Your Generics & Biosimilars Industry

Biosimilars Council
A Division of AAM

March 1, 2019

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Submitted via http://www.regulations.gov

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part D, and Part D Payment Policies and 2020 Draft Call Letter (CMS-2018-0154)

Dear Mr. Kouzoukas:

The Association for Accessible Medicines (AAM) and the Biosimilars Council (the Council) appreciate the opportunity to provide comments in response to the agency's *Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part D, and Part D Payment Policies and 2020 Draft Call Letter [CMS-2018-0154]* ("the Call Letter"). AAM and the Council (collectively referred to in these comments as "AAM") represent the manufacturers and distributors of finished generic and biosimilar pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. Generics represent greater than 90% of all prescriptions dispensed in the U.S. by volume, but only 23 percent of the cost expended on prescription drugs. AAM is the sole association representing America's generic pharmaceutical sector in the United States. AAM works to expand patient access to safe, quality and effective generic and biosimilar medicines, including by promoting a positive regulatory, reimbursement, political and policy environment, and supporting education about the safety and effectiveness of generics and biosimilars.

We applaud the continued attention of the U.S. Department of Health & Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS) and the Food & Drug Administration (FDA) as they work to reduce prescription drug costs for patients as part of the President's Blueprint. This is the core

mission of the generics and biosimilar medicines industry and was the Congressional intent in creating a pathway for FDA approval of lower cost generic and biosimilar medicines through the 1984 Hatch-Waxman Act[1] and the 2009 Biologics Price Competition and Innovation Act (BPCIA)[2].

In fact, encouraging competition and patient adoption of more affordable generic and biosimilar medicines is a critical component of achieving the Administration's goal of lowering patient out-of-pocket spending. In 2017, competition from generic medicines resulted in more than $265 billion in savings to the U.S. health care system - $82.7 billion in savings for the Medicare program.[3] Generic drugs comprise 90 percent of all prescriptions, but only 23 percent of all spending.[4]

Moreover, as the use of specialty and biologic drugs has increased to more than 40 percent of all drug spending[5], competition through specialty generic and biosimilar medicines is vital to lowering spending while ensuring patient access to needed therapies. Currently marketed biosimilars are, on average, priced 40 percent lower than their brand counterparts and are poised to provide significant savings to the Medicare program and its beneficiaries.[6]

Just as FDA plays a vital role through the review and approval of more affordable generic and biosimilar drugs, CMS influences patient access to these lower priced medicines through its ability to influence drug formulary design in Medicare and Medicaid. In order to meet its stated goal of lowering patient out-of-pocket costs, it is vital that the Administration work to ensure that federal programs encourage the use of lower-cost therapeutically equivalent generics and biosimilars. Accordingly, we submit the following comments that support CMS finalizing the following policies as part of its Call Letter for CY2020:

- requiring plans to automatically include generic and biosimilar medicines on generic formulary tiers immediately after launch;
- ensuring that plans place generics on generic tiers and brands on brand formulary tiers to reverse the practice of mixing generics on brand tiers; and
- creating a dedicated, more favorable specialty tier with lower beneficiary cost-sharing for generics and biosimilars.

CMS Should Require that Generic Drugs Are Placed on Generic Tiers and Brand Drugs Are Placed on Brand Tiers

In the Call Letter, CMS is considering and seeking comment on an "alternative" tiering policy for CY2020 that would discourage or prohibit sponsors from placing generics on brand formulary tiers or brand drugs on generic formulary tiers, and that would eliminate the non-preferred drug tier - practices that

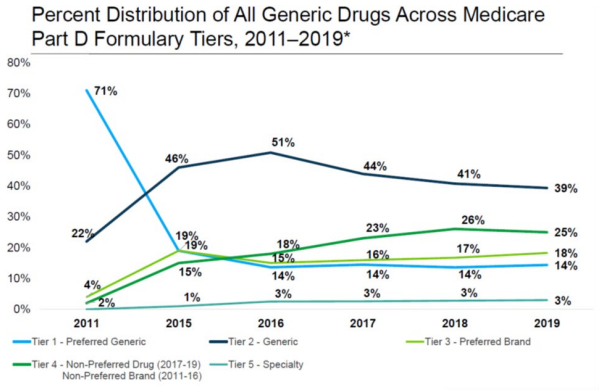
[1] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417 (1984).
[2] Biologics Price Competition and Innovation Act (Public Law 111–148).
[3] Association for Accessible Medicines, *2018 Generic Drug Access & Savings in the U.S.* http://RxAccessReport.us.
[4] *Ibid.*
[5] Food and Drug Administration (FDA), *Biosimilars Action Plan.* Available online: https://bit.ly/2ux50Ct.
[6] AAM Analysis of IQVIA WAC Data, December 2018.

