

**COMMERCIAL**  
GENERIC

**MEDICARE PART D**  
GENERIC

AAM White Paper

# Medicare and Commercial Plans Fail to Get New Generics to Patients

Part D Design Increases Patient Out-of-Pocket Costs

FEBRUARY 2020

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Association for Accessible Medicines



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## Summary

Although public polling continues to find high drug costs are a major concern for voters, health plans in the Medicare program and the commercial market are delaying patient access to new lower-priced generic competitors.<sup>1</sup>

New generic competitors to high-priced brand drugs are particularly important for patients. First generics – safe and effective medicines approved by the U.S. Food and Drug Administration (FDA) as the first competitor to a brand – benefit patients by introducing competition and lower prices. But although the FDA prioritizes the review and approval of first generics and has been approving generic drug applications at a record-setting pace, these lower-cost options are often unavailable to patients.

Association for Accessible Medicines (AAM) data released in September 2019 found first generics face significant delays in Medicare Part D formulary coverage and are routinely placed on expensive brand drug tiers with higher patient cost-sharing.<sup>2</sup> Specific policy features of the Medicare Part D program contribute to this failure. These include the design of the Part D Coverage Gap Discount Program (CGDP), the availability of brand drug rebates on high-priced brand drugs and the lack of a specialty tier for generic and biosimilar medicines.

New data reveal commercial health insurance plans are also slow to achieving full coverage of new generics – taking almost two years for new generics to be covered on more than half of commercial drug formularies.

Federal policymakers should update Medicare Part D to ensure first generics are covered at launch with lower cost-sharing, including through a dedicated tier for specialty generic and biosimilar medicines. These changes could save taxpayers more than \$7 billion over 10 years and reduce premiums for seniors by more than \$2.5 billion over 10 years, while also lowering their out-of-pocket costs.<sup>3</sup>

State lawmakers can also take steps to guarantee that patients obtain the savings of generic medicines by ensuring that state-regulated health plans prioritize coverage of lower-cost generics. Taken together, these policies would restore the competitive balance between high-priced monopoly brand drugs and generic competition.

- 1 Politico. Harvard T.H. Chan School of Public Health. (January 2019). "Americans' Health and Education Priorities for the New Congress in 2019." <https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2019/01/Politico-Harvard-Poll-Jan-2019-Health-and-Education-Priorities-for-New-Congress-in-2019.pdf>.
- 2 AAM. (September 2019). "Access Denied: Why New Generics Are Not Reaching America's Seniors." Available at <https://accessiblemeds.org/resources/reports/white-paper-access-denied-first-generics>.
- 3 Association for Accessible Medicines (AAM) estimate of budget effects of requiring first generic products to be placed on generic tiers from 2020 to 2029.

