Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs

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Introduction

Since its inception in 2006, the Medicare Part D program has offered prescription drug coverage through private plans that actively manage prescription drug benefits through the creation of formulary tiers and cost sharing; in 2018, 44 million beneficiaries had Part D prescription drug coverage.[1] While the formulary guidelines have changed over time, they have historically allowed Part D plans to keep premiums low and drive utilization to less expensive generic drugs, keeping down costs for both beneficiaries and the federal government.[2,3] In 2016, 86% of retail prescriptions paid for by Medicare Part D plans were generics, which accounted for just 16% of total Part D program spending.[4]

However, a previous Avalere analysis of plan years 2011 through 2015 found that plans were increasingly placing generic drugs on non-generic, higher drug tiers.[5] Subsequent to the years included in that analysis, in 2017, the Centers for Medicare & Medicaid Services (CMS) Part D formulary guidelines started to allow Part D plans to replace their "non-preferred **brand**" tier—typically tier 4—with a new "non-preferred **drug**" tier without any requirements on the proportion of brand and generic drugs that could be included in that tier.[6] This policy has led to plans increasingly moving generic drugs from a generic tier (i.e., Tier 1 or 2) onto a higher tier (i.e., Tier 3 or 4), raising average out-of-pocket (OOP) costs of generic drugs for beneficiaries, despite declining generic drug prices in the program.[7,8]

On January 30, 2019, in response to concerns about this trend in generic drug tiering in Part D, in Part II of the 2020 Advanced Notice and Call Letter (ANCL), CMS announced the agency was considering changing the Medicare Part D tier formulary guidelines to prohibit or restrict plans' ability to place generic drugs on non-generic tiers. CMS expects that restricting or prohibiting generic drugs from being placed on brand formulary tiers would encourage utilization of more generics, reduce OOP costs for seniors, and limit beneficiary confusion.[9]

In this analysis, Avalere estimates the implications of CMS' potential new requirement on beneficiary cost sharing, plan liabilities, and the implications for plans' share of total costs for beneficiaries. Avalere additionally quantifies the increase in generic drug placement on non-generic tiers from 2016—the year before the non-preferred drug tier was implemented—through 2019.

Background

Medicare Part D Tiering Overview

Medicare beneficiaries enrolled in the Part D program can select from a standalone prescription drug plan (PDP) or Part D coverage bundled with their medical benefit through a Medicare Advantage plan with prescription drug coverage (MA-PD). Since the program's inception in 2006, plan benefit designs have included a growing number of formulary tiers. From 2006 through 2011, PDPs and MA-PDs largely offered a benefit with 3-4 formulary tiers—comprised of a single generic tier, 2 brand tiers (preferred and non-preferred), and a single specialty drug tier.[10] Under this structure, generic drugs were concentrated on the generic tier (Tier 1).[11,12]

Formularies with 5 tiers—generally comprised of 2 generic tiers (preferred generic and non-preferred generic), 2 brand tiers, and a specialty tier—were introduced in 2009 and 3-6% of Part D beneficiaries enrolled in such plans.[13] By 2012, 50% percent of beneficiaries were enrolled in 5-tier plans.[14] For 2016, to avoid beneficiary confusion, CMS eliminated the non-preferred generic tier and named it simply the "generic" tier.[15] By the 2018 benefit year, 95% of PDPs and 81% of MA-PDs had moved to a 5-tier benefit structure.[16]

Prior Avalere Analysis of Medicare Part D Formulary Trends, 2011–2015

As Part D plans were increasingly moving toward 5-tier formularies, they were also progressively placing generic drugs on higher tiers. In a white paper released in May 2018, Avalere analyzed tier placement and cost sharing of generic drugs in the Medicare Part D program for 2011 and 2015 to see how plans covered generics in the years prior to the creation of the "non-preferred drug" tier.[17] In 2011, plans placed generic drugs on the lowest tier (Tier 1) 71% of the time; by 2015, plans placed covered generics on Tier 1 only 19% of the time, on Tier 2 46% of the time, and on Tier 3 or higher 35% of the time.[18] This change represents a 53-percentage-point decrease in the proportion of generics being placed on the lowest tier between 2011 and 2015. The Avalere May 2018 analysis focused on the same basket of generic drugs that were available in 2011 and 2015 in the Medicare Part D program. Importantly, higher cost sharing for generics and movement of generics to higher tiers did not correspond with an increase in the underlying price of generic drugs.[19,20]