are driving higher out-of-pocket costs for beneficiaries[7]. We commend CMS' focus on the impact of formulary design in directly affecting patient out-of-pocket spending. We also commend the Agency for its statement that Part D sponsors should prioritize formulary placement for generics and biosimilars through favorable tier placement relative to branded products.

Patients are Paying more for Generic Drugs in Medicare, even as the Prices are Unchanged[8]

CMS has been a leader in providing plan sponsors additional flexibility to encourage the use of lower-cost generic and biosimilar drugs.[9] However, recent data from Part D indicates that generic drugs are increasingly being placed on higher tiers with higher cost-sharing, sometimes in a disadvantaged position compared to the higher cost brand. A recent Avalere Health report found that in 2011, 71 percent of generic drugs were placed on tier 1, representing the lowest cost-sharing available for patients. By 2015, due to changes in sponsor formulary design to manage increasing costs of brand products, only 19 percent of generic drugs were placed on tier 1; almost half (46 percent) of all generic drugs were placed on tier 2 and the remaining 35 percent of generic drugs were placed on tier 3 or higher. This has occurred equally among both high and low-cost generics even though prices for generic drugs have remained flat or fallen.[10]

In a report released this week that expanded on their previous white paper, Avalere examined Medicare data from 2016 – 2018. Their analysis shows that in 2016, plans covered generic drugs on the generic tier (Tier 2) 51 percent of the time – by 2019, that number had declined to only 39 percent of the time. This was accompanied by continued growth in the placement of generics on Tiers 3 and 4. In 2019, 43 percent of generics were placed on either Tier 3 (Preferred Brand) or Tier 4 (Non-Preferred Drug).[11]



[7]Avalere Health: Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs." February 28, 2018. Available at: https://bit.ly/2IDOdqG. Accessed: February 28, 2018.

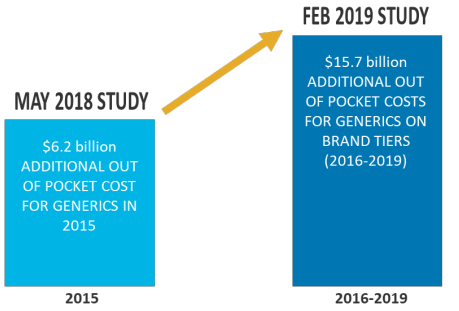
[8] Avalere Health: "Generic Drugs in Medicare Part D: Trends in Tier Structure and Placement." May 22, 2018). Available at: https://bit.ly/2kx8cIP. Accessed: July 5, 2018.

[9] CMS "Contract Year (CY) 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P)"

[10] Avalere Health: "Generic Drugs in Medicare Part D: Trends in Tier Structure and Placement." May 22, 2018). Available at: https://bit.ly/2kx8cIP. Accessed: July 5, 2018.

[11] Avalere Health: Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs." February 28, 2018. Available at: https://bit.ly/2IDOdqG. Accessed: February 28, 2018.

These practices are particularly harmful to already vulnerable Medicare beneficiaries. According to Avalere's analysis, in 2019, "the two 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."[12] From 2011 to 2015, this tactic has led to a 97 percent increase – $6.2 billion – in additional out-of-pocket spending by Medicare beneficiaries, even though prices for those drugs were largely unchanged or declined. This has caused beneficiaries to spend more for drugs that cost only a fraction of the price of their branded counterparts, preventing patients from realizing the full value of low-cost generic medicines. In fact, the analysis estimated that beneficiaries would have saved $15.7 billion over the past three years - and $4.1 billion in out-of-pocket savings in 2019 alone - if the policy proposed in the CMS Call Letter had been in effect.[13]