# Findings

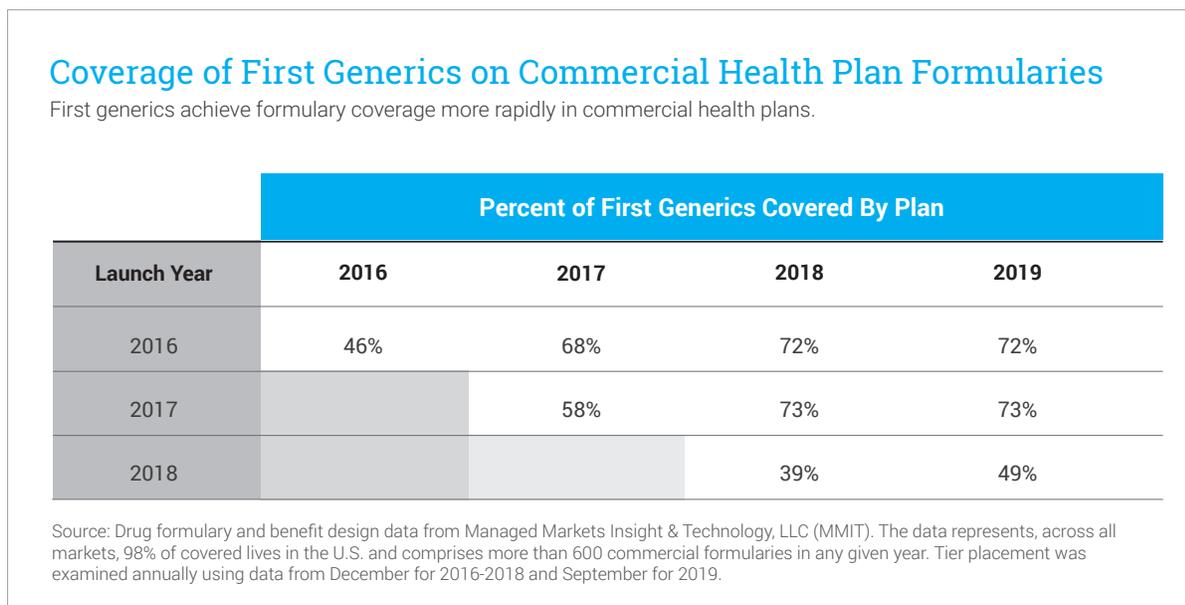
## Commercial Formularies Often Delay Coverage of First Generics

As previously shown, it takes nearly three years before first generics are covered on 50% of Medicare Part D formularies.<sup>4</sup> This “phase-in” period restricts patient access to lower-cost generics, unnecessarily imposing high cost-sharing for brand drugs even though lower-cost medications are available.

Commercial plan formularies also delay coverage of first generics.<sup>5</sup> Analysis of drug formulary and benefit design data representing 98% of covered lives in the U.S. and more than 600 commercial formularies demonstrates that first generics face coverage delays among a substantial portion of commercial drug formularies. Although first generics are included on commercial health plan formularies faster than in Medicare drug plans, policymakers should be concerned by the fact that only 75% of health plans are covering new lower-priced generic drugs even three years after launch.

Moreover, this coverage appears to plateau after two years (Figure 1), and policymakers should examine whether this data signals a worsening coverage trend.

Figure 1



4 AAM. (September 2019). “Access Denied: Why New Generics Are Not Reaching America’s Seniors.” <https://accessiblemeds.org/resources/reports/white-paper-access-denied-first-generics>.

5 To quantify the formulary coverage for, and subsequent patient access to, first generics in Medicare Part D and commercial health plans, AAM analyzed all first generics that were marketed (i.e., available for purchase) from 2016 to 2019. AAM then determined the percentage of Part D formularies and commercial formularies that included these products (at the molecule level) as covered drugs in the year of approval and subsequent years.

It is important to note that these poor coverage rates are not explained by generic drug prices. Nor is the difference in coverage rates among Medicare and commercial plans. The price for these products is the same across markets, and the generic drug supply chain is structured to drive generic drug prices down as more generic manufacturers compete for placement by wholesalers and pharmacies.<sup>6</sup> First generics launched between 2016 and 2018 are priced, on average, 30% less than their reference brand at launch and declined to more than 50% less by the second year.<sup>7</sup> The recent report by FDA examining launch prices of new generic competitors echoes these findings. FDA found that median first generic launch prices were 40% less than brand on net and 49% less than brands using list price.<sup>8</sup> It is clear that the reason Part D plans are not covering low-cost first generics is not because of their prices. Rather, it is a direct result of the perverse incentives in the Medicare Part D program that drive plans to prioritize brand drugs with high rebates over patient savings.

6 AAM. "Introduction to the Generic Drug Supply Chain and Key Considerations for Policymakers." <https://accessiblemeds.org/sites/default/files/2017-10/AAM-Generic-Brand-Drug-Supply-Chain-Brief.pdf>.

