Impact of increasing the Medicare Part D specialty threshold

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EXECUTIVE SUMMARY

Medicare Part D, the prescription drug program for seniors, offers comprehensive pharmacy coverage with a complex benefit design. Most Part D plans offer "tiered" benefits that establish varying levels of cost sharing for different types of drugs, including a specialty tier for high-cost Part D drugs.

Under Centers for Medicare and Medicaid Services (CMS) rules, Part D plans can use specialty tiers 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 no deductible
- Only Part D drugs with sponsor-negotiated prices that exceed the monthly cost threshold defined by CMS may be placed in the specialty tier

The threshold for inclusion of a drug in the specialty tier is currently $600. This threshold has not been updated since 2008, when it was increased from $500. The monthly cost considered for qualification in the specialty tier is before rebates.

We modeled the impact of increasing the threshold from the current $600 to $700, $750, and $800 on patient spending, Part D premiums, Part D plans, the federal reinsurance program, and drug manufacturers using historical Part D data and sample Part D benefits and formularies. The figure below summarizes the results.

FIGURE 1: IMPACT OF INCREASING PART D SPECIALTY TIER THRESHOLD FROM CURRENT $600 LIMIT - ILLUSTRATION FOR TYPICAL MARKET SEGMENTS

	Formulary and Benefits* – Specialty Cost Threshold Scenarios								
	Non-low-income PDP			Non-low-income MA-PD			Low-income PDP**		
	$700	$750	$800	$700	$750	$800	$700	$750	$800
Member Cost Sharing	($0.01)	($0.01)	($0.02)	$0.00	($0.01)	($0.01)	($0.01)	($0.01)	($0.02)
Member Premiums	$0.01	$0.02	$0.03	$0.01	$0.01	$0.01	$0.01	$0.02	$0.03
Plan Liability	$0.01	$0.02	$0.03	$0.01	$0.01	$0.01	$0.01	$0.02	$0.03
Federal Reinsurance	($0.01)	($0.01)	($0.02)	$0.00	($0.01)	($0.01)	($0.01)	($0.01)	($0.02)
Manufacturers' CGDP***	$0.01	$0.01	$0.01	$0.00	$0.00	$0.00	$0.00	$0.01	$0.01

* Source: 2015 formularies available from CMS for the following: Non-low-income PDP: United Healthcare enhanced PDP; Non-low-income MA-PD: Humana enhanced MA-PD; Low-income PDP: CVS basic PDP
**CVS basic PDP enrollment is composed of 55% low-income and 45% non-low-income members.
*** Medicare Coverage Gap Discount Program

Our modeling assumes typical pharmacy cost trends without any unusual drug price changes in response to a threshold change. However, as a sensitivity test, we identified the drug that contributed the most to the member premium changes in the above table and doubled its contribution. This produced a member premium increase of, at most, $0.04 PMPM, across the scenarios.

According to our modeling, raising the minimum specialty price threshold from $600 per month to $700, $750, or $800 per month is likely to have minimal to no effect on member premiums, plan liability, bid amount, federal reinsurance, or the manufacturer's coverage gap discount program liability. Part D member premiums are rounded to the nearest $0.10; therefore, we project that increasing the specialty cost threshold to the maximum scenario of $800 per month would usually have no impact on the member premium.

