact to members, Part D sponsors, and federal reinsurance from eliminating specialty tiers?

High cost sharing for drugs can create an affordability issue for some members. Flat dollar co-payments, such as $50 per script, can be considered expensive, but 33% coinsurance can require much higher patient out-of-pocket payments for expensive drugs. This study is intended to convey information about the relationship between benefit designs, costs to payers, and members' out-of-pocket costs for specialty-tier drugs.[1]

As shown in the body of the report, "actuarially equivalent" benefit designs can be used to reduce the member's out-of-pocket spending on specialty-tier drugs through increases in cost sharing for other drugs. We found that a typical PDP could move all covered specialty-tier drugs to other brand tiers and provide a similar actuarial value through an increase in cost sharing of $7 per non-preferred brand script, or $1 per preferred brand script, or a $5 increase in the deductible, assuming no change in the underlying population or drug utilization patterns.

Beneficiaries using specialty-tier drugs through the year will likely reach the catastrophic coverage limit (i.e., the cost threshold at which 80% federal reinsurance begins) under any of the basic Part D plans. For beneficiaries who use no specialty-tier drugs, the alternative designs that reduce out-of-pocket spending on specialty-tier drugs would result in a relatively small increase in cost sharing. The biggest proportional impact would be on beneficiaries using specialty-tier drugs but not spending enough to reach the coverage gap limit. These beneficiaries could see a large decrease in cost sharing.

1. Because Medicare beneficiaries who receive low-income subsidies are not subject to high cost sharing, we have excluded them from our benefit options modeling.

Removing the specialty tier also has an impact on federal reinsurance spending, as the lower initial cost sharing delays the accumulation of members' out-of-pocket expenses (TrOOP) until the coverage gap, and therefore delays entrance into the catastrophic coverage benefit corridor. This would reduce federal reinsurance payments to plans by between 1% and 2%, through increases in plan liability or member cost sharing.

The benefit design changes modeled in this report do not impact premium amounts. Because actuarially equivalent and basic alternative plans must provide the same value as the defined standard Part D coverage, any benefit enhancement that would increase the actuarial value of the coverage needs to be balanced by a corresponding decrease in benefits to maintain the equivalence. Thus, the resulting premium for alternative coverage would be consistent with the basic Part D premium charged for the defined standard Part D plan.

As with other segments of the economy, it is impossible to precisely predict the impact of specialty medicines on health care costs. The reader should consider that the figures in this report are based on assumptions and cannot capture impacts such as changes in the regulatory environment or scientific developments, so these figures should be reviewed carefully for their applicability for any particular purpose. The figures presented in this report are national averages developed from historical databases. Actual results will likely differ for many reasons, including statistical fluctuations.

This report was funded by Pfizer Inc. It should not be interpreted as an endorsement of any particular legislation by Milliman. Two of the authors, Gabriela Dieguez and Bruce Pyenson, are members of the American Academy of Actuaries and meet the qualification standards to render the opinions expressed in this report. The report reflects the authors' findings and opinions. Because extracts of this report taken in isolation can be misleading, we ask that this report be distributed only in its entirety.

Background on Specialty-tier Therapies in Medicare Part D

Today's specialty drugs include the latest product innovations used to treat complex, chronic, rare, and life-threatening conditions and are used by thousands of patients. The term "specialty drug" is not consistently defined. Specialty drugs often consist of complex molecules and may include bioengineered proteins and blood derivatives. Many specialty drugs are administered to the patient by injection or infusion in the physician's office or are self-injected; however, they can be oral drugs. They may require special handling such as refrigeration or radiation shielding. These drugs are often considered high-cost, with a prescription ranging in cost from several hundred to thousands of dollars.

Prescription drug tiers are used in insurance benefit designs to apply different cost-sharing levels to different categories of drugs. Traditional drug benefit plans have fixed co-payments for drugs using the standard three tiers (generics, preferred brands, and non-preferred brands). In the Medicare prescription drug program (Medicare Part D), most Part D sponsors have established benefit designs with coinsurance from 25% to as much as 33% for specialty drugs (as defined by the Centers for Medicare and Medicaid Services [CMS]), and plans include these drugs in a fourth tier commonly known as the specialty tier.

Virtually all Medicare prescription drug plans (PDPs) that use co-payment structures (tiered benefits) have created a specialty tier for Medicare Part D drugs.[2] CMS allows the use of specialty tiers in Part D if formularies and benefit designs comply with the following:

- Only one tier is designated as a specialty tier.
- Cost sharing in the specialty tier is limited to a maximum of 25% after the deductible and before the initial coverage limit – or limited to 33% in plans with decreased or no deductible under alternative prescription drug coverage designs.
- Only Part D drugs with sponsor-negotiated prices that exceed the dollar-per-month amount established by CMS in its annual Call Letter may be placed in the specialty tier. This threshold has been set at $600 for the past five years.

The focus of this paper is specialty-tier drugs—drugs that are placed on a specialty tier in the Medicare Part D program. Specialty-tier drugs, as they are defined in Medicare Part D, do not include drugs covered through Medicare Part A or Part B, such as drugs administered in a hospital, hospital outpatient setting, or physician office.

Why are specialty tiers an issue?