7 AAM. (September 2019). "Access Denied: Why New Generics Are Not Reaching America's Seniors." <https://accessiblemeds.org/resources/reports/white-paper-access-denied-first-generics>.

8 Conrad, R, Ph.D. and Lutter, R, Ph.D. (Dec 2019). "Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices." <https://www.fda.gov/media/133509/download>.

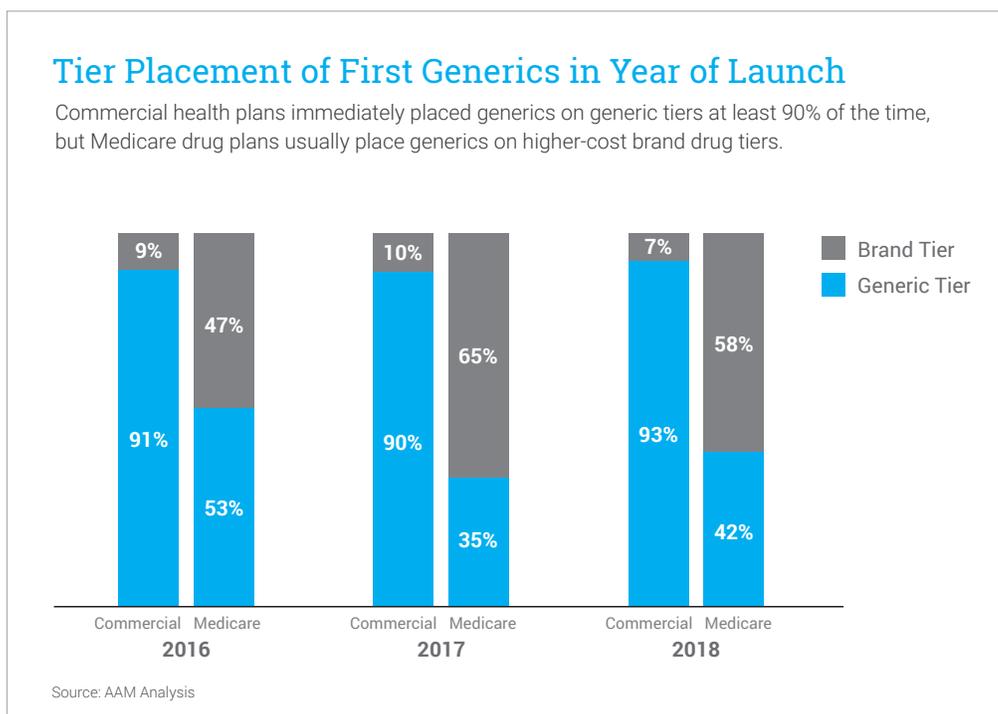
## Commercial Formularies Place First Generics on Generic Tiers More Often Than Medicare

Formulary coverage is an important first step to ensure patient access to first generics, but proper tier placement is critical to realizing the full value of lower-priced generic competition.

When Medicare Part D plans finally cover first generics, they consistently place those generics on non-generic brand tiers with higher cost-sharing for seniors (Figures 2 and 3).<sup>9</sup>

This trend appears to worsen with time. First generics are placed on generic tiers most frequently in their initial year of launch. But by the third year after launch, more formularies covering first generics placed them on higher-cost brand tiers, despite additional generic approvals and lower generic prices. This means patients may pay the same – or more – for a generic than for the higher-cost brand drug.