[14]

Appropriate Incentives Are Essential to Encouraging Use of Lower Cost Options

This dramatic rise in out-of-pocket cost for patients has a significant impact on adherence and beneficiary health outcomes. Historically, when plans have placed generics on preferred generic or non-preferred generic tiers with low copays, while simultaneously placing brand drugs on preferred brand or non-preferred brand tiers with higher copays or coinsurance, patients have been 2-3 times more likely to adhere to their treatment regimen.[15] In fact, in 2017, the average generic was available in the U.S. for a copay of only $6.06, whereas the average cost-sharing for a brand was more than $40.[16] This differential drives the high rate of generic drug utilization resulting in billions in annual savings for the patient, the plan or payor, and it means that patients are more likely to achieve desired health outcomes. The placement of generics on higher tiers jeopardizes this success and increases the risk of medication abandonment.

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[12] Avalere Health: Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs." February 28, 2018. Available at: https://bit.ly/2IDOdqG. Accessed: February 28, 2018.
[13] *Ibid.*
[14] Avalere Health: "Generic Drugs in Medicare Part D: Trends in Tier Structure and Placement." May 22, 2018). Available at: https://bit.ly/2kx8cIP. Accessed: July 5, 2018.; Avalere Health: Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs." February 28, 2018. Available at: https://bit.ly/2IDOdqG. Accessed: February 28, 2018.
[15] Association for Accessible Medicines, 2018 Generic Drug Access & Savings in the U.S. http://RxAccessReport.us.
[16] *Ibid.*

Placing Generics on Higher Tiers Causes Patient Confusion

As CMS has noted, the practice of co-mingling generics and brands on formulary tiers and then using tier labels that do not accurately reflect the makeup of the tier can lead to beneficiary confusion. Many rules and requirements for Part D plans are predicated on the notion that when they shop for plans, beneficiaries have complete and accurate information on all prescription drugs they will take during a calendar year. While this is the case for some beneficiaries on chronic therapies, other beneficiaries either start new therapies or switch therapies mid-year. Those beneficiaries must select their plan for the year using the information available to them during the enrollment period.

Patients should have confidence the tier labels provide an accurate description of the products covered on that tier, so that when they select a plan they may make an informed decision based on their own treatment needs. Likewise, when a beneficiary and his or her prescriber discuss therapy options and decide on a treatment plan, the beneficiary should be able to reasonably estimate his or her potential out-of-pocket costs before arriving at the pharmacy so that access to therapy is not needlessly delayed. Therefore, AAM agrees with CMS that generics should be treated as generics and brands should be treated as brands with respect to formulary placement.

Placing Generics on Higher Tiers Increases Taxpayer Spending

Creating cost-sharing differentials between tiers is one of the most common ways to encourage beneficiaries to choose the most therapeutically-appropriate, lowest-cost option available. To drive desired beneficiary behavior, higher cost-sharing tiers should be reserved for higher-priced drugs for which a lower-cost therapeutic option exists. Until recently, plans generally incorporated this concept into their benefit design. However, as the Avalere analysis cited above found, plans have increasingly separated the net cost of the drug from the drug's tier placement, as evidenced by elevating generic drugs to higher tiers despite their lower cost. This may decrease a beneficiary's incentive to choose a generic drug and lead him or her to choose a higher-priced brand drug instead, driving up costs for the Medicare program.

In fact, last year, a report issued by the HHS Assistant Secretary for Planning and Evaluation (ASPE) found that patients and taxpayers could have saved almost $3 billion in 2017 if all Medicare beneficiaries had taken advantage of generic substitution opportunities instead of filling prescriptions with brand-name drugs.[17]

CMS Should Immediately Adopt its Proposal To Eliminate the Non-Preferred Drug Tier

AAM and the Council applaud the Administration's proposal in the Call Letter to eliminate the non-preferred drug tier, and we encourage CMS to implement this policy in CY2020. We agree with CMS that finalizing this policy will "encourage the utilization of more affordable generics and biosimilars, lower

[17] U.S. Department of Health and Human Services Office of the Assistance Secretary for Planning and Education. Data Point: Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D (July 23, 2018). Available at: https://aspe.hhs.gov/system/files/pdf/259326/DP-Multisource-Brands-in-Part-D.pdf. Accessed: February 13, 2019.

out-of-pocket costs and avoid beneficiary confusion." This proposal is vital to ensuring that patients realize the full value of lower-priced generic medicines. Banning the inclusion of generics on brand tiers responds to a dangerous trend and would immediately reduce out of pocket spending for millions of seniors.

