January 27, 2025

The Honorable Jeff Wu
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Submitted via http://www.regulations.gov

RE: Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly [CMS–4208–P]

Dear Acting Administrator Wu,

The Association for Accessible Medicines (AAM) and its Biosimilars Council appreciates the opportunity to provide comments in response to CMS's proposed rule titled, *Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.*

AAM is the nation's leading trade association for manufacturers of generic and biosimilar prescription medicines. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines. The Biosimilars Council works to increase patient access to lifesaving, high-value biosimilar medicines.

Ensuring the rapid adoption of lower cost generic and biosimilar medicines is essential to managing patient costs and taxpayer spending alike. Over the last ten years, generic and biosimilar medicines have provided more than $3.1 trillion in savings to U.S. patients and the healthcare system. In 2023 alone, these medicines provided more than $445 billion in savings, including more than $137 billion in savings for the Medicare program.[1] Because of their low-cost and high-value, generic and biosimilar medicines today account for more than 90 percent of all prescriptions dispensed in the US but only 13.1 percent of drug spending.

Unfortunately, barriers erected by pharmacy benefit managers (PBMs) have slowed adoption of new generic and biosimilar medicines. Left unchecked, these practices will further undermine the generic and biosimilar markets, driving up costs for patients and taxpayers. As the agency notes, "Part D sponsors

[1] AAM. (September 2024). "2024 Generic and Biosimilar Medicines Savings Report." Accessible at: AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf (accessiblemeds.org)

601 NEW JERSEY AVE, NW • SUITE 850 WASHINGTON, DC • 20001 • PHONE 202-249-7100 • FAX 202-249-7105 accessiblemeds.org /accessiblemeds

and their PBMs engage in practices that favor, intentionally or unintentionally, more expensive [reference drugs and biological products] over generic [drug]s, biosimilar [product]s, and other lower cost [Part D] drugs in terms of formulary placement or non-placement."[2] CMS requested comments on two key questions:

1. The prevalence of manufacturer rebates and the extent to which such rebates influence formulary decisions that reduce Part D beneficiaries' access to generic drugs, biosimilar products, and other lower cost drugs; and
2. Whether further programmatic actions within CMS's current statutory authority are necessary to prevent Part D formularies from excluding or disfavoring coverage of generic drugs, biosimilar products, and other lower cost drugs.

We commend the agency's proposal to review whether a plan's formulary and utilization management (UM) practices with respect to these drugs constitute a drug UM program that is ''cost-effective,'' ''reasonable and appropriate,'' and inclusive of ''incentives to reduce costs," and an evaluation of whether the formulary includes generic drugs, biosimilar products, and other lower cost Part D drugs. Additionally, we support the proposed plan to review the formulary placement of these products compared to reference drugs or biological products, and whether they are subject to different utilization controls. We encourage the agency to finalize these proposals as written.

However, CMS can, and should, do more to ensure that Part D enrollees benefit from rapid access to lower cost generic drugs and biosimilar products as soon as those products are available:

- Plan sponsors should be required to provide an explanation and justification when a formulary does not cover a new generic drug or biosimilar product, including whether the formulary is instead covering or preferring the reference product or an alternative product and attest that the covered or preferred reference drug or biological product is lower net cost at the unit level.

- The formulary review and approval process should ensure, at a minimum, that Part D plan sponsors cover generic drugs and biosimilar products at comparable rates to coverage in the commercial market.

Below, we describe how adoption of new generic and biosimilar medicines – once the backbone of savings for patients and taxpayers – is slowing. We encourage CMS to align the policies and incentives of the Part D program to ensure use of lower cost generic drugs and biosimilar products first.

New Generics & Biosimilars Bring Lower Costs – but Adoption is Slowing

Generic and biosimilar medicines continue to provide critical savings throughout the healthcare system and are particularly valuable to Medicare Part D. But even though generics and biosimilars offer demonstrably lower net prices, Medicare prescription drug plan (PDP) and Medicare Advantage Prescription Drug (MA-PD) plan adoption of new generic drugs and biosimilar products has decreased