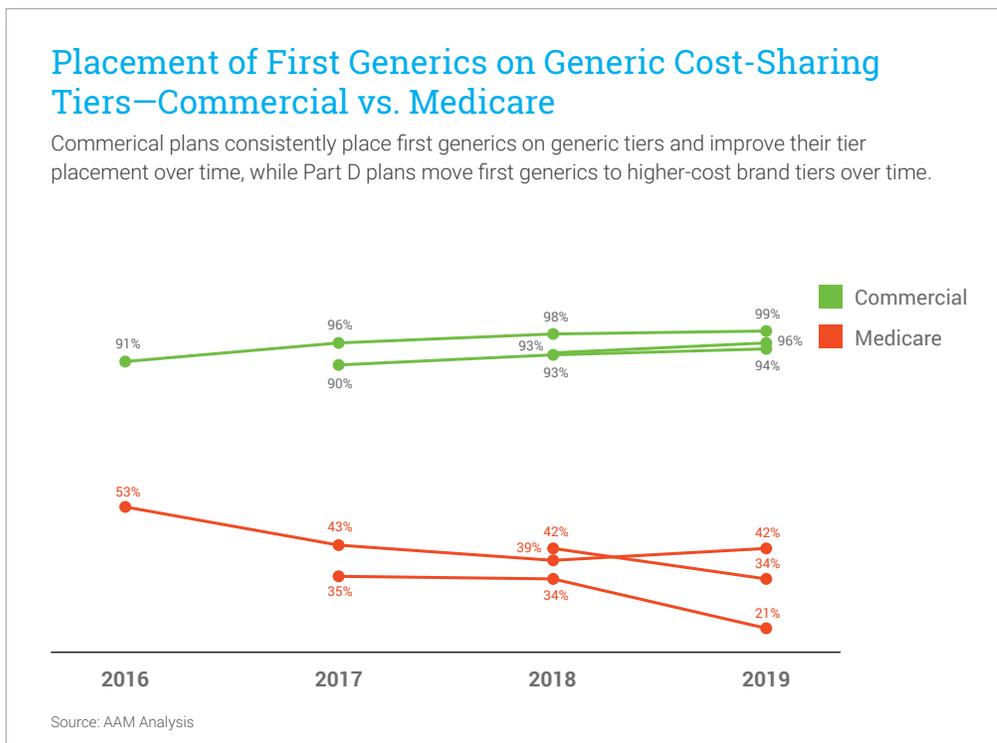
Figure 2



9 AAM. (September 2019). "Access Denied: Why New Generics Are Not Reaching America's Seniors." <https://accessiblemeds.org/resources/reports/white-paper-access-denied-first-generics>.

In contrast, commercial health plans consistently placed generics on lower-cost generic tiers – more than 90% of the time – and placement on generic tiers improved over time. Unlike Medicare plans, commercial plans placed first generics on generic tiers more often as their price decreased, responding appropriately to the changes in the market.

Figure 3



## Discussion

There are structural and incentive-based reasons for poor coverage of generics at launch and improper tier placement. For both commercial plans and Part D plans, there are significant incentives, such as manufacturer rebates, for plans to place brand medicines on preferred or similar tiers.

Additionally, the significantly worse coverage rates for first generics in Medicare can be traced to unique structural components of the Part D program: the design of the CGDP, the availability of brand drug rebates and the lack of a dedicated specialty tier for lower-priced generics and biosimilars.

Created to help alleviate patient out-of-pocket costs in the coverage gap, the CGDP requires brand drug manufacturers to provide 70% discounts on brand drugs dispensed in the coverage gap. Ironically, this creates an incentive for a plan to lower its financial liabilities, and increase Medicare's financial liabilities, by preferring higher-priced brand drugs.<sup>10</sup> In fact, researchers have found that Medicare patients can pay more out-of-pocket costs for generic medications than for brand-name drugs.<sup>11</sup> By counting brand drug discounts as patient spending, the CGDP effectively moves a high-cost patient through the coverage gap and into the catastrophic phase of the Part D benefit more quickly. This is a powerful incentive for plans to advantage higher-cost brand drugs over generics.

The availability of high rebates on high-priced brand drugs is also a significant factor in plan decisions on coverage and tier placement of new generics, even when a generic has a lower net price. This is due to the ability of brand manufacturers to leverage rebates for multi-year formulary deals and to bundle multiple brand drugs in a rebate arrangement.