As part of the proposal, CMS sought input on several issues related to the implementation of its proposal, including:

- a plan's ability to meet the actuarial equivalence tests in the bid pricing tool;
- The anticipated impact on premiums and beneficiary cost sharing, including CMS established cost-sharing thresholds and other tier requirements; and
- formulary drug coverage and other formulary benefit design impacts, including sponsors' negotiations with manufacturers.

In its recent analysis, Avalere found that restricting tier composition is unlikely to upset the ability of plans to meet actuarial equivalence tests in the Part D bid pricing tool. Generic drugs only account for 16 percent of total prescription drug spending in Medicare Part D and Avalere estimated that this policy change would result in a 4.5 percent increase in Part D plan prescription drug liabilities. This would represent only a marginal increase in total Part D plan liabilities (less than 3 percent).[18] By comparison, the policy change would produce more than $4 billion in annual out-of-pocket savings for beneficiaries.[19]

Moreover, CMS gives plans a range of tools to manage costs as a means to keep premiums flat while still covering high priced brand drugs. Recently, CMS has taken important steps to give plans further flexibility[20], and plans should be aggressively working to manage high brand drug prices. While plan sponsors and CMS must meet and enforce program requirements, beneficiaries who take generic drugs should not be held financially responsible for pricing decisions made by brand manufacturers. Additionally, Part D plans should not have the ability to "mask" brand drug price increases by moving low-cost generic products to higher cost-sharing tiers.

To that end, we believe implementation of this proposal would still allow plans to leverage negotiation power with manufacturers, while minimally impacting beneficiary premiums and enabling plans to meet actuarial equivalence standards.

CMS Should Encourage Plan Sponsors to Add a "Generic" Specialty Tier with Lower Coinsurance for Biosimilars and Generics

CMS also requested comments on whether biosimilars should be treated the same as generic medications for purposes of this policy, and if biosimilars and generic medications should be eligible for

[18] Avalere Health: Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs." February 28, 2018. Available at: https://bit.ly/2IDOdqG. Accessed: February 28, 2018.
[19] *Ibid*.
[20] CMS "Contract Year (CY) 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P)"

specialty tier placement if their cost exceeds the specialty tier threshold. AAM strongly supports the treatment of biosimilars as generics for the purposes of tier placement under this proposal.

Currently, generics exceeding the specialty tier threshold are eligible for specialty tier placement. However, beneficiaries are disadvantaged when using a generic drug that exceeds the specialty threshold due to the level of coinsurance many Part D plans charge beneficiaries for generic drugs on the specialty tier. Moreover, the presence of only a single specialty tier limits the ability of health plans to encourage the use of lower cost generics or biosimilars through preferred formulary placement.

Nearly all Part D plans charge coinsurance for drugs that exceed the specialty tier threshold.[21] The specialty tier coinsurance ranges from 25 percent to 33 percent (the most allowed by CMS guidelines) of the cost of the drug. Numerous studies have found that higher out-of-pocket costs under current Part D policies are associated with markedly higher rates of abandonment of new specialty drug prescriptions[22]; reductions and delays in treatment initiation following a new diagnosis or disease progression[23]; delays between refills or treatment interruptions[24]; and earlier discontinuation of treatment.[25] Enabling plan sponsors to establish a generic specialty tier with lower coinsurance may increase beneficiary adherence by lowering out-of-pocket costs, improve overall health outcomes, and produce savings to the Medicare program by encouraging greater adoption of generic and biosimilar medicines.