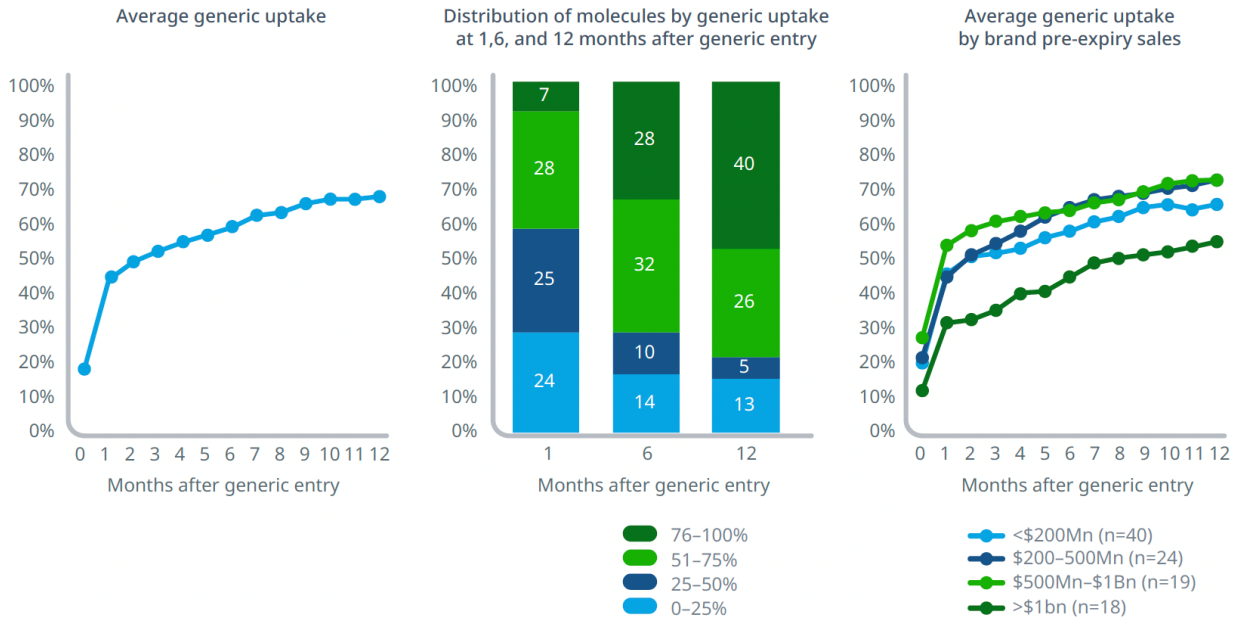
[2] Centers for Medicare and Medicaid Services, Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, at 99470. Available at: https://www.govinfo.gov/content/pkg/FR-2024-12-10/pdf/2024-27939.pdf

601 NEW JERSEY AVE, NW • SUITE 850 WASHINGTON, DC • 20001 • PHONE 202-249-7100 • FAX 202-249-7105 accessiblemeds.org /accessiblemeds

over the past several years. Analysis covering both commercial and Medicare Advantage claims data from 2012-2017 confirms a notable decrease in generic utilization with mean generic uptake for products in the first year after generic entry decreasing from 76.9 percent to 58.5 percent.[3] The analysis concludes this trend toward suboptimal plan uptake of "cheaper and equally effective generic drugs leads to increased US healthcare spending and hinders patient medication adherence."[4]

More recent IQVIA analyses show that these trends have only worsened, with new generic adoption rates slowing dramatically in recent years. Over a five-year period between 2018-2022, average generic drug uptake within 1-year after launch was limited to 67 percent. [5] This trend contrasts sharply with more historic models, which saw generics capturing 80-90 percent of script share within months.

Exhibit 48: Overall generic uptake for small molecule generics entering 2018–2022



Source: IQVIA National Sales Perspective, Aug 2023; IQVIA Institute, Nov 2023.

Medicare Policies Continue to Reward PBMs for Use of Reference Products instead of Generic Drugs or Biosimilar Products

These trends are driven by Medicare design favoring PBM use of higher cost medicines, including through rebates and fees, combined with consolidation and market control of the three leading PBMs that control nearly 80 percent of the market. In essence, these three entities – intermediaries with no

[3] Rome, B. N., Lee, C. C., Gagne, J. J., & Kesselheim, A. S. (2019). Factors associated with generic drug uptake in the United States, 2012 to 2017. *Journal of Generic Drugs*, 15(2), 123-135. Available at: Factors Associated With Generic Drug Uptake in the United States, 2012 to 2017

[4] Ibid.

[5] IQVIA Contributors. (May 2024). The Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024

601 NEW JERSEY AVE, NW • SUITE 850 WASHINGTON, DC • 20001 • PHONE 202-249-7100 • FAX 202-249-7105 accessiblemeds.org /accessiblemeds

fiduciary duty to patients – determine the formulary choices for almost all Americans. All three of the large PBMs operate their own specialty and mail-order pharmacies.

