Biosimilars in Medicare Part D: pricing dynamics and considerations

Commissioned by the Drug Pricing Lab at Memorial Sloan Kettering

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An influx of biosimilars may be coming to the Medicare Part D market in 2023 as multiple manufacturers launch biosimilars of Humira. This white paper explores the dynamics affecting biosimilars in Medicare Part D and key stakeholder considerations under the current and proposed Part D benefit design for 2024.

While most biosimilars in the US are currently covered by Medicare Part B, we anticipate the upcoming entry of additional biosimilars in the Medicare Part D market. The Drug Pricing Lab at Memorial Sloan Kettering asked that we summarize the dynamics affecting biosimilars in the current Medicare Part D marketplace. In this white paper, we explore how biosimilar pricing and rebate strategies affect plan costs and coverage in Medicare Part D. We view this analysis from the lens of Humira: the largest biologic in Part D spend set to face biosimilar competition (expected in 2023). For example, our analysis indicates:

- A biosimilar offering no rebate and a 25% discount can increase Medicare Part D plan costs by 40% under the current Part D benefit design relative to a reference biologic with a 25% rebate, or an equivalent net price (list price less rebate) (Figure 1). This is offset by reductions in member cost-share and federal reinsurance.
- A biosimilar with no rebate would need to be priced at least 50% lower under the current Part D benefit design than a reference biologic with a 25% rebate to be cost neutral to the plan sponsor (Figure 2).
- With the proposed Build Back Better Act[1] (which would modify the Part D benefit design), a biosimilar with no rebate would need to be priced at least 35% lower under the revised Part D benefit design than a reference biologic with a 25% rebate to be cost neutral to the plan sponsor (Figure 3).
- The break-even relationship between discounts and rebates for plans would decrease from 2:1 to 4:3 under the revised Part D benefit design for a biologic / specialty drug with a cost of $6,000 per month. This means that where $1 of rebates is equivalent to $2 of discounts in the current design, $1 of rebates would be equivalent to approximately $1.35 in discounts under the revised design from the plan sponsor's perspective (Figure 3).

This white paper presents perspectives under both the current Part D benefit design and the proposed Part D benefit design under the Build Back Better (BBB) Act (which was passed by the United States House of Representatives on November 19, 2021, and is currently working its way through the Senate).[2] This paper does not reflect the impact of the point-of-sale rebate rule,[3] as this would be delayed indefinitely under the BBB Act.

What are biologics and biosimilars?

Biologic drugs are a diverse category of products that are generally large, complex molecules.[4] Examples include autoimmune (e.g., Humira), oncology or cancer, and diabetic insulin products. Biologic products compete with each other and biosimilars for market share.

Biosimilar drugs are biologics that are highly similar to and have no meaningful clinical differences from an existing reference biologic. Like the generic alternatives to brand drugs, biosimilars introduce product competition after a period of exclusivity to an innovator biologic. However, biosimilars are different from generics, as they are often more complex to manufacture, cannot be identically replicated, and are generally more expensive.[5]

In 2010, Congress passed the Biologics Price Competition and Innovation Act (BPCIA) to create an abbreviated pathway for the Food and Drug Administration (FDA) to approve biosimilars.[6] As of September 2021, the FDA has approved 31 biosimilars, of which 20 are available in the US. In addition, more than 100 future biosimilars are currently in development across 22 reference biologics.[7]

What dynamics affect biosimilars?

There are multiple dynamics in the US that affect utilization of biosimilars. Recent legislative efforts encourage biosimilar coverage in Medicare Part D, such as the Bipartisan Budget Act of 2018, which identifies biosimilars as applicable drugs for the Coverage Gap Discount Program (CGDP).[8] This removed a major incentive for plans to exclude these products from their formularies. We describe remaining key barriers below.

REBATE DYNAMICS

Existing rebate dynamics may limit biosimilar uptake in the Medicare Part D market. The current design may favor high list price, high rebate products, even if the net price (list price less rebate) is equivalent.