***“Rebating has disadvantaged consumers, and it’s been used as a tool to block generic entry.”***

- Former FDA Commissioner Scott Gottlieb, M.D., November 6, 2019<sup>12</sup>

10 Medicare Payment Advisory Commission (MedPAC). (April 30, 2019). Statement of James E. Mathews, Ph.D. “Payment policy for prescription drugs under Medicare Part B and Part D.” Before the Subcommittee on Health Committee on Energy and Commerce U.S. House of Representatives Medicare Payment Advisory Commission (MedPAC). “Chapter 14: Status Report on the Medicare Prescription Drug Program (Part D).” Report to the Congress: Medicare Payment Policy, March 2017. [http://www.medpac.gov/docs/default-source/reports/mar17\\_medpac\\_ch14.pdf](http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf).

11 Dusetzina, Stacie B, et al. “Sending the Wrong Price Signal: Why Do Some Brand-Name Drugs Cost Medicare Beneficiaries Less Than Generics?” Health Affairs (Project Hope), U.S. National Library of Medicine, July 2019, <https://www.ncbi.nlm.nih.gov/pubmed/31260351>.

12 Cipriano, M. (Nov. 7, 2019). “Gottlieb: Branded Industry ‘Gaming’ Tactics Have Shifted From Regulatory to Commercial Space.” Pink Sheet.

This challenge of rebate blocking is particularly acute in the Medicare program. Once a beneficiary is in the catastrophic phase of the benefit, the manner in which brand drug rebates are shared between plans and the Medicare program incentivizes coverage of high-cost, high-rebate brands, even when their net cost is higher for Medicare.<sup>13</sup> This is because the rebate calculation is based on the share of each plan's gross spending above the catastrophic threshold, even though plans generate rebates based on drug spending below the out-of-pocket threshold as well. Put simply, although a plan is responsible for only 15% of costs in the catastrophic phase of the benefit, it retains a substantially higher percent of the brand drug rebates. In fact, the availability of these rebates can allow a plan to make money on high-cost, high-rebate branded drugs even though it costs more for the Medicare program.

Last, the Medicare program has established a single specialty tier for medicines with a negotiated price exceeding a specific threshold (\$670 per month in 2020), and specialty medicines account for an increasing share of total pharmaceutical spending.<sup>14</sup> However, as more generics come to market competing with high-priced, specialty medicines, this framework can increase out-of-pocket spending for seniors because it undermines Medicare plans' ability to provide lower cost-sharing for lower-priced specialty generics and biosimilars. Plans are then left with placing specialty generics and biosimilars on tiers with the same or higher cost-sharing as their higher-priced reference brand product.

While this issue is most pronounced in Medicare, due to the program-specific specialty tier issues, generic drugs nonetheless face similar issues in the commercial market. The generally limited number of commercial tiers, often encompassing a generic, branded and specialty tier, can lead to limited opportunities for tier differentiation for specialty generics and biosimilars.

13 Office of Inspector General, Department of Health and Human Services. (Feb. 6, 2019). "Proposed Rule. Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees." Federal Register.

14 IQVIA. (May 09, 2019). "Medicine Use and Spending In the U.S."

## Solutions

Policymakers can take immediate steps to improve patient access to lower-cost generics.

At the federal level, policymakers should adopt three simple reforms to update the Part D program and ensure that seniors receive the full benefit of lower-cost generics and biosimilars. These policies will meaningfully and immediately reduce out-of-pocket costs for Part D patients and generate savings for the Medicare program through increased utilization of lower-priced drugs. Policymakers should:

1. Ensure Medicare Part D plans cover all generic products at launch, particularly first generics;
2. Provide for placement of all generic products on tiers designated as generic and removed from brand tiers; and
3. Create a separate specialty tier to allow for differentiation among specialty brands and generics.

Likewise, state policymakers should take steps to ensure that state-regulated health plans prioritize coverage of lower-cost generics.