Therefore, AAM recommends CMS encourage plans to establish a Part D "generic" specialty tier with lower-cost sharing for biosimilars and generics that exceed the specialty cost threshold. The ability for plans to impose a lower coinsurance rate on generic and biosimilar products through the establishment of a generic specialty tier, as well lower cost-sharing for those biosimilars that do not meet the specialty threshold on lower cost-sharing generic tiers, would help to mitigate high costs for patients and drive utilization toward lower-cost alternatives. Today, there are more than 60 generics presently used in Part D that meet the CMS specialty threshold. As manufacturers invest in bringing generic and biosimilar

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[21] Kaiser Family Foundation. Medicare Part D: A First Look at Prescription Drug Plans in 2018. October 13, 2017. Accessible online: https://www.kff.org/report-section/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2018-findings/.

[22] Doshi, Jalpa, et al. "Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents." *American Society of Clinical Oncology Journals*, Dec. 2017, ascopubs.org/doi/full/10.1200/JCO.2017.74.5091.

[23] Doshi, Jalpa, et al. "High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients With Newly Diagnosed Chronic Myeloid Leukemia." *AJMC*, Mar. 2016, www.ajmc.com/journals/supplement/2016/improving-patient-access-to-critical-therapies-in-the-age-of-cost-sharing/high-cost-sharing-and-specialty-drug-initiation-under-medicare-part-d-a-case-study-in-patients-with-newly-diagnosed-cml.; Li, P, et al. "Association of High Cost Sharing and Targeted Therapy Initiation among Elderly Medicare Patients with Metastatic Renal Cell Carcinoma." *Current Neurology and Neuroscience Reports.*, U.S. National Library of Medicine, Jan. 2018, www.ncbi.nlm.nih.gov/pubmed/29195016.

[24] Olszewski, Adam, et al. "Subsidies for Oral Chemotherapy and Use of Immunomodulatory Drugs Among Medicare Beneficiaries With Myeloma." *American Society of Clinical Oncology Journals*, May 2017, ascopubs.org/doi/full/10.1200/JCO.2017.72.2447.; Li, Pengxiang, et al. "Impact of Cost-Sharing Increases on Continuity of Specialty Drug Use: A Quasi-Experimental Study." The Canadian Journal of Chemical Engineering, Wiley-Blackwell, 24 July 2017, onlinelibrary.wiley.com/doi/full/10.1111/1475-6773.12744.

[25] Doshi, Jalpa. Et al. "Biologic Therapy Adherence, Discontinuation, Switching, and Restarting Among Patients With Psoriasis in the U.S. Medicare Population." *Journal of the American Academy of Dermatology*, June 2016, https://www.jaad.org/article/S0190-9622(16)00128-6/abstract.

competition to high-priced specialty drugs and biologics facing patent and exclusivity expiration, these numbers will only increase. Therefore, it is essential the Administration act immediately to create a market structure that encourages investments in developing generic or biosimilar alternatives to high priced brand specialty drugs. This will be critical to ensuring a sustainable market and increased patient access to new specialty generics, biosimilars, and interchangeable biologics.

The Call Letter's Alternative Proposal is Critical to Ending Rebate Traps that Block Patient Access to Generics and Biosimilars

AAM commends CMS for its expectation "that FDA-approved, therapeutically equivalent generics would be automatically included on a generic formulary tier immediately after launch".[26] Increasingly, generic and biosimilar medicines are facing challenges to being included on any tier on a formulary – often the result of anti-competitive brand drug "rebate traps", which are conditioned on formulary exclusion of a lower-cost generic or biosimilar medicine. This anti-competitive practice blocks patient access to lower-cost generic or biosimilar products and forces additional costs on the U.S. health care system. The most pernicious form of this "trap" are "stacked" or "bundled" rebates.

As we have seen, the manufacturer of an originator product may even withdraw the rebates on a basket of products ("bundling") in the event that the contracted entity utilizes a biosimilar or generic in place of the reference product.[27] If brand-name manufacturers can eliminate the financial viability of manufacturing less-expensive competitor products, there will be no incentive for future investment, effectively ensuring long-term market protection far beyond congressional intent. Given the severity of this issue, AAM applauds the Administration for openly reprimanding this practice. Secretary Azar and FDA Commissioner Gottlieb have criticized the use of rebate traps, and the issue of rebate traps is under consideration by the agency as part of a separate rulemaking.