Part D Plans Begin Using New "Non-Preferred Drug" Tier in 2017; Higher Proportion of Generic Drugs Placed on Non-Generic Tiers

Since the creation of Medicare Part D, plans have had considerable flexibility as to how they design formularies and tier structure, as long as they meet CMS' formulary design requirements. Those requirements, prior to 2017, included that (1) tier labels (i.e., brand or generic) should correspond to the predominant type of drugs placed on that tier (i.e., the majority of drugs

placed on that tier), and (2) cost sharing for each tier cannot exceed maximum standards that correspond both to a coinsurance percentage and a copay dollar amount.[21]

In 2017, CMS announced a major change to the formulary structure of Part D, allowing plans to choose to use either a "non-preferred drug" tier or a "non-preferred brand" tier. The "non-preferred drug" tier allows plans flexibility on the proportion of brands or generics that comprise the tier. The name of the tier also made explicit the inclusion of both brand and generic drugs on the tier.[22] CMS acknowledged that "the new non-preferred drug tier likely will contain a greater proportion of generic drug products than the current non-preferred brand tier composition."[23] Specifically, CMS hypothesized that plan sponsors would include lower-cost generics on the "non-preferred" tier "in an effort to … maintain actuarial equivalence" and keep premiums flat.[24] In 2019, 99% of PDPs and 89% of MA-PDs were using the "non-preferred drug" tier.[25]

CMS Requests Information on Requiring Part D Plans to Place Generic Drugs Only on Generic Tiers or Discouraging Generics on Brand Tiers

On January 30, 2019, in Part II of the 2020 Advanced Notice and Call Letter (ANCL), CMS announced the agency was considering changing the Medicare Part D tier formulary guidelines, potentially reversing the change allowed beginning in 2017. Under the proposal, CMS would prohibit or discourage Medicare Part D plans from placing generic drugs on brand tiers and vice versa, as well as eliminate the non-preferred drug tier. CMS' stated goal of the policy is to help lower patient OOP costs for beneficiaries, increase generic utilization, and avoid beneficiary confusion around tier naming.[26]

CMS summarized its potential proposal by noting that, "[g]oing forward, under such a policy, drug tiers would no longer include a mix of generic and brand products. Generics would be part of generic formulary tiers and brands would be part of brand formulary tiers."[27]

As part of this request for information, Avalere estimated the potential savings for patients under this proposed policy as well as estimated implications for Part D plan liabilities, using Part D prescription drug event (PDE) data from 2016 to 2017 and CMS' Public Use Files (PUFs) with Part D benefit and formulary design information for 2016–2019.