Payers create specialty tiers to help manage the cost of certain drugs. Drug benefit formulary tiers are designed to encourage patients to use less costly alternatives. However, in the case of specialty tier drugs, there may be fewer, if any, less costly alternatives.

CMS believes specialty tiers in Part D allow plans to "appropriately project drug costs and calculate risk, allowing for lower cost sharing on non-specialty tier drugs, and promoting a tiered co-payment structure for generic and brand drugs."[3] However, cost-sharing amounts for high-cost specialty-tier drugs can be

2. Hoadley, J. et al. (September 2011). *Analysis of Medicare Prescription Drug Plans in 2011 and Key Trends Since 2006*. Kaiser Family Foundation Issue Brief. Retrieved from http://www.kff.org/medicare/upload/8237.pdf.
3. CMS Medicare Prescription Drug Benefit Symposium, March 2010.

significant and shift more of the cost of the drug onto the patient who uses these drugs. For example, a specialty tier 25% coinsurance on a $600/month drug is equivalent to a co-payment of $150. By contrast, the CMS-established co-payment limit for the non-preferred, non-specialty drug tier is $95[4] (2013), a $55 difference.

In general, as cost sharing increases, utilization decreases. Studies have linked high patient out-of-pocket costs to decreasing adherence to medications. These studies, which focused on specific disease populations, suggest that prescription abandonment rates increase with patient cost-sharing amounts above $100.[5,6] The high cost-sharing requirement for the specialty tier could discourage some patients from initiating or completing a high-cost treatment.

[4] This maximum also applies to plans designs with coinsurance values in excess of the standard benefit of 25%.

5. Streeter, S.B., Schwartzberg, L., Husain, N.,Johnsrud, M. (2011). Patient and plan characteristics affecting abandonment of oral oncolytic prescriptions. *American Journal of Managed Care*. 2011;17(5 Spec No.):SP38-SP44.
6. Gleason, P. et al. (2009). Association of prescription abandonment with cost share for high-cost specialty pharmacy medications. *Journal of Managed Care Pharmacy, 15*(8): 648-58.

How much do specialty-tier drugs contribute to payer costs?

We estimate that specialty-tier drug costs in 2012 were about $31 per member per month (PMPM) (before cost sharing) for Part D plans for Medicare, aged, non-dual beneficiaries. To help put these figures in perspective, we provide nationwide average PMPM costs for several health services in Figure 1, which shows that spending on specialty-tier drugs represents a small percentage of overall spending on drugs. Overall drug spending represents about one-quarter of Medicare health care spending for this population.

Figure 1: Specialty-Tier Drug Spending Compared With Other Categories of Health Care Spending, 2012

Medicare, Aged, Non-dual Population	
	Estimated 2012 Gross PMPM Spending[7]
Service Category	
Drug Spending:	
Non-specialty-tier drugs in Part D	$248
Specialty-tier drugs in Part D	31
Specialty drugs covered under medical benefit	23
Other Spending:	
Hospital inpatient	$351
Skilled nursing	84
Hospital outpatient	156
Physician	321
Other	34

The above figures do not include plan administrative costs and are before a reduction for member cost sharing.

There is broad concern that expensive biotechnology products may consume an increasing portion of future health care spending. Whether this increase affects the outpatient prescription drug benefit design elements, such as the specialty tier, depends on whether these drugs will be paid through the medical or prescription drug benefit. To shed light on this issue, the authors examined investment analysts' forecasts for the products we consider specialty-tier drugs.

Forecasts for new specialty drugs come with uncertainty. Any such forecast must balance many factors, including the likelihood of new drug approvals, patent expirations and the introduction of biosimilars, future prices, and, of course, the use of these drugs. Our examination, which is not reported further in this document, does not clearly indicate that the portion of health care spending on specialty-tier prescription drugs will increase rapidly.

7. Milliman Ages 65 and Over Health Cost Guidelines™ (2012).

Background on Actuarial Equivalence

What is actuarial equivalence?

Two different benefit designs are "actuarially equivalent" if they provide, on average, the same total expected benefit value. Actuarial equivalence is determined for a benefit design based on the population's expected average cost. The concept of actuarially equivalent benefit designs is widely used in the insurance industry and is used by Medicare to regulate Part D benefit designs, where "actuarial equivalence" relates to permissible variations on the Defined Standard Part D plan.

Because equivalence is determined across a population of members, it does not guarantee that members with higher- or lower-than-average claim costs will experience the same out-of-pocket costs under two equivalent plan designs. Benefit differences between two actuarially equivalent plans can have a very different impact on out-of-pocket costs for members whose drug expenditures are much higher or lower than the average population drug expenditures. This is the case for beneficiaries requiring costly specialty-tier drugs, because coinsurance for these drugs results in larger than average out-of-pocket expenses.

For this analysis, we modeled Part D actuarially equivalent plan designs with the goal of quantifying the impact of eliminating the specialty tier (with coinsurance ranging from 25% to 33%) and moving specialty-tier drugs into a three-tier prescription drug benefit structure. We note that the term "actuarially equivalent" can have two meanings: It can refer to equivalence in expected value, as described above, or it can indicate a specific type of basic Part D coverage as defined by CMS. We use the broad definition in this report unless indicated otherwise.

Because much of the language is technical, with terms that are specific to the Medicare Part D benefit, we provide background on the Part D program and include basic definitions in the next section.