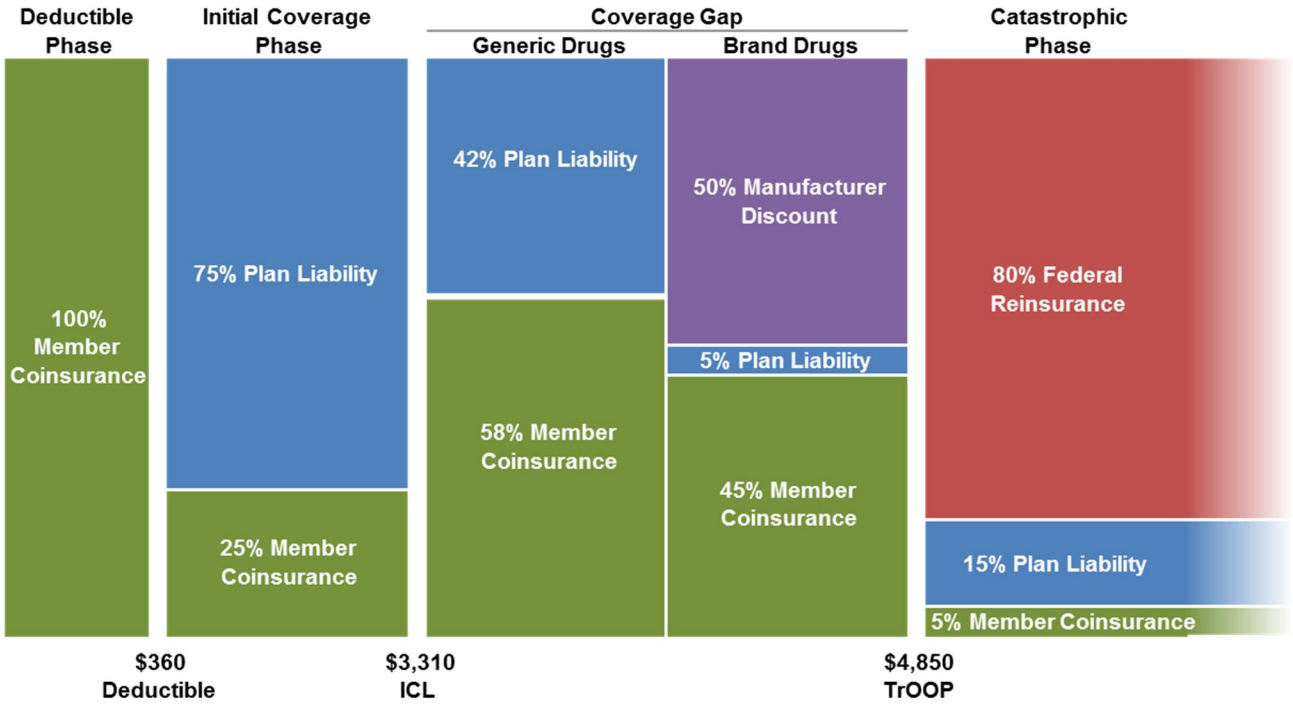
BACKGROUND

Currently, a prescription drug's monthly cost must be $600 or higher to meet CMS's rules for inclusion in the specialty tier. Specialty drugs have, on average, higher cost sharing than non-specialty drugs; therefore, a threshold higher than $600 for a drug to be included in the specialty tier means that some drugs now considered to be specialty drugs would be subject to lower patient cost sharing, which has the potential to increase plan costs and member premiums. This study examines the extent to which increases in the threshold would actually have those effects.

The Part D benefit

The defined standard benefits are prescribed by CMS and represent the minimum level of coverage that a plan must provide to its members. The defined standard benefits are characterized by four benefit phases: deductible, initial coverage limit (ICL), coverage gap, and catastrophic phase. Figure 2 depicts the 2016 defined standard benefits and the responsibility for each payer.

FIGURE 2: DEFINED STANDARD BENEFITS FOR 2016



Note:
Both member and manufacturer liability accumulate toward true out-of-pocket (TrOOP) expenses.
Deductible and ICL are based on allowed costs. TrOOP is based on accumulated cost sharing.
Low-income members are not eligible for manufacturer discount or Patient Protection and Affordable Care Act cost-sharing reductions in the gap. Cost-sharing reductions are instead provided through Low-Income Cost-Sharing (LICS) subsidies. Additionally, the plan and manufacturers do not have any liability for low-income members in the gap.

Most plans offer benefits that are equivalent to or better than the defined standard offering, but typically include tiered benefits with lower cost sharing for generic and preferred brand drugs, and higher cost sharing for non-preferred brand and specialty products. Due to the tiered benefits, an increase in the specialty cost threshold would result in changes to the member cost sharing for users of the specialty drugs that would no longer exceed the (increased) threshold. These changes would also impact the plan liability, the federal reinsurance, and the coverage gap discount program amounts. This report examines those changes.