Analysis of Medicare Part D Drug Tier Placement

Changes in Tier Placement of Generic Drugs, 2016–2019

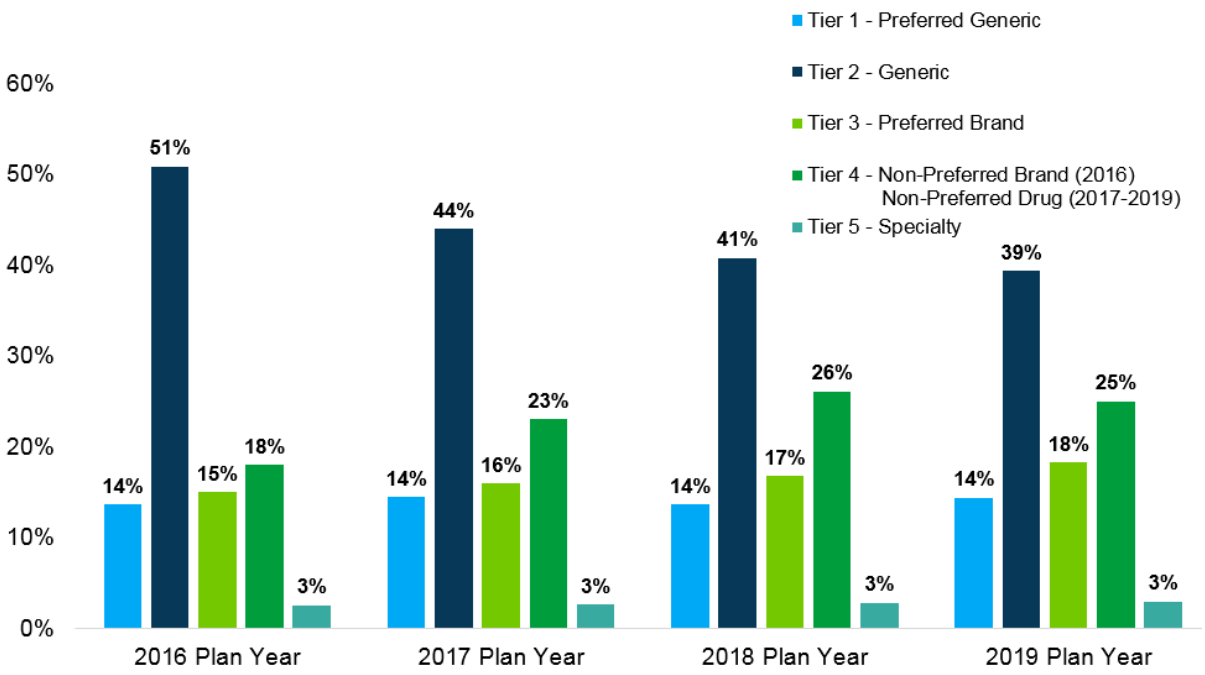
For years 2016 through 2019, plans placed Medicare Part D covered generic drugs on the lowest tier (preferred generic) only 14% of the time (Figure 1). In 2016, plans placed covered generic drugs on the generic tier (Tier 2) 51% of the time. By 2019, plans placed covered

generic drugs on Tier 2 39% of the time. This change represents a 12-percentage-point decrease in generics being placed on Tier 2, the generic tier between 2016 and 2019.

In 2016, plans placed covered generic drugs on the generic tier (Tier 2) **51%** of the time. By 2019, plans placed covered generics drugs on Tier 2 **39%** of the time.

Similarly, in 2016, plans placed covered generic drugs on the non-preferred brand tier (Tier 4) 18% of the time. The introduction of the non-preferred drug tier in 2017 and the elimination of the requirement that a majority of drugs on that tier be branded products led to the percentage of covered generics on that tier increasing to 25% by 2019, a 7-percentage-point increase.

Figure 1. Percent Distribution of All Generic Drugs on Part D Formulary Tiers, 2016–2019