Background on the Medicare Part D Prescription Drug Benefit

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added a prescription drug benefit for Medicare-eligible beneficiaries, termed "Part D." Part D provides prescription drug benefits to those who enroll in the program and pay a monthly premium. The program design generally promotes competition among companies selling prescription drug benefits (Medicare Advantage Prescription Drug-MA-PD and Prescription Drug Plan-PDP-plans) and encourages Medicare beneficiaries to shop for the plan that provides them with the best value.

Standard Part D benefits

The standard Part D benefit is designed to provide substantial drug coverage, but it includes a complex cost-sharing structure. Under **defined standard** (DS) Medicare coverage in 2013, the enrollee pays[8]:

- A $325 deductible.
- A 25% coinsurance for annual drug spending between $325 and $2,970 (the initial coverage limit, or ICL).
- A 79% coinsurance on generic drugs and 47.5% on brand drugs, for annual drug spending between $2,970 and $6,954.52[9] (the coverage gap), up to the true out-of-pocket (TrOOP) threshold of $4,750.
- For annual drug spending over $6,954.52 (catastrophic corridor), the greater of:
  - A 5% coinsurance.
  - A $2.65 copayment for generics or multi-source preferred drugs.
  - A $6.60 copayment for all other drugs.

Each year, CMS changes these thresholds within the benefit corridors to reflect changes in drug spending.

PDP benefit options

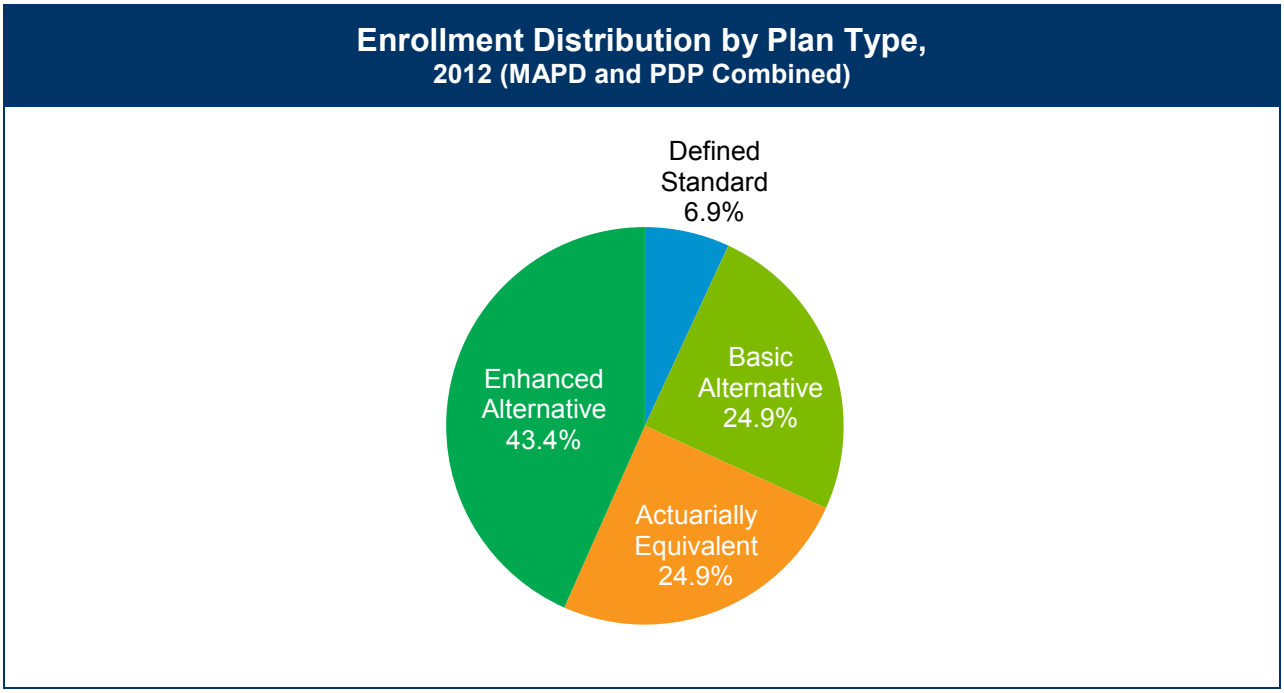
Two of the alternatives to the DS plan are called **actuarially equivalent** (AE) and **basic alternative** (BA) plans, and are based on the benefit value of the defined standard. These three plans make up the "basic" coverage options available to Medicare beneficiaries.

About 57% of Part D enrollees in Medicare Advantage Prescription Drug (MA-PD) and PDP plans had **basic coverage** (DS, AE, and BA plans) in 2012.[10] The remainder of Part D members have **enhanced alternative coverage**, which are plans with additional features—such as reduced cost sharing, expanded drug product coverage, low or no deductible, or gap coverage—that charge higher premiums. Most enhanced alternative plans use a specialty tier. Enhanced alternative plans are often offered by MA-PD

8. Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, p. 39. Center for Medicare and Medicaid Services, April 2, 2012.
9. The TrOOP parameter shown is the estimated gross spending for applicable beneficiaries (those eligible for the gap discount program). Non- applicable beneficiaries are subject to a TrOOP of $6,733.75.
10. Milliman analysis of 2012 CMS Part D Landscape Source Data.

organizations because they can buy-down the higher Part D premium with Part C surplus rebates. We note that the Medicare Advantage phased-in payment reductions to Part C that started in 2012 may limit the ability of MA-PD plans to offer enhanced coverage in the future. The chart in Figure 2 shows the distribution of enrollment by type of plan.