PBMs extract sizable rebates from reference manufacturers in exchange for limiting generic and biosimilar manufacturers' ability to gain market share when a generic or biosimilar launch occurs.[6] PBMs often exclude low-priced generic drugs and biosimilar products from their formularies if the PBMs can collect more in rebates by using the reference product.[7] Further, using "bundled rebates", the manufacturer of a reference product may withdraw or threaten to withdraw some or all of the rebates on a basket of products ("bundling") if the contracted entity—typically the health plan—utilizes a generic drug or biosimilar product in place of the reference product. These perverse rebate practices lead to PBMs blocking or delaying coverage and formulary status for lower cost generic drugs or biosimilar products.[8]

Evolution of Manufacturer Rebates and PBM Fee Models are Influencing Plan Coverage Decisions

Rebates are mostly used for high-cost, reference drugs and biological products in competitive therapeutic classes.[9] While PBMs have traditionally used manufacturer rebates as the mechanism to establish preferential product placement on plan formularies, PBMs are now more likely to utilize the fees and other, more elaborate, discounts tied to product list prices, PBM dispensing channel revenue and even PBM private-label products to boost profits. Contract negotiations around rebates, fees, discounts, and other price concessions often occur with limited transparency into contract terms and conditions, which are considered trade secrets and vary widely.

PBMs share the blame for increasing drug costs because their demands for increased rebate and fee amounts drive manufacturers to raise list prices to maintain their profit margins net of those higher rebates.[10] In fact, drug rebates and list prices have been found by the USC Schaeffer Center for Health Policy and Economics to be positively correlated where, on average, a $1 increase in rebates is associated with a $1.17 increase in list price.[11] These practices lead to higher out-of-pocket costs for beneficiaries. When a Part D beneficiary faces coinsurance – which is frequently the case with high-cost specialty medications – the coinsurance is calculated based on the product's negotiated price, which is generally closer to list price, not the net cost for the plan after accounting for rebates.

[6] AAM, Hatch-Waxman Turns 40 (Feb. 2024), https://accessiblemeds.org/resources/press-releases/aam-white-paper-hatch-waxman-turns-40.
[7] Trish, E., Stat, PBMs Are Inflating the Cost of Generic Drugs (June 30, 2022).
[8] AAM Report, Middlemen Increasingly Block Patient Access to New Generics (January 2023).
[9] The Medicare Payment Advisory Council, Initial findings from MedPAC's analysis of Part D data on drug rebates and discounts, April 7, 2022, Available at: https://www.medpac.gov/wp-content/uploads/2021/10/MedPAC-DIR-data-slides-April-2022.pdf

[10] Tomicki, S, Dieguez, G, Alston M. A primer on prescription drug rebates: Insights into why rebates are a target for reducing prices, May 21, 2018. Available at: https://www.milliman.com/en/insight/a-primer-on-prescription-drug-rebates-insights-into-why-rebates-are-a-target-for-reducing
[11] Van Nuys, K, Ryan M, Ribero R, Sood N. The Association Between Drug Rebates and List Prices, February 11, 2020. Available at: https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/

601 NEW JERSEY AVE, NW • SUITE 850 WASHINGTON, DC • 20001 • PHONE 202-249-7100 • FAX 202-249-7105 accessiblemeds.org /accessiblemeds

Medicare Part D Redesign Failed to Address Perverse Rebate Incentives Favoring High List Price Products.

Policymakers sought to partially address these challenges through structural changes to the Medicare Part D benefit with the goal of reducing patient and government spending and modifying plan incentives. Among other changes, the Inflation Reduction Act (IRA) eliminated the Part D coverage gap and increased plan liability. But it also left PBM use of rebates untouched. It is increasingly clear that these policy changes have not altered PBM incentives for generic or biosimilar adoption under current formulary designs.

Lack of coverage can restrict patient access to lower-cost generic drugs and biosimilar products.[12] A formulary trend analysis conducted by Avalere examining both Part D and commercial payer coverage rates for new generics launched between 2016 and 2025 illustrates this point. Historical models show Part D plan sponsors coverage rates for first generics lag well behind commercial plan coverage of the same drug products. For example, it appears to take roughly three years before new generics are covered by more than half of all Medicare drug plans. On the other hand, on average, at least 50 percent of non-Medicare commercial plans typically cover first generic drug(s) and biological product(s) within the year after launch.

Although the Part D redesign intended to encourage faster Medicare adoption of new generics, data shows no improvement in the rate of generic formulary coverage in 2025, the first year of redesign implementation. In fact, the rate of new generic drug coverage actually *declined* in some cases. Across all first generics launched in 2024, an average of 24 percent of Medicare plans provided coverage in 2025.[13] Even for first generic drugs launched in 2021, the coverage rate among Part D plans was limited to 42 percent. The data are clear: Part D enrollees are being denied access to new, lower price generic medicines.