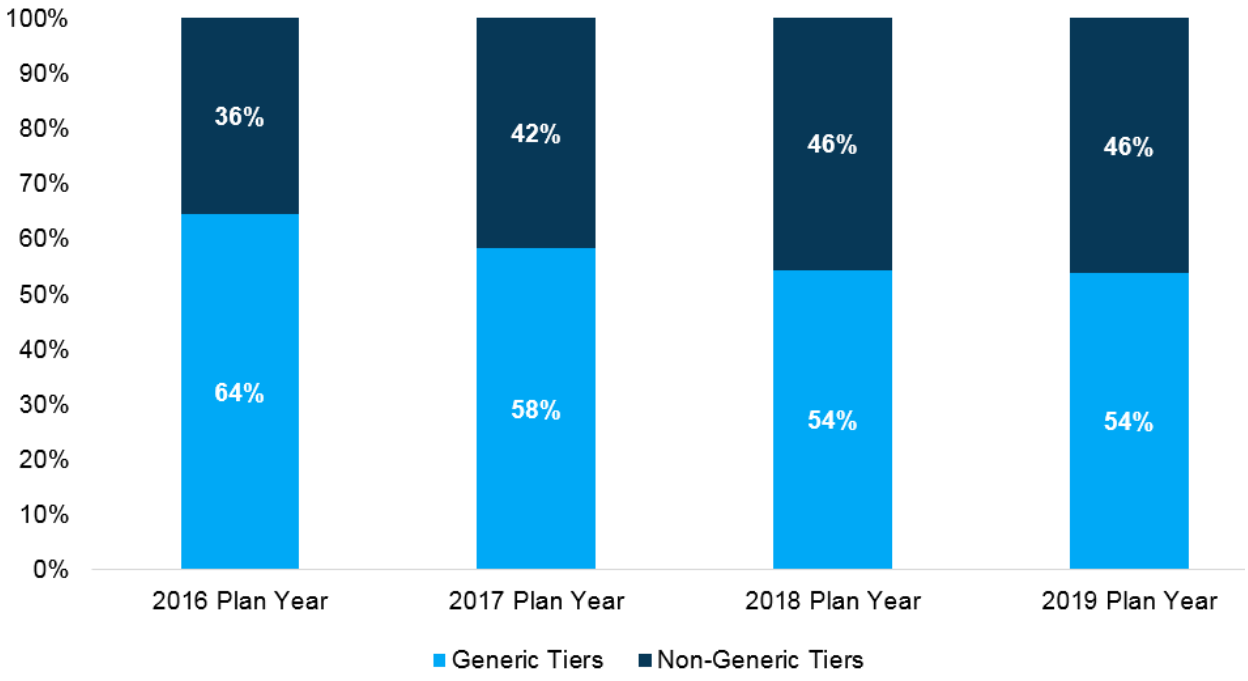


These findings demonstrate the continued trend of Part D plans moving generics to higher tiers. Creation of the non-preferred drug tier in 2017 appears to have led to plans in particular to move Part D covered generic drugs from the generic tier (Tier 2) to non-generic tiers.

In 2016, plans covered generics on generic tiers **64%** of the time.
By 2019, that percentage had dropped to **54%**.

When analyzing the results by grouping the 5-tier structure into generic tiers and non-generic tiers, defined as any tier that is not designated specifically for generics, the data shows a 10-percentage-point increase in the share of covered generics placed on non-generic tiers (Figure 2). In 2016, plans covered generics on generic tiers 64% of the time. By 2019, that percentage had dropped to 54%.

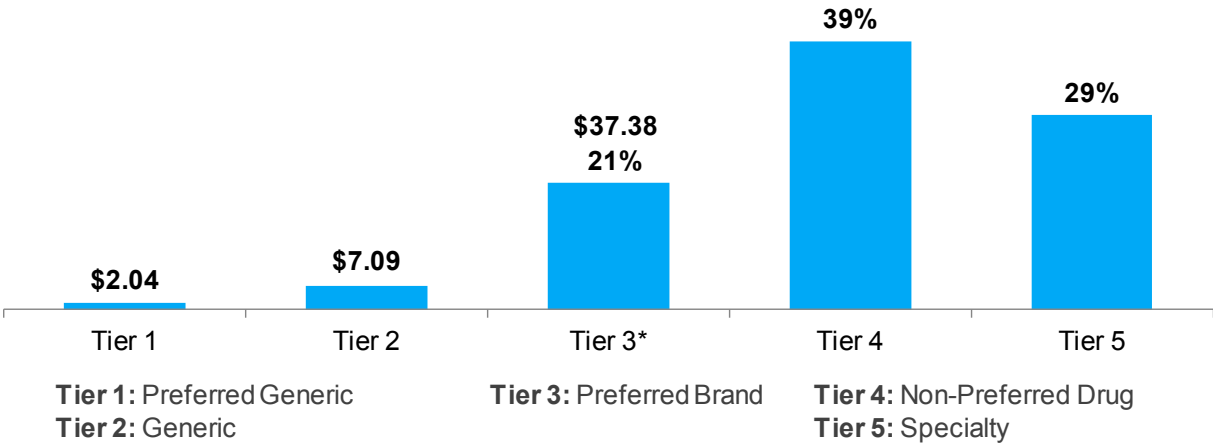
Figure 2. Distribution of All Generic Drugs on Generic and Non-Generic Tiers, 2016–2019