Market segments: Integrated or standalone Part D benefits, low-income "benchmark," and enhanced plans

Part D coverage can be obtained through an integrated Medicare Advantage-Part D (MA-PD) plan or a standalone Part D plan (PDP). Both MA-PDs and PDPs may offer basic (defined standard or equivalent benefits) or enhanced coverage.

PDPs that target a low-income population offer benefits that are equivalent to the defined standard design and set their premium amount equal to the regional low-income benchmark, determined by CMS, resulting in a fully subsidized premium to the member.

Many MA-PDs and PDPs offer "enhanced" benefits, with benefits in excess of the defined standard (DS) as described below:

- DS deductible can be reduced
- DS initial coverage limit (ICL) can be increased
- Cost-sharing reductions
- Supplemental drugs
- Additional gap coverage
- Must have a supplemental premium

We modeled the impact of increasing the specialty tier cost threshold on three distinct market segments: non-low-income MA-PD, non-low-income PDP, and low-income PDP. In our models, we mirrored the benefit offered by the largest plan, by 2015 membership, in each segment. These benefit designs are shown in Figure 3.

FIGURE 3: PART D BENEFIT DESIGN BY MARKET SEGMENT - 2015

	Part D Benefit Design		
	Non-low-income PDP	Non-low-income MA-PD	Low-income PDP
Plan Type	Enhanced	Enhanced	Basic Alternative
Part D Deductible	$0	$0	$0
Coverage Gap	Defined Standard	Defined Standard	Defined Standard
Retail Copays/Coinsurance			
Preferred Generic	$4.00	$5.00	$8.50
Non-Preferred Generic	$6.25	$9.50	
Preferred Brand*	$40.00	$43.50	$31.50
Non-Preferred Brand**	$85.00	47.25%	44.50%
Specialty	33.00%	33.00%	33.00%
Mail Copays/Coinsurance			
Preferred Generic	$0.00	$0.00	$21.25
Non-Preferred Generic	$6.25	$0.00	
Preferred Brand*	$120.00	$130.50	$78.75
Non-Preferred Brand**	$255.00	47.25%	44.50%
Specialty	33.00%	Not Covered	Not Covered

* In Part D, both preferred and non-preferred brand tiers may include generic products.

**The 2016 maximum cost sharing for non-preferred brands up to the ICL, as determined by CMS, is 50%, up to a maximum *average* 30-day copay of $100. Average copay is calculated across all non-preferred brands in the tier.

Typically, members pay 33% coinsurance for specialty drugs in 2015. Copays are common on preferred brands while non-preferred brands may be subject to either a copay or coinsurance. In the benefit designs above, coinsurance for brands not in the specialty tier (blending preferred and non-preferred brand cost sharing) is, on average, less than the 33% effective coinsurance for specialty drugs.

Note that even though plans may impose coinsurance for non-preferred brands as high as 50%, the maximum allowable cost sharing for non-preferred brands cannot exceed $100 (per 30-day supply), on average, resulting in an effective cost-sharing amount that is well below that of specialty drugs.

FINDINGS

Based on our analysis of typical formularies and benefit designs, raising the minimum specialty cost threshold from $600 per month to $700, $750, or $800 per month would have a minimal effect on member premium, plan liability, federal reinsurance, and manufacturers' coverage gap discount program liability.

Specialty drugs that may be affected by higher thresholds

We identified 14 drugs that could reasonably reach the current $600 to $800 specialty cost threshold in 2016 and therefore could be placed in a specialty tier in our scenarios. Figure 4 shows the drugs affected if the threshold were to increase to $700, $750, or $800 per month, and which drugs would fall in each scenario.