Nonetheless, it is important to note the interaction between this tiering proposal and the proposed changes to the anti-kickback treatment of rebates. Given the CMS Office of Actuary (OACT) analysis of the "Proposed Safe Harbor Regulation" estimates an increase in premiums[28], the proposed changes to the treatment of rebates could increase the interest by plan sponsors to place more generics and biosimilars on higher tiers to offset lost revenue. If this change occurs, the increased cost sharing for these low-cost drugs could reduce potential savings CMS has estimated for beneficiary out-of-pocket cost. While AAM will comment more fully in a separate letter to the effects of the new proposed rule to amend the safe harbor protections for rebates under the anti-kickback statute, it is important that CMS finalize its proposal to place generics and biosimilars on generic tiers and brands on brand tiers.

[26] CMS "Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter".
[27] The Center for Biosimilars: "Pfizer Execs Underscore the Need for a Level Playing Field for Biosimilars." Available at: https://bit.ly/2wLDMLQ. Accessed: May 15, 2018.
[28] CMS Office of the Actuary (OACT), "Proposed Safe Harbor Regulation" Report.

Conclusion

AAM urges CMS to finalize the "alternative" tiering policy for CY2020 and require plans to automatically include generic and biosimilar medicines on generic formulary tiers immediately after launch; ensure that plans place generics on generic tiers and brands on brand formulary tiers; and encourage plans to establish a more favorable generic and biosimilar specialty tier. Finalizing this policy will undoubtedly meet the goal outlined in the President's Blueprint to lower out-of-pocket costs for patients. These changes will reduce the potential for beneficiary confusion, and prevent health plans from using commoditized generics to manipulate the drug benefit program's formulary structure by placing generic drugs on higher tiers and disincentivizing their use relative to brands.

Implementing these policies would lead to a consistent shift of generic and biosimilar products to tiers with lower cost-sharing, thereby promoting patient access, increased adherence, and greater affordability. Such a shift would promote savings for the Medicare Part D program as more patients use lower-cost generics, and further the Administration's goals of promoting a robust biosimilar and specialty generic market.

Importantly, these policies still allow Part D plans to utilize their negotiating power to achieve lower prices and set their formularies within existing Medicare requirements. To ensure beneficiary access to biosimilars and ensure that patients and taxpayer benefit from the full value of new generic and biosimilar launches, CMS should clearly state in the final Call Letter its expectation that plans prioritize rapid uptake of generics and biosimilars with lower list prices.

We appreciate the opportunity to provide these comments. We look forward to continuing to work with CMS to expand patient access to more affordable alternatives to brand name medicines. If you have any additional questions, please do not hesitate to contact me at (202) 249-7100 or Christine.Simmon@accessiblemeds.org.

Sincerely,

Christine Simmon
Senior Vice President Policy & Strategic Alliances, AAM
Executive Director, Biosimilars Council

Attachment

- Analysis by Avalere Health: "Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs."

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

February 2019

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Avalere

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 towards 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