Implications of Potential Tier Change on Patient Cost Sharing

As generic drugs are placed on higher, non-generic tiers, patient cost sharing for these medications can increase. Under the benefit design requirements in Medicare Part D, beneficiaries generally pay more cost sharing for drugs placed on tiers for brand drugs (i.e., Tiers 3 and 4) than on tiers for generic drugs (i.e., Tiers 1 and 2). In an analysis of cost sharing for 2019 Medicare Part D prescription drug plans (PDPs), Avalere found that the 2 generic tiers had a weighted average cost sharing of $2 and $7 respectively. Branded tiers had substantially higher cost sharing, with the non-preferred drug tier averaging 39% coinsurance (Figure 3).

Figure 3. Enrollment Weighted Average Cost Sharing for 5-Tier Medicare Part D Prescription Drug Plan Formularies, 2019[28, 29]



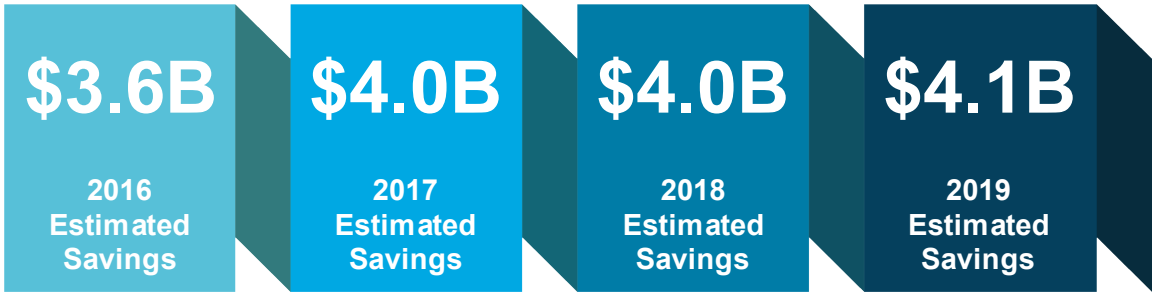
*Most Medicare Part D Prescription Drug Plans (PDPs) charge coinsurance for the preferred brand tier (average of 21% in 2019), while most Medicare Advantage prescription drug plans (MA-PDs) charge copayments for Tier 3, preferred brand drugs (average of $37.38 in 2019).

To estimate the potential for patient OOP savings due to the CMS proposal, Avalere determined the difference in cost sharing if generic drugs covered by the plan, utilized by beneficiaries, and placed on non-generic tiers, were moved down to the highest generic tier. Assuming constant utilization and plan formulary management, the difference is the estimated cost sharing amount that could be saved by Part D beneficiaries, or the federal government in the case of low-income Medicare Part D beneficiaries with subsidized cost sharing, using generic drugs under the CMS potential policy of using separate tiers for brand and generic drugs.

Avalere found that patient cost sharing would have been **$15.7 billion** lower for generic drugs from 2016–2019 under CMS' potential policy to require Part D plans to place generics only on generic tiers.

Avalere's analysis found that on aggregate, patient cost sharing would have been $15.7 billion lower for generic drugs from 2016–2019 under this potential policy, averaging $3.9 billion per year as a result of placing generic drugs on lower tiers (Figure 4). The placement of a substantial number of generic medications on non-generic tiers, as shown in Figure 2, leads to higher OOP spending for generics not currently on generic tiers.

Figure 4. Estimated Beneficiary Savings Under a CMS Policy Requiring Generic Drugs on Generic Tiers, 2016–2019*



*Savings applies to beneficiaries taking generic medications.