[12] Association for Accessible Medicines Contributors. (January 2023). Middlemen Increasingly Block Patient Access to New Generics. https://accessiblemeds.org/sites/default/files/2023-01/AAM-Middlemen-Block-Patient-Access-New-Generics-2023.pdf

[13] (November 2024) PY 2023, 2024, 2025 Medicare Part D and Commercial Coverage of First Generics and Corresponding Brands, Analysis Prepared for AAM.

601 NEW JERSEY AVE, NW • SUITE 850 WASHINGTON, DC • 20001 • PHONE 202-249-7100 • FAX 202-249-7105 accessiblemeds.org /accessiblemeds

Percent of First Generics Covered by Medicare Part D Plans by Formulary Year										
Launch Year	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
2016	22%	31%	63%	58%	60%	62%	61%	55%	56%	54%
2017		12%	25%	58%	65%	65%	64%	61%	65%	62%
2018			17%	27%	51%	54%	54%	53%	54%	54%
2019				31%	59%	72%	72%	70%	71%	70%
2020					21%	41%	60%	58%	58%	59%
2021						23%	46%	45%	44%	42%
2022							39%	44%	45%	58%
2023								39%	45%	34%
2024									23%	24%

Restrictive Coverage and Utilization Management Practices Are Used Across Multiple Products, Both Generic and Biosimilar

The proliferation of rebates paid by manufacturers of reference products to PBMs has complicated market incentives and dynamics and created PBM schemes, including "'brand" for generic" contracting, that ultimately limit first generic coverage. To better understand these practices, AAM engaged IQVIA to help identify case studies in which payers preferred reference products rather than a generic alternative.[14] IQVIA found that across multiple reference products, Part D plans blocked coverage of generic substitutes through PBM point-of-service rejections at rate of 62 percent even six months after loss of exclusivity (LOE). These plan and PBM coverage and utilization management practices limited generic product script share to 53 percent for the period examined.[15]

As part of its analysis, IQVIA examined select script share rates under four large Part D plans for first generic substitutes for brand Restasis®, Lyrica®, Ranexa®, and Invega®, noting the following trend.[16]

- Under Plan #1 formulary design, generic Restasis failed to exceed 10 percent script share post-LOE in February 2022, while approval rates never exceeded 40 percent and were below 20 percent for three of those five quarters.

- Under Plan #2, generic versions of Lyrica were limited to approximately 50 percent script share and approximately 30 percent approval rates for two quarters post-LOE until script share and approval rates increased to more than 98 percent.

[14] IQVIA. (June 2023) Exclusion of New Generics Brand-for-Generic ("B4G") Contracting Case Studies, Analysis Prepared for AAM.,
[15] Ibid.
[16] Part D plans examined were Aetna, Centene, Cigna and Humana.

601 NEW JERSEY AVE, NW • SUITE 850 WASHINGTON, DC • 20001 • PHONE 202-249-7100 • FAX 202-249-7105 accessiblemeds.org /accessiblemeds

- Plan #3 limited generic Ranexa in the Medicare D channel as approval rates hovered at approximately 25 percent for two quarters post-LOE.

- Approval rates for generic Invega under Plan #4 in the Medicare D channel settled at just approximately 40 percent for the six quarters post-LOE while new patient script share settled around 25 percent.

Slow Adoption of Biosimilar Adalimumab and Biosimilar Insulin Represent Real-world Case Studies in the Challenges of Misaligned Incentives in the Market

These coverage challenges are not limited to lower cost generic drugs but can be plainly seen in biosimilar products – most recently in biosimilar adalimumab and biosimilar insulin.[17] In 2023, AAM found that commercial plans, employers and patients missed out on savings up to $6 billion because of rebate schemes by PBMs.[18] The report highlights the strategy created by PBMs to protect $2 billion in profits by suppressing adoption of lower-cost versions of Humira® and identifies several factors that ultimately limited biosimilar market share, including:

- Humira remained a costlier option than adalimumab biosimilar products for health plans even after discounts, with a net price of approximately $2,100 for one month's supply compared to <$1000 for some biosimilar versions.
- Slow biosimilar uptake was driven by Humira® contracting and rebating practices and large PBM payer controls. A transition to biosimilar products would disrupt the traditional PBM profit model, as they would take in less in rebates and WAC-based fees, losing up to 84 percent of profit.

- Additionally, since nearly 80 percent of Humira® volume is dispensed by large, PBM-affiliated specialty pharmacies, lost revenue from dispensing Humira biosimilars would negatively impact large PBMs with vertically integrated pharmacies.