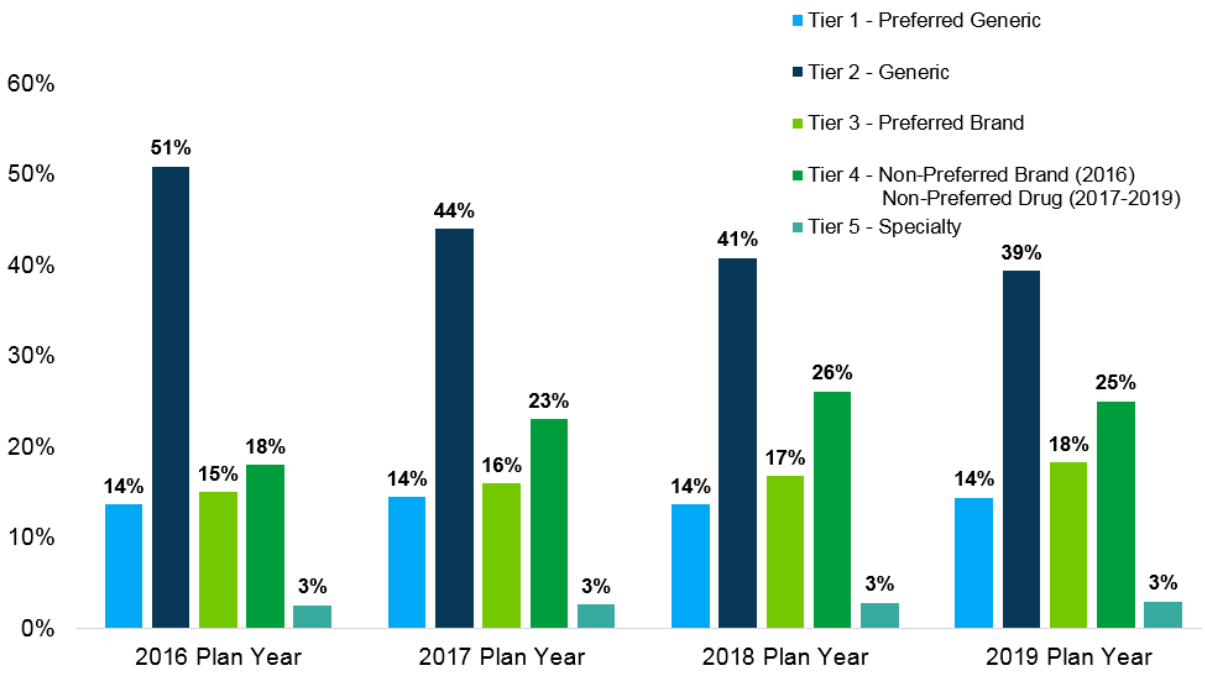
For years 2016 through 2019, plans placed Medicare Part D covered generic drugs on the lowest tier (preferred generic) only 14% of the time (Figure 1). In 2016, plans placed covered generic drugs on the generic tier (Tier 2) 51% of the time. By 2019, plans placed covered