Figure 2: Enrollment Distribution by Plan Type



Source: Milliman analysis of 2012 CMS Part D Landscape Data.

Because the majority of Part D enrollees are in plans with basic coverage, we focus our modeling on benefit design options for these plan types. It is important to note that both the AE and BA options must be actuarially equivalent to the DS plan, even with varying benefit designs and cost-sharing requirements. That is, the value of the coverage is equal to the value provided by the DS plan. Therefore, these plans are only allowed to charge a basic Part D premium similar to that of the DS plan. Furthermore:

- Actuarially equivalent (AE) plans must use the same deductible and initial coverage limit (ICL) as the DS plan. Plans can change cost sharing up to the ICL and/or within the catastrophic coverage portion of the benefit, from the DS amounts. Alternatives include the use of tiered co-payments for generics, preferred, or non-preferred drugs. However, within the initial coverage limit and catastrophic corridor, the actuarial value of the benefits must be the same as for the DS plan

- Basic alternative (BA) plans can reduce the deductible, change the initial coverage limit, and vary cost sharing in any period from the DS provisions, including use of tiers, as long as the design passes specific actuarial equivalence tests outlined in the CMS regulations

Enhancements introduced by the Affordable Care Act

The Affordable Care Act (ACA) introduced enhancements to the Part D program. Starting January 1, 2011, patients that enter the coverage gap (from the ICL to TrOOP) received a 50% discount on covered brand-name drugs purchased at a pharmacy or by mail order. The discount is subsidized by the pharmaceutical manufacturers, and is referred to as the Coverage Gap Discount Program.

In addition, Part D plans began to cover a portion of drug spending in the coverage gap, starting in 2011 for generic drugs and in 2013 for brand drugs. When fully implemented by 2020, Part D will cover 25% of the cost of brand drugs and 75% of the cost of generic drugs in the coverage gap. Combined with the 50% brand discounts from manufacturers, beneficiaries will eventually pay 25% coinsurance from the time they satisfy their deductible until they reach the catastrophic threshold. This change is also known as "the closing of the Part D coverage gap."

The analyses reported in this paper take into account these enhancements unless noted otherwise.

The Medicare Low-Income Cost-sharing Subsidy (LICS)

Part D cost sharing is either zero or greatly reduced for Medicare low-income (LI) beneficiaries, funded by the low-income cost-sharing subsidy (LICS). Qualifying enrollees fall into one of four categories that define their reduced cost sharing (2013 values):

- Institutionalized enrollees at or below 150% of the federal poverty level (FPL) pay no cost sharing.
- Enrollees at or below 100% of FPL pay no deductible and a $1.15 / $3.50 generic / brand co-payment up to the catastrophic limit.
- Enrollees between 100% and 135% of the FPL pay no deductible and a $2.65 / $6.60 generic / brand copayment up to the catastrophic limit.
- Enrollees between 135% and 150% of the FPL pay a $66 deductible, 15% coinsurance up to the catastrophic limit, and a $2.65 / $6.60 generic / brand co-payment after that.

For all four categories, the TrOOP accrues as if the low-income (LI) enrollee were paying the plan's regular cost sharing. In other words, for the purpose of calculating federal reinsurance amounts, cost-sharing subsidy amounts are considered part of an enrollee's out-of-pocket cost.

Because LI members are subject to only minimal cost sharing, we have excluded them from our benefit options modeling. As discussed later in this report, LI members have higher use of specialty tier drugs than NLI members.

Results: Benefit Design Alternatives and Considerations

This section explores important considerations and several benefit design alternatives for PDPs to cover specialty-tier drugs without utilizing specialty tiers, while still meeting CMS's actuarial equivalence requirements.

Modeling the impact of the elimination of specialty tiers in Part D

We modeled Medicare Part D actuarially equivalent plan designs to quantify the impact of eliminating the specialty tier and moving specialty-tier drugs into a three-tier prescription drug benefit structure. Our modeling incorporates the changes in the coverage gap introduced by the PPACA (i.e., 50% manufacturer's discount on brands, 21% coverage for generic drugs, and 2.5% coverage for brand drugs in the gap for 2013).

We present our results for three scenarios. Scenario 1 shows our estimates assuming all plans are required to make the change to a 3-tier structure (that is, there is a change in current CMS policy so that specialty tiers are prohibited). Scenarios 2 and 3 provide sensitivity testing of our results. We include these scenarios to illustrate the impact of adverse selection, if there is no across-the-market move to eliminate the specialty tier. That is, Scenarios 2 and 3 consider the adverse selection that could occur if some plans choose to eliminate specialty tiers and others do not make the benefit design change.

The scenario descriptions are as follows:

- Scenario 1: Prohibition on specialty tiers in Part D – assumes current specialty-tier drug spending levels for 2013 (no adverse selection).
- Scenario 2: No prohibition on specialty tiers in Part D – assumes that adverse selection would cause a two-fold increase in specialty-tier drug spending for 2013 for the plans that choose to eliminate the specialty tier.
- Scenario 3: No prohibition on specialty tiers in Part D – assumes that adverse selection would cause a four-fold increase in specialty-tier drug spending for 2013 for the plans that choose to eliminate the specialty tier.