Patients within specific therapeutic areas are also estimated to experience savings in generic drug cost sharing if all covered generics are placed on generic tiers. Avalere examined 5 therapeutic classes (all but one are considered protected classes in Medicare Part D) and estimated the aggregate beneficiary savings for beneficiaries who use generic drugs in those classes (Table 1). Beneficiaries taking antidepressant drugs were estimated to save the most in cost sharing, followed by those taking antipsychotics and cardiovascular (Table 1). Studies have found lower cost sharing can translate to increased medication initiation and adherence.[30,31,32,33]

Table 1. Estimated Savings to Beneficiaries Utilizing Generic Drugs Across 5 Therapeutic Classes, 2016–2019

Estimated Medicare Part D Beneficiary Out-of-Pocket Savings, by Therapeutic Class, 2016–2019				
Therapeutic Class	**CY 2016**	**CY 2017**	**CY 2018**	**CY 2019**
Cardiovascular Agents	$348 M	$497 M	$503 M	$509 M
Antidepressants (Mental Health)	$484 M	$520 M	$540 M	$561 M
Antipsychotics (Mental Health)	$403 M	$415 M	$424 M	$434 M
Antineoplastics (Oncology)	$156 M	$199 M	$216 M	$235 M
Anticonvulsants	$217 M	$209 M	$215 M	$222 M

Implications of Proposed Tier Policy Change on Health Plan Costs

CMS' request for comment on requiring generic drugs to be placed on generic tiers or discouraging their inclusion on branded tiers has implications outside of reducing beneficiary OOP spending on generic drugs. Previous statements from CMS have noted that Medicare Part D plans place generics on higher tiers as a way to maintain actuarial equivalence and limit premium increases.[34] For Part D plans, moving generic drugs from higher to lower tiers results in plans bearing a higher proportion of drug spending costs and, thus, increasing their liability and actuarial value (AV).

Avalere's analysis finds that requiring generic drugs to be placed on generic tiers would be associated with a 4.5% increase in Part D plan liabilities for prescription drugs in 2019 (Table 2). This increase, as a share of total Part D plan liabilities is relatively small, as generic drugs make up a small percentage of total spending in Medicare Part D, at 16% in 2016.[35,36]

Additionally, Avalere estimates the share of total costs that would be paid by Medicare Part D plans, relative to total costs, and the expected cost increase expected to be borne by plans under this policy. Under current policy in 2019, Part D plans pay an average of 63% of total drug costs. Under a new requirement to place all covered generic drugs on generic tiers, Part D plans would pay an average of 65% of total drug costs (Table 2).

Table 2. Estimated Impact on Health Plan Share of Costs in Medicare Part D, 2016–2019

	CY 2016	CY 2017	CY 2018	CY 2019
Estimated Percentage Increase in Plan Liability for Prescription Drugs	4.4%	4.5%	4.9%	4.5%
Current Policy Estimated Plan Share of Total Costs in Medicare Part D	61.7%	62.6%	62.6%	62.6%
Estimated Plan Share of Total Costs in Medicare Part D Under Proposal	64.4%	65.4%	65.6%	65.4%

Part D plan movement of generic drugs to non-generic formulary tiers has likely contributed to the stability and relative low cost of Part D plan premiums since 2010.[37] Other factors, such as cost sharing, utilization management tools, and benefit structure also contribute to plans' ability to manage costs and maintain actuarial value requirements. Should this potential policy change be implemented, Part D plan liability and AV will rise, leading to higher premiums for beneficiaries unless plan sponsors pursue other levers to control premiums, such as changes to

formulary coverage and manufacturer contracting strategies as well as benefit designs, tier placement, and utilization management.