FIGURE 4: DRUGS INCLUDED IN SPECIALTY TIER BY PRICE THRESHOLD SCENARIO, BASED ON EXPECTED NEGOTIATED PRICES IN 2016

Drug Class	Drug Name	Included in Specialty Tier in 2016 Threshold Scenarios	Expected Negotiated Monthly Price in 2016
Loop Diuretics	Edecrin	$800, $750, $700, $600	$1,350
Glucocorticosteroids	Budesonide	$800, $750, $700, $600	$900
Anticonvulsants – Benzodiazepines	Onfi	$800, $750, $700, $600	$900
Inflammatory Bowel Agents	Pentasa	$750, $700, $600	$780
Anticonvulsants - Misc.	Vimpat	$750, $700, $600	$780
Pseudobulbar Affect (PBA) Agents	Nuedexta	$700, $600	$720
Immunosuppressive Agents – Topical	Elidel	$700, $600	$720
Interstitial Cystitis Agents	Elmiron	$600	$690
Dibenzapines / Quinolinone Derivatives / Benzisoxazoles	Saphris	$600	$660
Inflammatory Bowel Agents	Lialda	$600	$660
Digestive Enzymes	Creon	$600	$630
Digestive Enzymes	Zenpep	$600	$630
Immunosuppressive Agents	Prograf	$600	$600
Immunosuppressive Agents	Mycophenolic Acid DR	$600	$600

Drugs expected to be priced at or above $800 per month in 2016 were placed in the specialty tier in all of the scenarios and were therefore not affected by the threshold increase. To the extent that the expected price of any of the 14 drugs listed would exceed the threshold in a given scenario, such

drug would not be affected by the threshold increase (for example, drugs with expected monthly cost in excess of $750 will not be affected in the $750 or $800 threshold scenarios).

Impact on member, plan, federal reinsurance, and coverage gap discount program

There are four sources of funding in the Part D market: the member, the plan sponsor (with subsidies from CMS), the federal government through subsidies to plans and the federal reinsurance in the catastrophic coverage phase, and brand manufacturers through the coverage gap discount program (when brand drugs are filled by non-low-income members in the gap). As the specialty threshold increases, the expected member cost sharing decreases while the Part D premium increases, as shown in Figure 5. The figure also displays the impact on plan liability, which closely resembles the member premium impact.

FIGURE 5: MEMBER IMPACT DUE TO SPECIALTY TIER PRICE THRESHOLD INCREASE FROM CURRENT $600 LIMIT – 2016 PMPM, BASED ON 2016 EXPECTED PRICES

	Market Segment Specialty Cost Threshold Scenarios								
	Non-low-income PDP			Non-low-income MA-PD			Low-income PDP		
	$700	$750	$800	$700	$750	$800	$700	$750	$800
Member Cost Sharing	($0.01)	($0.01)	($0.02)	$0.00	($0.01)	($0.01)	($0.01)	($0.01)	($0.02)
Member Premiums	$0.01	$0.02	$0.03	$0.01	$0.01	$0.01	$0.01	$0.02	$0.03
Plan Liability	$0.01	$0.02	$0.03	$0.01	$0.01	$0.01	$0.01	$0.02	$0.03

Drugs with expected prices between $600 and $800 in 2016 were placed in the specialty tier according to the specialty cost threshold for each scenario. If a drug's price fell below the proposed threshold for a given scenario, we assumed that such drug would be placed either in the preferred or non-preferred brand tier. The assumed tier placement was consistent with the drug's historical tier placement (for drugs not placed in the specialty tier by the same plan in prior years) or with the most common non-specialty tier placement by other plans, which resulted in about 75% of the utilization for these drugs shifting from the specialty tier into the preferred brand tier.

The average effective coinsurance for non-specialty brands in our analysis was between 21% and 26%. As drugs were moved away from the specialty tier into other tiers in our model, the average coinsurance for these drugs decreased (from 33% to 21%-26%), resulting in a reduction in member cost sharing and therefore in lower member true out-of-pocket (TrOOP) expenses.

As the specialty cost threshold increased, lower TrOOP amounts would cause members to remain in the gap longer, resulting in less spending in the catastrophic phase. Figure 6 shows the impact on federal reinsurance and the Manufacturers' Coverage Gap Discount Program (CGDP) by market segment and scenario.