We use AE and BA plans in our modeling, although similar techniques and results would apply to enhanced alternative plan designs.

Eliminating the specialty tier results in minimal increase in cost sharing on other tiers

We found that a typical PDP could move all covered specialty-tier drugs to other brand tiers and provide a similar actuarial value through an increase in cost sharing of $3 to $5 per non-preferred brand script, or $0.50 to $2 per preferred brand script, or a $4 increase in the deductible, in the absence of adverse selection.

Figure 3: Sample Actuarially Equivalent Benefit Designs, Cost Sharing up to the ICL, 2013

Scenario 1: All Plans Eliminate the Specialty Tier			
Plan Type	Four-Tier Benefit Structure [a] Baseline	Actuarially Equivalent Three-Tier Benefit Structure Option 1 [b]	Actuarially Equivalent Three-Tier Benefit Structure Option 2 [b]
Basic Alternative (BA)	$0 deductible $7 / $42 / $80 / 33%	$0 deductible $7 / **$42.50** / $80	$0 deductible $7 / $42 / **$83**
Actuarial Equivalent (AE)	$325 deductible $6 / $25 / $45 / 25%	$325 deductible $6 / **$27** / $45	$325 deductible $6 / $25 / **$50**
Basic Alternative (BA)	$125 deductible $6.50 / $35 / $70 / 25%	**$129** deductible $6.50 / $35 / $70	

[a] *Generic/preferred non-preferred/specialty*
[b] *Generic/preferred/non-preferred, no gap coverage; specialty drugs included in Tiers 2 and 3.*
[a, b] *Mail order co-payment 3 times retail co-payment.*

As shown in Figure 3, we estimate that, to maintain actuarial equivalence, shifting the fourth tier (specialty tier) drugs in a BA benefit design to other tiers will increase the second tier (preferred brand) co-payment by $0.50 **OR** the third tier (non-preferred brand) co-payment by $3. This assumes no co-payment changes in the other tiers.

Figure 3 also shows that shifting the fourth tier drugs for an AE benefit design to other tiers would require a $2 increase in the second tier co-payment to maintain actuarial equivalence, **OR** a $5 increase in the third tier co-payment, assuming no co-payment changes in the other tiers.

Finally, the third example shows that, after shifting the fourth tier drugs to other tiers, a BA plan must increase its deductible by $4 to maintain actuarial equivalence, assuming no cost-sharing changes in any of the tiers.

In our modeling, when the specialty tier is eliminated, most of these covered Part D drugs shift to the non-preferred brand tier (third tier) with others included in the preferred brand tier (second tier).

As discussed above, basic Part D plans cannot pass on the additional cost (of eliminating the specialty tier and moving specialty-tier drugs into a three-tier prescription drug benefit structure) to members in the form of premium (i.e., basic plans cannot charge an additional "supplemental" premium). Therefore, the only benefit design option plans have to compensate for removing the specialty tier is to increase member cost sharing on other tiers or the deductible.

As shown later in this report, few members utilize specialty-tier therapies, which is one of the factors that makes it possible for plans to eliminate the specialty tier with only modest changes in benefit design. In addition, most beneficiaries who use specialty-tier drugs reach the coverage gap. These beneficiaries would reach the coverage gap even if there were no specialty tier. Thus, this is another contributing factor to the fairly modest increase in cost sharing in other tiers after removing the specialty tier.

Impact of eliminating the specialty tier on member costs

The impact of removing the specialty tier on a member's out-of-pocket costs will vary depending on which drugs the member utilizes, on which tiers those drugs are placed, and the member's total and out-of-pocket accumulated spending. Details of our modeling are discussed in the Methodology section.

The elimination of the specialty tier may result in lower cost sharing for specialty-tier drugs. This lower cost sharing could, in principle, encourage greater use of specialty-tier drugs. However, it is our opinion that the existence of the coverage gap in the Part D benefit design largely eliminates this potential "induced" utilization. Relatively few beneficiaries use specialty-tier drugs, and most who do reach the initial coverage limit fairly quickly. Thus, the lower cost sharing (before the gap is reached) may not induce much greater utilization.

Beneficiaries who use specialty-tier drugs through the year will likely reach the catastrophic coverage threshold under any of the basic Part D plan options. For beneficiaries who do not use specialty-tier drugs, the alternative designs suggested above would result in relatively little increase in cost sharing. The biggest proportional cost impact of eliminating the specialty tier would be on beneficiaries using specialty-tier drugs but not spending enough to reach the coverage gap, although they are the minority of specialty users, as shown in Figure 6. These beneficiaries could see a large decrease in cost sharing.

Modeling adverse selection: Scenarios 2 and 3

Adverse selection occurs when individuals select from benefit options based on their individual needs, resulting in unexpected risk concentrations in some benefit plans. For example, suppose a PDP offers two benefit options at the same premium, one with a specialty tier but somewhat lower co-payments in non-specialty drug tiers—and another one with slightly higher co- payments but no specialty tier. People who expect to need specialty-tier drugs will tend to choose the plan without the specialty tier. Conversely, people who do not expect to use specialty-tier drugs will tend to choose the plan with the lower co-payments, even though this plan has a specialty tier. After the individuals make their plan selections, the plan without the specialty tier could end up with a greater portion of higher-risk (and higher-cost) beneficiaries than the plan with the specialty tier.