- This combined loss of PBM and affiliated specialty pharmacy profits exceeding $2B annually may have driven PBM contracting and rebating practices, leading to the slow adoption of biosimilar adalimumab in favor of Humira.

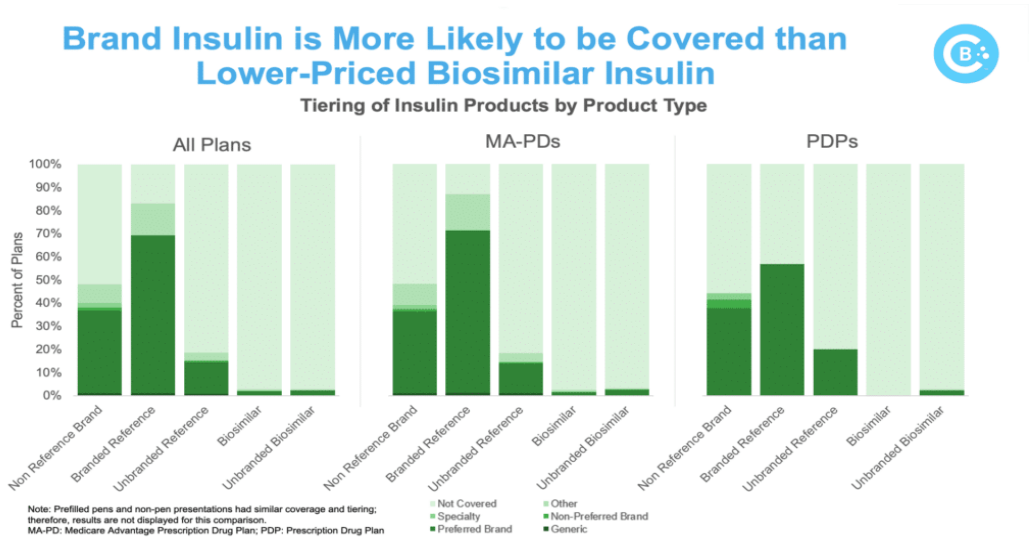
In Medicare, an analysis by Avalere Health on behalf of the Biosimilars Council, found that, across the five largest Medicare Part D parent organizations in 2023 (United Healthcare, Humana, CVS, Centene, and Cigna), biosimilars were substantially less likely to be covered than their reference products. *More specifically, while brand Humira was covered 99% of the time by these MA-PD and PDP plans, lower-priced biosimilars were only covered 6% of the time.*[19]

Likewise, PBMs also significantly restricted access to biosimilar insulin, with the five major payers offering better coverage for the brand while blocking or limiting coverage for the lower-cost biosimilar. While brand insulin Lantus was covered by Part D plans 83 percent of the time, biosimilars Rezvoglar

[17] Biosimilars Council. (April 2, 2024) Biosimilars Council Releases New Report: PBM Rebate Schemes to Suppress Biosimilar Humira Cost U.S. Patients $6 Billion, Available at https://biosimilarscouncil.org/news/pbm-rebate-suppress-biosimilar-humira/
[18] IQVIA. (April 2024) Adalimumab Biosimilar Tracking: Q1 Readout, Available at https://biosimilarscouncil.org/wp-content/uploads/2024/04/04022024_IQVIA-Humira-Tracking-Executive-Summary.pdf
[19] Avalere Health Contributors. (December 2023) Biosimilar Coverage, Tiering, and Management in Part D, Analysis Prepared for AAM, Available at https://biosimilarscouncil.org/resource/pbms-block-patient-access-lower-priced-biosimilar-insulin/

601 NEW JERSEY AVE, NW • SUITE 850 WASHINGTON, DC • 20001 • PHONE 202-249-7100 • FAX 202-249-7105 accessiblemeds.org /accessiblemeds

and Semglee were covered by Part D plans only 5 percent of the time. The results among Medicare Advantage plans were even worse, with biosimilars being covered only 3% of the time.[20]



PBM Use of Bundled Rebates also Limit Generic and Biosimilar Access and Extend Reference Product Manufacturer Control in High-cost Therapeutic Areas

Using bundled rebates, the manufacturer of a reference product may withdraw or threaten to withdraw some or all of the rebates on a basket of products ("bundling") if the contracted entity—typically the health plan—utilizes a generic drug or biosimilar product in place of the reference product. By participating in such schemes, the plan sponsor supports product hopping schemes that move patients to newer, high-cost, reference products instead of new generics or biosimilars.