FIGURE 6: MANUFACTURERS' GAP AND FEDERAL REINSURANCE IMPACT DUE TO SPECIALTY TIER PRICE THRESHOLD INCREASE FROM CURRENT $600 LIMIT – 2016 PMPM, BASED ON 2016 EXPECTED PRICES

	Market Segment Specialty Cost Threshold Scenarios								
	Non-low-income PDP			Non-low-income MA-PD			Low-income PDP		
	$700	$750	$800	$700	$750	$800	$700	$750	$800
Federal Reinsurance	($0.01)	($0.01)	($0.02)	$0.00	($0.01)	($0.01)	($0.01)	($0.01)	($0.02)
Manufacturers' CGDP	$0.01	$0.01	$0.01	$0.00	$0.00	$0.00	$0.00	$0.01	$0.01

Sensitivity testing

We performed sensitivity testing to measure the changes in the results above if a highly utilized specialty drug with negotiated prices between $600 and $800 per month were to enter the market. We identified the drug that contributed the most to member premium changes, Vimpat, and doubled its contribution. As shown in Figure 7, the addition of a significant specialty drug priced between $750 and $800 would result in minimal changes to our $800 specialty cost threshold scenario results.

FIGURE 7: MEMBER, MANUFACTURER, AND FEDERAL REINSURANCE IMPACT DUE TO SPECIALTY TIER PRICE THRESHOLD INCREASE FROM CURRENT $600 LIMIT TO $800 – 2016 PMPM, ASSUMING A NEW, HIGHLY UTILIZED SPECIALTY DRUG ENTERS THE MARKET WITH A 2016 NEGOTIATED PRICE OF $750 TO $800 PER MONTH

	Market Segment $800 Specialty Cost Threshold Scenario		
	Non-low-income PDP	Non-low-income MA-PD	Low-income PDP
Member Cost Sharing	($0.03)	($0.01)	($0.03)
Member Premiums	$0.04	$0.02	$0.04
Plan Liability	$0.05	$0.02	$0.05
Federal Reinsurance	($0.03)	($0.01)	($0.03)
Manufacturers' CGDP	$0.02	$0.01	$0.01

METHODOLOGY

Identification of drugs potentially in the specialty tier in 2016

We used Milliman's 2014 Part D Consolidated Database (PDCD) to estimate the average daily negotiated price by brand name for all drugs that can potentially be included in the 2016 specialty tier based on price, for effective prices of $600 to $800, as defined in our scenarios. We excluded drugs that had less than $0.05 PMPM spending from the analysis. These drugs accounted for less than 5% of spending for drugs priced between $600 and $800 per month, and we expect them to have a non-material impact on the results. The PDCD has Part D data from about 2 million individual lives.

Our starting list included all drugs with average negotiated prices within 20% of the daily price threshold for each scenario (80% of $700, $750, or $800). The 2015 average daily price for each of these drugs was then estimated by applying the MediSpan Average Wholesale Price (AWP) trend from July 2014 to July 2015 to the starting 2014 values. To obtain the estimated 2016 average daily price, we assumed a 10% price increase from the 2015 estimates.

From this initial list, we excluded drugs that are not likely to be included in the specialty tier for the following reasons:

- Drug cost is not estimated to exceed the $600 monthly specialty threshold in 2016 after applying the trends above
- Drug treats specific conditions (i.e., insulin for diabetes) that are likely to be perceived as discriminatory under CMS formulary rules
- Drug is indicated for short duration (i.e., antibiotics) and the effective monthly cost is therefore not expected to exceed the threshold
- Drug is generic and currently not in the specialty tier (based on the specialty tier placement in 2015)
- Drug is branded and either lost patent protection or is expected to lose patent protection by 2016

We also considered new drug launches with potentially high utilization (such as the PCSK-9 class) and determined that these are not likely to fall into the $600 to $800 monthly negotiated price range.

Our 10% price increase assumption for 2016 is consistent with recent past trends and with our expectations for brand drug pricing for 2016; it does not consider any strategic decisions by manufacturers with regard to the specialty tier threshold.