The vast majority of PDPs use specialty tiers for actuarially equivalent designs. Adverse selection can occur for many reasons, but it would likely be more pronounced if one plan eliminated its specialty tier and competing plans did not. If all plans eliminated the specialty tier, this source of adverse selection would go away.

Because a concentration of individuals who require high spending on drugs can dramatically increase a PDP's cost, we performed sensitivity analysis to measure the impact of adverse selection in equivalent plans after eliminating the fourth (specialty) tier. Nationally, for non-low-income members, about 0.4% (rounded) of Part D PDP utilization is for specialty-tier drugs. For testing purposes, we assumed that adverse selection (an increase in specialty-drug users) could bring this ratio to 0.7% or even 1.4% of total utilization. For these sensitivity analyses, we estimated actuarially equivalent benefit structures to our sample benefit designs. We also adjusted the second- and third-tier average cost per script to reflect the change in mix due to the inclusion of specialty-tier therapies in the brand tiers. The sensitivity testing is provided in Figure 4.

Figure 4: Sample Actuarially Equivalent Benefit Designs, Cost Sharing up to the ICL, 2013

Scenarios 2 and 3: Some Plans Eliminate Specialty Tier Assuming 2x and 4x Specialty Drug Utilization			
		Actuarially Equivalent Three-Tier Benefit Structure [b]	
Plan Type	Four-Tier Benefit Structure [a] Baseline	Two-fold Increase Scenario 2	Four-fold Increase Scenario 3
Basic Alternative (BA)	$0 deductible $7 / $42 / $80 / 33%	$0 deductible $7 / $42 / **$86**	$0 deductible $7 **/ $43 / $83**
Actuarial Equivalent (AE)	$325 deductible $6 / $25 / $45 / 25%	$325 deductible $6 / **$26** / **$50**	$325 deductible $6 / **$26** / **$53**
Basic Alternative (BA)	$125 deductible $6.50 / $35 / $70 / 25%	**$133** deductible $6.50 / $35 / $70	**$137** deductible $6.50 / $35 / $70

[a] *Generic/preferred/non-preferred/specialty*
[b] *Generic/preferred/non-preferred, no gap coverage; specialty drugs included in Tiers 2 and 3.*
[a, b] *Mail order co-payment equals 3 times retail co-payment.*

In Figure 4, we calculate the benefit design changes needed to eliminate the specialty tier if specialty-tier utilization were to increase two or four times above currently observed levels by 2013. Figure 4 illustrates that a two-fold increase in specialty-tier drug utilization, from our starting assumption of 0.4% to 0.7%, would require relatively modest increases in either the brand co-payments or deductible levels. However, an unlikely four-fold increase in specialty utilization to 1.4% would require more significant benefit adjustments to achieve actuarial equivalence, such as increasing co-payments on both the preferred and non-preferred-brand tiers by as much as $1 and $8, respectively (assuming no changes in cost sharing for generic drugs), or increasing the deductible by $12, assuming no other changes in benefit design.

Demographic characteristics of Part D users of specialty-tier drugs

Specialty-tier drug users represent a very small fraction of the total Part D enrollment: Roughly 1.7% of non-low-income (NLI) enrollees and about 4.8% of low-income (LI) enrollees filled at least one specialty-tier script in 2011. However, these patients accounted for about 15.4% of total NLI drug spending and about 24.0% of total LI spending in 2011.[11] The table in Figure 5 shows these results in greater detail.

11. See Methodology section for explanation of how specialty-tier drug utilization and spending were calculated.

Figure 5: Specialty-Tier Drug Users' Share of Total Part D Enrollment and Total Drug Spending, 2011

By Age Group, Gender, and LI Status				
	Users of Specialty-Tier Drugs			
	% of Enrollment by Age-Gender Group		% of Total Drug Spending	
Age-Gender Group	NLI	LI	NLI	LI
Male 0–64	4.9%	8.0%	40.1%	37.5%
Male 65–69	1.4%	2.7%	15.0%	19.6%
Male 70–74	1.4%	2.3%	13.4%	15.1%
Male 75–79	1.5%	2.0%	12.6%	12.0%
Male 80–84	1.5%	2.1%	10.8%	10.4%
Male 85+	1.5%	1.9%	9.1%	8.3%
Female 0–64	4.8%	7.0%	38.3%	31.0%
Female 65–69	1.4%	2.8%	15.4%	16.9%
Female 70–74	1.4%	2.5%	13.4%	12.7%
Female 75–79	1.4%	2.3%	11.9%	11.3%
Female 80–84	1.4%	2.2%	10.1%	9.8%
Female 85+	1.3%	1.9%	6.9%	7.8%
Institutional	1.7%	4.2%	5.8%	13.4%
Total	**1.7%**	**4.8%**	**15.4%**	**24.0%**

Figure 5 also shows that the under-65 population, who became eligible for Medicare through disability, is more likely to use specialty-tier drugs. On average, the specialty-tier spending of this group represents

almost 40% of their total drug spending. The disabilities in this age group are the likely cause for their greater use of specialty-tier drugs.