For instance, since the introduction of more than 20 lower priced biosimilars, large PBMs actually shifted more patients from Humira to newer reference products with high prices than to all adalimumab biosimilars combined.[21] This trend, driven by script share shifting to other high-cost products in the therapeutic area, continued into Q3 of 2024 as brand script share limited adalimumab biosimilar growth to 1 percent.[22]

[20] Ibid.

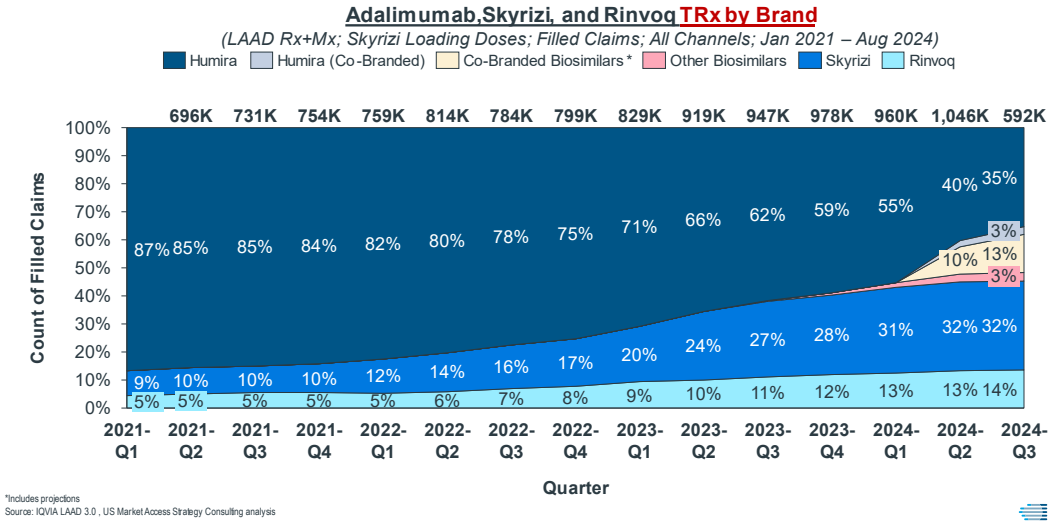
[21] IQVIA. (July 2024) Adalimumab Biosimilar Tracking: Q2 Readout, Available at https://biosimilarscouncil.org/wp-content/uploads/2024/08/202408-IQVIA-AAM-Adalimumab-Biosimilar-Launch-Tracking-Q3-Report.pdf

[22] IQVIA. (November 2024. Adalimumab Biosimilar Tracking: Q4 Readout.

601 NEW JERSEY AVE, NW • SUITE 850 WASHINGTON, DC • 20001 • PHONE 202-249-7100 • FAX 202-249-7105 accessiblemeds.org /accessiblemeds

Despite a drop in Humira share between 2024 Q2 and Q3, switching to Skyrizi and Rinvoq limited biosimilar growth to 1%

Biosimilar TRx is outnumbered by Skyrizi, Rinvoq, and branded Humira by a factor of 8.6 to 1 in 2024-Q3



AAM Recommends CMS Formulary Review Should More Effectively Push Part D Plans to Place Lower-Cost Generic Drugs and Biosimilar Products First

These findings both demonstrate the distortionary effects of plan and PBM coverage and rebating practices in Medicare Part D and spotlight a straightforward pathway the agency can use to improve patient access to these products. We encourage CMS to finalize its proposal to address these practices and to further examine the extent to which rebate contracting is limiting Part D beneficiaries' access to generics, biosimilars, and other lower cost drugs.

However, CMS can, and should, do more. Specifically, CMS should take immediate steps to better measure drug product net cost to ensure rebates and fees that drive formulary design and product placement result in a lower net cost *at the unit level*. This includes requiring sponsors to provide an explanation and justification when a formulary does not cover a generic drug or biosimilar product, including whether the formulary is instead covering or preferring the reference product or an alternative product; what rebates, fees or other contractual arrangements apply; and attest that the covered or preferred reference drug or biological product is lower net cost at the unit level. This would ensure that PBM contracting practices are delivering transparent, unit-level savings to payers and Part D enrollees when a reference drug or biological product is covered or preferred over a generic drug or biosimilar product.

Further, CMS could modify its formulary review and approval criteria to examine Part D plan sponsor coverage of generic drugs and biosimilar products compared to coverage rates for those products in the commercial market. It is important to recognize that, although the commercial market also suffers from the perverse incentives favoring use of higher-priced reference products, it nonetheless demonstrates higher coverage rates for many new generic drugs and biosimilar products on commercial formularies.