Conclusion

Generic drugs in Medicare Part D have experienced a shift from nearly exclusive placement on generic tiers prior to 2012 to nearly evenly divided placement between generic and non-generic tiers in 2019. That trend, encouraged by the creation of the non-preferred drug tier in 2017, has resulted in higher beneficiary cost sharing for generic medications over time, reducing the incentive for beneficiaries to take lower priced generic medications. As CMS considers options to incent lower-priced medications to reduce OOP costs in the Part D program, a requirement for generic drugs to be covered only on generic tiers could achieve this objective, saving patients who take generic drugs an estimated $4.1 billion in 2019 (Figure 4). At the same time, formulary tier policies that would generally keep generic and brand drugs on separate tiers as considered in the CY2020 ANCL, would shift the cost of higher priced brand drugs back to Part D plans and could result in higher plan premiums and other potential changes to plan design in reaction to those higher costs.

Methodology

Avalere analyzed CMS PUFs with Medicare Part D formulary and benefit design information for 2016–2019, as well as the Part D Prescription Drug Event (PDE) data from 2016 to 2017, under the terms of a CMS research data use agreement (DUA).

Avalere excluded beneficiaries enrolled in the Employer Group Waiver Plans (EGWPs) from the analysis. The study used the brand/generic indicator assigned to drugs in the formulary data as well as PDE data. Part D plans name and define their tiers in a variety of ways. For consistency this analysis aggregated different names into six tier categories: Generic, Preferred Generic, Preferred-Brand, Non-Preferred Brand, Non-Preferred Drug, and Specialty.

Avalere estimated the potential reduction in beneficiary OOP spending due to all generic drugs being placed on generic tiers by assessing cost-sharing associated with generic drugs across different tiers as well as generic drug utilization, i.e., number of prescriptions. In compliance with the CMS DUA, no more than 20% of all Medicare Part D beneficiaries were included in the aggregate analysis and in any particular therapeutic class analysis. We estimated reductions in OOP spending using generic prescription counts reflecting the applicable, randomized beneficiary samples and inflated the amounts to account for the total Part D population.

For the years 2016 and 2017, Avalere analyzed actual utilization for generic medications from PDE data. Assuming constant plan formulary management for the years 2018 and 2019, Avalere projected the expected OOP savings based on the historical growth in the utilization of generic drugs from 2016 to 2017. For all years of the analysis, 2016 to 2019, Avalere used

actual plan formulary design and tiering information for generic drugs from the CMS' PUFs. For all the generic drugs that are placed on non-generic tiers, Avalere assumed that, under the CMS proposal, these products are shifted to the highest generic tier for that plan. The difference between beneficiary cost-sharing based on current tier placement and the hypothetical cost-sharing for that same drug and volume, by plan, were it placed on a generic tier was aggregated and presented as the potential amount to be saved by beneficiaries or the federal government via reduced low-income subsidies. For the purposes of this savings estimate, Avalere assumed consistent cost-sharing across all Part D benefit phases.

Avalere segmented the estimated savings by five therapeutic areas: Cardiovascular Agents, Antidepressants, Antipsychotics, Antineoplastics and Anticonvulsants, as defined by the United States Pharmacopeia (USP) drug classification included in the Medicare Model Guidelines for covered by Part D drugs.

In addition, Avalere estimated the impact on health plan costs as a result of the shift in tier placement for generic drugs due to the CMS proposal. For the years 2016 and 2017, Avalere aggregated the plan liability amounts from the 2016 and 2017 PDE data. For the years 2018 and 2019, Avalere projected the expected plan liability based on the total Part D spending growth in the Medicare Trustees Report. [38] Accounting for the beneficiary savings due to all generic drugs being placed on generic tiers, to act as a liability to the Plans, Avalere calculated the estimated increase in Plan liability for Prescription Drugs, compared to current plan liability.

Avalere's analysis of 2019 formularies is a point in time analysis and does not account for new generic entries during the 2019 calendar year. In the proposed rule, CMS requests comments on whether to require generic and biosimilar Medicare Part D formulary placement upon launch. Avalere's modeling does not attempt to model this potential proposal and does not assume any additional or expanded generic or biosimilar Medicare Part D formulary placement in the years studied. Finally, Avalere's analysis also does not estimate higher patient utilization of generic drugs due to lower tier placement nor shifts in utilization from branded products to generic products due to lower cost sharing for generics.

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