Impact of drug spending on specialty-tier users' out-of-pocket costs

Specialty-tier drug users have significantly higher spending levels than the average Part D enrollee. This increased total drug spending results in a far greater percentage of specialty-tier users entering the various corridors of the Part D benefit. The table in Figure 6 summarizes these results.

Figure 6: Percentage of Enrollees Reaching the Part D Spending Thresholds, Average Part D Members and Specialty-tier Drug Users, 2011

MAPD and PDP Enrollees				
NLI Members	Average Enrollee	Specialty-Tier Drug Users		
		MAPD and PDP	PDP	MAPD
$310 Deductible	79%	100%	100%	100%
$2,840 ICL	25%	89%	90%	84%
$4,550 TrOOP (catastrophic corridor)	6%	64%	66%	56%
LI Members	Average Enrollee	Specialty-Tier Drug Users		
		MAPD and PDP	PDP	MAPD
$310 Deductible	77%	100%	100%	100%
$2,840 ICL	40%	94%	94%	91%
$4,550 TrOOP (catastrophic corridor)	17%	80%	80%	72%

As shown in Figure 6, virtually all specialty-tier drug users (NLI and LI) have drug spending above the Part D deductible level, while 79% of the average Part D NLI enrollees do. Furthermore, while only about 6% of all Part D NLI enrollees hit TrOOP, 64% of NLI specialty-tier drug users do. These percentages are even higher for the LI population, where 17% of all LI enrollees hit the TrOOP while 80% of LI specialty-tier drug users do.

Each of the percentages above is higher for PDP enrollees when compared to MA-PD enrollees. This can be explained by the type of beneficiary purchasing stand-alone prescription drug coverage (PDP) versus a beneficiary purchasing integrated medical and prescription drug coverage (MA-PD). In general, MA-PD members do not enroll solely because of the prescription drug benefits, while PDP members tend to expect high prescription drug use.

Impact of removing the specialty tier on costs to members, PDPs, and federal reinsurance

The first part of this analysis explores the impact of removing the specialty tier on Part D beneficiaries' cost sharing. However, Part D benefits are financed by three stakeholders – the federal government (through subsidies and federal reinsurance), Medicare beneficiaries (through premiums and cost sharing), and the health plan or so called Part D sponsor (e.g., MA-PDs and PDPs). In this section, we examine the impact of removing specialty tiers on the average spending of each stakeholder, in particular the federal government. To determine this impact, we eliminated the specialty tier on our sample BA and AE plans and adjusted the benefit designs for actuarial equivalence.

As our modeling demonstrated, a typical PDP could move all covered specialty-tier drugs to other brand tiers and avoid impact to financial plan liabilities through an increase in either the deductible or cost sharing for other tiers. In addition, removing the specialty tier has an impact on the federal reinsurance spending, as the lower initial cost sharing acts to delay the accumulation of members' out-of-pocket expenses (TrOOP) through the coverage gap, and therefore delays entrance into the catastrophic coverage corridor. This would reduce federal reinsurance payments to plans by about 1% to 2%.

The fact that members spend more time *on average* in the coverage gap than they did before the elimination of the fourth tier does not mean that members are spending more out-of-pocket. As before, members will remain in the coverage gap corridor until they reach TrOOP. While in the coverage gap, members will still benefit from the 50% manufacturer's brand discount.

The table in Figure 7 shows the average cost impact to PDPs, members' out-of-pocket expenses, and the federal reinsurance subsidy when the benefits are adjusted to achieve actuarial equivalence after removing the specialty tier.

Figure 7: Percentage Cost Shifting after Eliminating the Specialty Tier Through Benefit Adjustments

With Deductible or Co-payment Changes to Achieve Equivalence to DS Plan						
Plan Type	Four-tier Benefit Structure [a]	Three-tier Benefit Structure [b]	Member Coinsurance [c]	Federal Reinsurance	PDP Liability	Total Costs
Basic Alternative (BA)	$0 deductible $7 / $42 / $80 / 33%	$0 deductible $7 / $42 / $83	0.0%	-2.1%	0.8%	0%
Actuarially Equivalent (AE)	$325 deductible $6 / $25 / $45 / 25%	$325 deductible $6 / $27 / $45	0.7%	-1.4%	-0.2%	0%
Basic Alternative (BA)	$125 deductible $6.50 / $35 / $70 / 25%	$129 deductible $6.50 / $35 / $70	0.0%	-1.5%	0.5%	0%

[a] *Generic / preferred / non-preferred / specialty.*
[b] *Generic / preferred / non-preferred, no gap coverage; specialty drugs included in tiers 2 and 3.*
[a, b] *Mail order co-payment 3 times retail co-payment.*
[c] *Excludes impact on 50% manufacturer's discount in the coverage gap.*

As expected, the impact on the PDP is neutral. This is because our modeling focuses on basic Part D coverage, such as AE and BA designs that are, by definition, actuarially equivalent to the DS plan. In our example, the member's cost sharing for brand drugs has been increased to compensate for the shift of specialty-tier drugs to other tiers. Therefore, the actuarial value of the PDP coverage does not change.