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

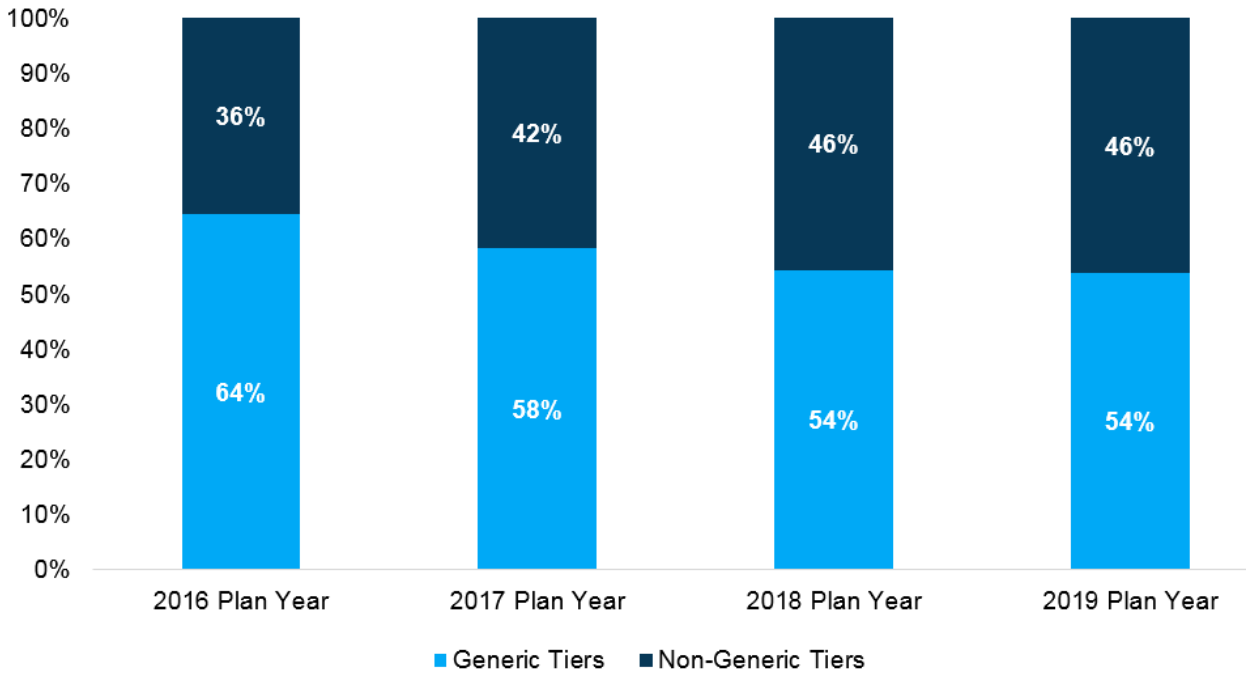


These findings demonstrate the continued trend of Part D plans moving generics to higher tiers. Creation of the non-preferred drug tier in 2017 appears to have led to plans in particular to move Part D covered generic drugs from the generic tier (Tier 2) to non-generic tiers.

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%.

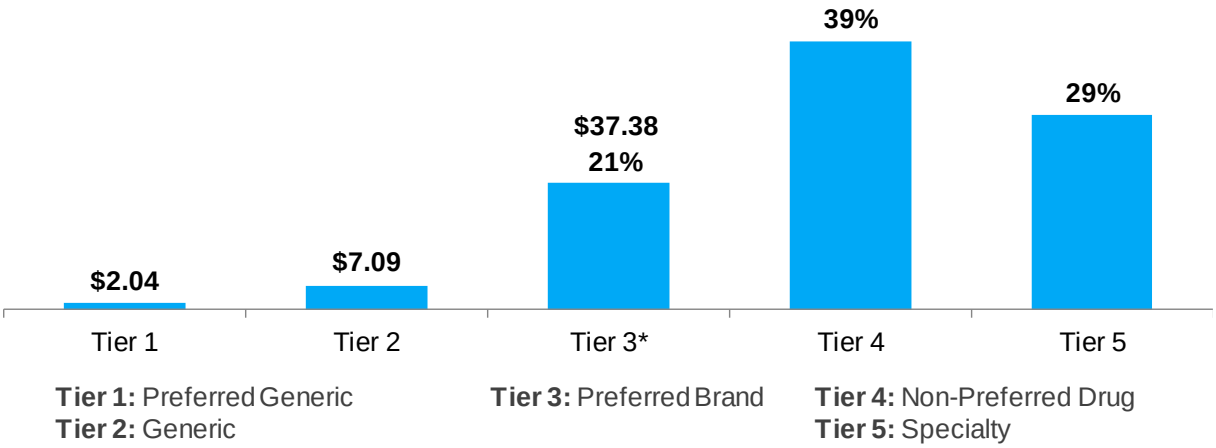
Figure 2. Distribution of All Generic Drugs on Generic and Non-Generic Tiers, 2016–19



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]



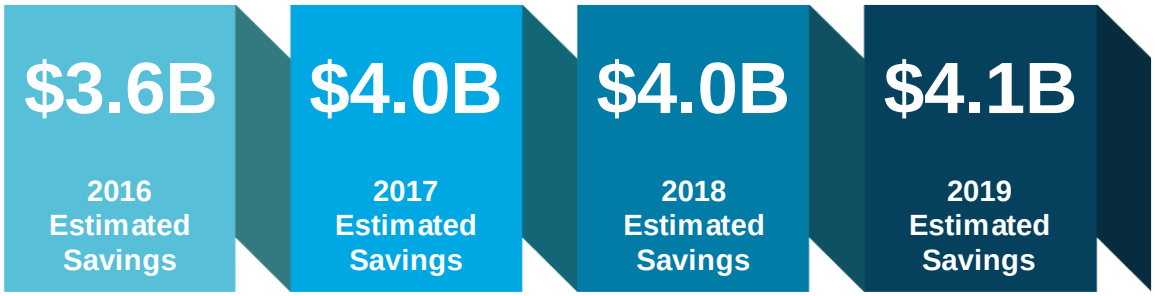
*Most Medicare Part D Prescription Drug Plans (PDPs) charge coinsurance for the preferred brand tier (average of 21% in 2019), while most Medicare Advantage prescription drug plans (MA-PDs) charge copayments for Tier 3, preferred brand drugs (average of $37.38 in 2019).

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]

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.[36] 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), included in the Inovalon's Medical Outcomes Research for Effectiveness and Economics Registry (the MORE^2 Registry®).

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.[37] 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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