These policies would support greater patient access to lower-cost generics, ensuring America's patients will continue to realize substantial savings from their generic medications and the sustainability of a robust, competitive generics market that delivers quality, savings and value.

## Conclusion

First generics are a linchpin for patient and health care system savings, as well as for the sustainability of an industry that provides competition to expensive brand-name drugs. Generic drugs deliver 90% of America's prescription drugs at only 22% of total spending, but first generics face significant challenges to market sustainability – in large part as a direct result of Medicare Part D formulary obstacles that undermine patient adoption.<sup>15</sup> This harms future generic competition and deprives patients access to lower-priced generic medicines, forcing them to continue to pay for higher-cost brand drugs. Policymakers should act to ensure that America's patients, as well as the overall health care system, realize the full promise of lower-priced generic competition.

15 AAM. (May 13, 2019). "The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings In the U.S. Report." <https://accessiblemeds.org/resources/press-releases/11th-annual-edition-aam-access-savings-report-finds-generic-savings>.

## Methodology

This analysis was conducted on drug formulary and benefit design data from Managed Markets Insight & Technology, LLC (MMIT) to assess drug coverage and tier placement in the commercial market for first generics approved by FDA and commercialized since 2016. The data represents, across all markets, 98% of covered lives in the U.S. and comprises more than 600 commercial formularies in any given year.

Tier placement was examined annually using data from December for 2016-2018 and September for 2019. To facilitate tier placement analysis across plans with different tier structures, the data is standardized from a product's raw status (tier number or name given by the plan) into a "universal" tier status, which standardizes formularies into four tiers: Generic, Preferred Brand, Non-Preferred Brand and Specialty.

The average percent of times the drugs are covered in each plan year were computed across products from each launch year using plan-product combinations from 2016-2019. For products covered each year, by launch year, the analysis assessed the average percent of times the drugs are covered on specific tiers; Generic, Preferred Brand, Non-Preferred Brand and Specialty.

# Appendix

Figure 4

## Commercial and Medicare Part D<sup>16</sup> Tiering Results: First Generic Products from 2016 to 2019

**Tier coverage for products covered in a given year, by launch year, when covered.**

2016 Launches	% Placed on Generic Tiers: Commercial Market	% Placed on Generic Tiers: Medicare Part D	% Placed on Brand Tiers: Commercial Market	% Placed on Brand Tiers: Medicare Part D
2016	91%	53%	9%	47%
2017	96%	43%	4%	57%
2018	98%	39%	2%	61%
2019	99%	42%	1%	58%
2017 Launches	% Placed on Generic Tiers: Commercial Market	% Placed on Generic Tiers: Medicare Part D	% Placed on Brand Tiers: Commercial Market	% Placed on Brand Tiers: Medicare Part D
2017	90%	35%	10%	65%
2018	93%	34%	7%	66%
2019	94%	21%	6%	79%
2018 Launches	% Placed on Generic Tiers: Commercial Market	% Placed on Generic Tiers: Medicare Part D	% Placed on Brand Tiers: Commercial Market	% Placed on Brand Tiers: Medicare Part D
2018	93%	42%	7%	58%
2019	96%	34%	4%	66%

Source: Medicare formulary data as of September in each plan. Data from 2019 is for the most recent months available. Analysis excluded coverage of 2019 launches that may be added to formulary through mid-year formulary updates permitted by CMS.

Commercial drug formulary and benefit design data from Managed Markets Insight & Technology, LLC (MMIT). The data represents, across all markets, 98% of covered lives in the U.S. and comprises more than 600 commercial formularies in any given year. Tier placement was examined annually using data from December for 2016-2018 and September for 2019.

16 AAM. (September 2019). "Access Denied: Why New Generics Are Not Reaching America's Seniors." <https://accessiblemeds.org/resources/reports/white-paper-access-denied-first-generics>.



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