601 NEW JERSEY AVE, NW • SUITE 850 WASHINGTON, DC • 20001 • PHONE 202-249-7100 • FAX 202-249-7105 accessiblemeds.org /accessiblemeds

We believe that CMS oversight in Medicare Part D should lead to higher rates of coverage for these products to protect patient access and reduce patient out of pocket costs. CMS should review coverage rates of these products in Medicare Part D to understand why there is such a significant lag compared to commercial market formularies.

CMS has Clear Authority to Issue Regulations to Prevent Part D Formularies from Excluding or Disfavoring Coverage of Generics, Biosimilars, and Other Lower Cost Drugs.

Under the Medicare Modernization Act, CMS has broad authority to promulgate regulations to aid in the implementation, administration and oversight of the Medicare Part D benefit. Throughout the law, there are references to the Secretary developing and adopting regulations and standards as well as references to implementing the benefit.[23] This authority clearly extends to formulary design and requirements including placement of generic drugs on lower formulary tiers as well as mandatory coverage for generics that are new to the market.[24]

CMS has historically deferred to plan sponsors on many aspects of Part D beneficiary generic drug and biosimilar access, citing the non-interference clause in the Part D statute. We note, however, that the agency has additional authority here, as it has previously created additional formulary tiers with requirements related to out-of-pocket costs, and the Department of Health and Human Services has stated that *"[i]t has always been the Department's view that the non-interference provision does not exist in a vacuum and must be read in concert with Part D statutory obligations in connection with, for example, pharmacy network adequacy, consistency in treatment of drug costs, and the provision of adequate formularies."*[25]

Additional examples of the agency's engagement in this area include when it required plan sponsors or their PBMs that use a prescription drug pricing standard as the basis to pay network pharmacies to update their pricing metrics on January 1st of each year and every seven days thereafter.[26] Moreover, CMS has historically regulated the minimum composition for plan's formularies including mandatory coverage of two distinct drugs per class when outside of the six protected classes, required a Pharmacy & Therapeutics Committee establish a plan's formulary and that they approve the final plan formulary.[27] Plan sponsors, their PBMs and pharmacies are still free to negotiate any reimbursement, concessions, or payment structure in accordance with their preferences just as pharmaceutical manufacturers, plan sponsors and their agents are free to negotiate their rebate amounts, terms, and conditions.

[23] *See i.e.* 42 U.S.C. § 1395w-101(b) ("The Secretary shall establish a process for the enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in prescription drug plans consistent with this subsection.") and 42 U.S.C. § 1395w-101(c) ("The Secretary shall conduct activities that are designed to broadly disseminate information to part D eligible individuals (and prospective part D eligible individuals) regarding the coverage provided under this part.").

[24] 42 U.S.C. § 1395w-104(b)(3) giving the Secretary broad discretion in the area for formulary design and administration including working with the United States Pharmacopeia to develop therapeutic classes, establishing protected class of drugs and mandating an exception process.

[25] 85 Fed. Reg. 76666 (Nov. 30, 2020)

[26] *See* 42 C.F.R. 423.520(c) and 42 C.F.R. 423.505(b)(21), respectively.

[27] *See* 42 C.F.R. 423.120(b).

601 NEW JERSEY AVE, NW • SUITE 850 WASHINGTON, DC • 20001 • PHONE 202-249-7100 • FAX 202-249-7105 accessiblemeds.org /accessiblemeds

Taking these steps would result in access to lower cost medicines for thousands of America's patients without increasing premiums

Some plans and PBMs have previously argued that reducing brand rebate contracting or establishing transparent formulary, tiering and utilization management practices will lead to an increase in member premiums. This is a false assertion. Ensuring patient access to lower cost generics and biosimilars will immediately reduce patient out of pocket costs in many instances. Further, arguments suggesting that this could in some way increase costs or premiums are nonsensical. Rather, ensuring that formularies cover the lowest cost medicines, when measured at the unit level, will open the door to meaningful transparency and lower spending for patients and taxpayers alike, giving plans one more tool to establish more transparent pricing and to drive additional patient savings across their contracted pharmacy networks.