The resulting list of 14 drugs was used to analyze the impact of increasing the specialty threshold.

Identification of Part D market segments and typical formularies

We modeled the impact of increasing the specialty threshold separately for three Part D market segments: non-low-income PDP, non-low-income MA-PD, and low-income PDP. For each of these, we used the 2015 benefit design and Part D formularies of the largest plan (by enrollment), respectively:

- United Healthcare enhanced PDP (five-tier)
- Humana enhanced MA-PD (five-tier)
- CVS basic PDP (four-tier)

We analyzed the historical tier placement for each of the drugs with expected prices between $600 and $800 in 2016, and assumed that, once its price no longer meets the threshold for specialty tier in our scenarios, a drug will be placed back into its historical tier. For drugs that have been on the specialty tier for the last three years, we assumed their most common non-specialty tier placement by other Part D plans. This assumption resulted in about 75% of the drugs affected moving from the specialty tier to the preferred brand tier, and the other 25% of the drugs moving to the non-preferred brand tier. This split is largely consistent with the current distribution of brands not in the specialty tier.

Based on the Part D benefits described above (see also Figure 3), the average effective coinsurance for non-specialty brands was between 21% and 26%. The effective coinsurance was calculated by blending the preferred and non-preferred cost-sharing features for prescriptions filled in retail and mail pharmacies. These benefits resulted in a reduction in member cost sharing as drugs moved away from the specialty tier.

Actuarial analysis of the impact of increasing the specialty cost threshold

We modeled each specialty cost threshold scenario, market segment, benefit, and formulary using Milliman's Part D Analysis and Rating Tool model manual rates. The manual rates and adjustment factors in Milliman’s pricing models are based on 2013-2014 Part D experience, including more than 40 million member months across 34 U.S. regions and Puerto Rico. We adjusted Milliman’s manual rates for discounts, rebates, and retention levels based on Milliman’s research and calibrated the bid amounts to 2016 national averages, as published by CMS.

We compared members’ cost-sharing and premium levels, plan liability, federal reinsurance, and coverage gap discount amounts in each of the scenarios to determine the impact of a specialty cost threshold increase. The results assume no induced utilization as a result of a reduction in members’ cost sharing.

Rebates offered by brand manufacturers may impact formulary tier placement. We assumed that drugs that are currently eligible for the specialty tier but would not be eligible under a higher threshold may need to offer higher rebates to be placed in the preferred brand tier (as opposed to

the non-preferred brand tier). The higher rebates may partially offset the plan liability increases, thereby reducing the premium impact shown in our analysis.

We performed sensitivity testing of our results by assuming that a highly utilized specialty drug with negotiated prices between $600 and $800 per month would enter the market. We therefore doubled the utilization for Vimpat (the largest contributor to spending from our list of 14 drugs) in our models, and recalculated the results for the $800 threshold scenario.

LIMITATIONS

The results in this report were developed from historical data and assumptions as to future events. Several reasons, including random fluctuation, could lead to results that would be different from those presented in this report. In particular, the actual drugs that reach the specialty threshold in 2016 or the use of those drugs could prove different from what appears in our model.

Our analysis represents 2015 benefit designs of MA-PDs and PDPs with the highest enrollment as of the time of writing this report. While these benefits are typical in the market, different benefits may produce different results. As with any healthcare forecast, our work cannot capture all factors; we selected reasonable assumptions and simple scenarios for ease of illustration. Our analysis ignores any impact that the specialty tier price threshold may have on manufacturers' pricing or rebating decisions. We also ignore the impact of reduced member cost sharing in drug use.

DISCLOSURES

This report was commissioned by Avanir, a drug manufacturer. Because extracts of this report taken in isolation can be misleading, we ask that it be distributed only in its entirety.

The American Academy of Actuaries requires its members to identify their qualifications in communications. The co-authors, Jennifer Carioto, Gabriela Dieguez, and Bruce Pyenson, are Members of the American Academy of Actuaries and meet its qualifications to perform this work. The report reflects the authors' findings and opinions.