The above benefit design changes do not impact premium amounts. Because AE and BA plans are not allowed to charge a supplemental Part D premium, any benefit enhancement that increases the actuarial value of the coverage needs to be balanced by a corresponding decrease in benefits to maintain the same benefit value as the DS coverage. The resulting premium for the AE or BA plan is consistent with the basic Part D premium charged by DS plans.

We note, however, that enhanced alternative (EA) plans (enhanced Part D coverage that charges a supplemental premium in exchange for richer benefits than DS) do not need to satisfy actuarial equivalence. These plans may, therefore, adjust for the cost impact of eliminating the specialty tier either by increasing cost sharing on other tiers or by raising the supplemental premium amount. We do not illustrate an EA plan in Figure 7.

As shown above, beneficiaries pay on average 0.7% more in cost sharing for the AE plan, which is due to a higher deductible or co-payment in the initial coverage corridor. Individual beneficiaries may pay more or less, depending on the prescriptions they fill. Beneficiary cost sharing is calculated before the 50% manufacturer's brand gap discount in this example; therefore the 0.7% resulting increase in cost sharing excludes any changes in the manufacturer's discount received by beneficiaries that is due to the elimination of the specialty tier.

Figure 7 also shows a 1% to 2% decrease in the cost to the federal government for federal reinsurance payments. This is explained by the delay in members' accumulations of TrOOP, which causes fewer members to reach the catastrophic threshold.

Methodology

We restricted our Part D benefit design analysis and actuarial equivalence analysis to non-institutionalized and non-low-income beneficiaries because low-income members have minimal cost-sharing.

We define specialty-tier drugs as drugs that are placed on a specialty tier in the Part D program, as defined by CMS. We exclude drugs covered through Medicare Part A or Part B such as drugs administered in a hospital inpatient, hospital outpatient, or physician's office setting.

Our actuarial equivalence testing relies on non-low-income claim probability distributions that provide allowed spend levels based on average wholesale price for retail/mail and generic/preferred-brand/non-preferred-brand/specialty drug categories. Particular plans may vary significantly from these averages due to formulary, discount or other differences.

We assumed in our modeling that when the specialty tier is eliminated, most of these covered Part D drugs shift to the non-preferred-brand tier (third tier), while others shift to the preferred-brand tier (second tier). Our assumptions are based on our Part D experience.

For our analysis of Part D specialty-tier drug users, we examined prescription drug spending for the Part D population by age, gender, and institutional status. We determined total and specialty spending for each demographic group, for all specialty-tier drug users and nonusers in our database.

We analyzed non-low-income (NLI) and LI Part D populations separately. The LI population tends to be sicker, making them higher cost for MA-PDs and PDPs, and pays relatively low cost sharing due to the low-income cost-sharing subsidy (LICS). We created claim probability distributions from our data (separately for NLI and LI populations), for the MA-PD, PDP, and total Part D populations. Members were then assigned to a Part D threshold according to their total drug spending.

Data Validation and Limitations

Our analysis was based on 2011 Part D data that includes exposure across the 34 U.S. regions and Puerto Rico. The experience provides a credible representation of cohorts by region, income status, and age / gender as well as retail / mail, generic / brand / specialty, National Drug Code (NDC), and beneficiary annual spend level. However, particular Part D plans may vary significantly from these averages.

In our data, PDP enrollees' PMPM spending was about 20% higher than MA-PD enrollees' spending. Similarly, LI enrollees' PMPM spending was roughly twice that of NLI enrollees. For specialty-tier users, however, we found that costs did not vary significantly with low-income status. In other words, the spending associated with specialty-tier drugs seemed to be relatively stable across all demographic groups (the only exception being the institutional) regardless of LI status.

We note that our figures related to specialty-tier drug use and expenditures differ somewhat from those publicly released by CMS. For example, CMS has stated: "Based on a CMS analysis of 2009 formulary and prescription drug event (PDE) data, we found that only a small percentage (1.1%) of all Part D prescriptions had a 30-day equivalent cost of $600 or more, and that specialty tier drugs accounted for less than 6% of total Part D expenditures ($4.1 billion out of total expenditures of $72 billion). In 2009, the percentage of non-low-income subsidy (NLI) Part D beneficiaries that used specialty-tier drugs (as defined by the $600 threshold) was 7.4%)."[12]

This difference can be explained by how CMS has defined specialty-tier drugs. Their data are based on "specialty tier-eligible" drugs, and not on drugs actually placed in the specialty tier by a plan's formulary. They define specialty-tier drugs as those that cost an equivalent $600/month or more, while we define them as those drugs actually on a specialty tier from claims data. Not all drugs that meet the $600 threshold will automatically be placed on a specialty tier. In addition, our results closely resemble those presented at the 2008 CMS Part D Data Symposium after accounting for variables such as low-income status.

The figures presented in this report are national averages developed from historical databases. Actual results will likely differ for many reasons, including statistical fluctuations. As with other segments of the economy, it is impossible to precisely predict the impact of specialty medicines on health care costs. The reader should consider that the figures in this report are based on assumptions and cannot capture impacts such as changes in the regulatory environment or scientific developments, so these figures should be reviewed carefully for their applicability for any particular purpose.

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12. Letter from Jonathan Blum, Deputy Administrator and Director, Center for Medicare, CMS to Rep. Hank Johnson, May 27, 2010.