CMS Should Also Address PBM Formulary Design, Tiering and Utilization Management Practices that increase Patient Out-of-Pocket Costs

Beyond delaying coverage of new generic drugs and biosimilar products, PBMs and plans continue formulary and utilization management decisions that perversely result in unnecessary increases in patient out-of-pocket (OOP) costs for many generic drugs. An Avalere analysis of generic drug placement on Part D formularies from 2011 to 2021 underscores this trend. In 2011, 73 percent of generic drugs analyzed by Avalere were placed on Tier 1 (with a zero-dollar copay on average). Ten years later, only 15 percent of those drugs were still on Tier 1. And while the percentage of products on Tier 2 has increased from 21 percent to 36 percent, the most appalling figure is the spike in placement of generic drugs on Tier 3 – from 4 percent in 2011 to 24 percent in 2021.[28] This matters for patients, as the *average* copay charged by health plans is $0 for preferred generic drugs on Tier 1, $5 for (non-preferred) generic drugs on Tier 2, and $42 for products on Tier 3.[29] This is why patient OOP costs on generic drugs covered in Medicare from 2011 to 2019 exploded by 135 percent, even as the average price of those medicines fell by 38 percent.[30]

Today, generic drugs are placed on generic formulary tiers less than half the time, while the frequency of generic drugs on the preferred brand / preferred drug tier (tier 3) with higher cost sharing has skyrocketed. The result is higher OOP costs, with patients often paying several times the cost of the generic drug. In fact, in 2021, over 60 percent of seniors paid the "full cost" of a generic drug at least once – a staggering rate when one recalls that this reflects the cost a plan agrees to reimburse a pharmacy and is often several times the actual manufacturer's sales price. *Therefore, we encourage CMS to finalize the proposal to include a review of PBM utilization management techniques, including product tier placement, associated with generic drug and biosimilar products to ensure these practices align with the goal of improving access to and driving the dispensing of covered, lower-cost products.*

[28]Avalere Health Contributors. (April 2024). Trends in Generic Tiering in Medicare Part D, 2011-2021. Accessible at: Trends in Generic Tiering in Medicare Part D, 2011-2021 | Avalere

[29] Kaiser Family Foundation – Medicare Part D: A First Look at Medicare Prescription Drug Plans in 2022. Accessible at: Medicare Part D: A First Look at Medicare Prescription Drug Plans in 2022 | KFF

[30] Association for Accessible Medicines Contributors. (October 2022). Patients Pay More When Generic Drugs Are Placed On Non-Generic Tiers, Even Though Prices for Generics Are Going Down. Accessible at: Patients Pay More When Generic Drugs Are Placed On Non-Generic Tiers, Even Though Prices for Generics Are Going Down | AAM

601 NEW JERSEY AVE, NW • SUITE 850 WASHINGTON, DC • 20001 • PHONE 202-249-7100 • FAX 202-249-7105 accessiblemeds.org /accessiblemeds

Finally, while prior authorization (PA) and step therapy (ST) are not usually required for generic drugs appearing on Tier 1 and Tier 2, generic drugs appearing on Tier 3 or higher are often subject to PA or ST. Patients must often first fail the corresponding reference product to access the generic alternative. This routinely occurs in commercial plans, and we wish to bring to CMS's attention that we have heard anecdotally that it is occurring in stand-alone PDP and MA-PD plans as well.

Further, we are concerned that there may be a loophole in CMS's policy concerning the formulary checks, resulting in this going undetected. In the May 2019 final rule,[31] CMS delineated the checks included in the annual formulary review and approval process (84 FR 23835). Relative to the Step Therapy Criteria and Prior Authorization Criteria Reviews, CMS asserts that these criteria are compared with "best practices", "current industry standards", and "treatment guidelines". First, AAM notes that these checks are not enshrined in the regulatory text, although their rationale for their use stems from requirements at 42 CFR § 423.153(b).

It is our understanding that this preliminary review may be based on outlier methodology, and AAM is concerned that this may be prone to gaming, specifically potential or de facto collusion by the highly concentrated market of PBMs. In other words, if PBMs all impose fail-first PA or ST policies whose criteria require the use of the reference product before accessing the generic alternative, given the high concentration of PBMs in the market, there is a high likelihood that such clinically inappropriate criteria would not flag on an outlier check and thus would not receive further review. The language used by CMS to describe these formulary checks does not unequivocally prohibit the use of such clinically inappropriate PA and ST. *We encourage CMS to review these practices to reduce barriers to generic and biosimilar dispensing and thereby minimize the risk of patient confusion.*

Generic and biosimilar medicines are the backbone of accessible and efficient healthcare for America's patients and taxpayers. The agency has a critical opportunity to improve patient access, extend the fiscal sustainability of the Medicare program, and reduce drug costs for millions of Medicare enrollees by ensuring that America's patients have access to generics and biosimilars first.

Sincerely,

Craig Burton

Craig Burton
Senior Vice President, Policy & Strategic Alliances
Executive Director, Biosimilars Council

[31] CMS. "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses". May 23, 2019. Accessible at: Federal Register :: Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses

601 NEW JERSEY AVE, NW • SUITE 850 WASHINGTON, DC • 20001 • PHONE 202-249-7100 • FAX 202-249-7105 accessiblemeds.org /accessiblemeds