To illustrate this dynamic, Figure 1 shows the estimated Medicare Part D costs by stakeholder (member, Federal

government, pharmaceutical manufacturers, and plan sponsors) for three illustrative drug scenarios under the current Part D benefit design. The biologic scenario is based on the current cost for an average dose of Humira.

- **Biologic**: $6,000 monthly allowed cost, with a 25% rebate.
- **Biosimilar**: $5,000 monthly allowed cost, with a 10% rebate.
- **Biosimilar**: $4,500 monthly allowed cost, with no rebate.

Each of these illustrative scenarios has an identical net drug cost ($4,500 monthly), but different member, federal reinsurance and plan costs. Relative to the highest price/largest rebate biologic, the biosimilar with no rebate increases plan sponsor cost by 40%, while the biosimilar with a 10% rebate increases plan sponsor cost by 25%. In contrast, member cost-share for the biosimilars decreases by 10% to 15% relative to the highest price biologic, and federal reinsurance decreases by 3% to 5% for the biosimilar scenarios relative to the biologic scenario.

FIGURE 1: ILLUSTRATIVE ANNUAL STAKEHOLDER COSTS BIOLOGIC VS. BIOSIMILAR WITH VARYING REBATES UNDER CURRENT MEDICARE PART D BENEFIT

	BIOLOGIC $6,000 / Mo., 25% Rebate	BIOSIMILAR $5,000 / Mo., 10% Rebate	BIOSIMILAR $4,500 / Mo., 0% Rebate
Gross Drug Cost	$72,000	$60,000	$54,000
Manufacturer Rebate	$18,000	$6,000	$0
Net Drug Cost	$54,000	$54,000	$54,000
Member Cost-Share	$6,000	$5,400	$5,100
Federal Reinsurance	$37,000	$35,800	$34,950
Pharma CGDP[1]	$4,100	$4,100	$4,100
Plan Sponsor	$6,900	$8,700	$9,850

[1] *Coverage Gap Discount Program (CGDP)*

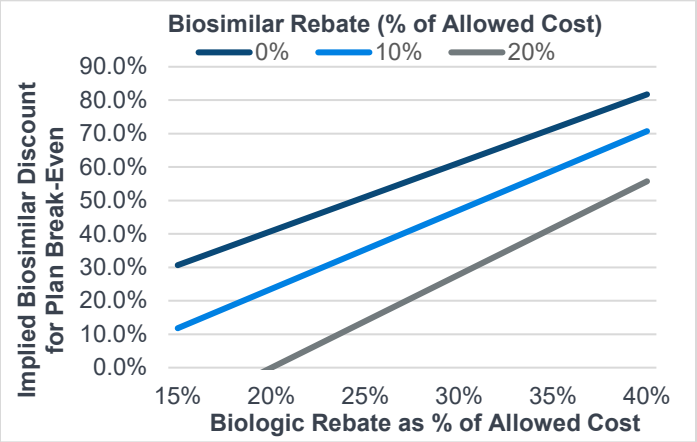
With the Part D benefit redesign in the BBB Act, the magnitude of differences between the scenarios would change, but the directional relationship would remain the same. We expand more on the Part D benefit redesign below.

PLAN BREAK-EVEN PRICES

From the perspective of the Medicare Part D plan sponsor, biosimilars offering no or limited rebates would need much lower list prices to compete with reference biologics offering a rebate under the current Part D benefit design.

Figure 2 illustrates the discount required for a biosimilar relative to a $6,000 per month biologic for the plan's cost to be equivalent, or "breakeven." The biosimilar discount price is calculated based on net cost to the Medicare Part D plan sponsor after accounting for member cost-sharing, federal reinsurance, CGDP, and manufacturer rebates. Figure 2 estimates the biosimilar gross cost discount relative to the biologic under varying rebate levels. Similar to the values presented in Figure 1, the biologic cost is based on the current cost for an average dose of Humira.

FIGURE 2: IMPLIED BIOSIMILAR DISCOUNT FOR PLAN BREAKEVEN WITH $6,000 PER MONTH BIOLOGIC UNDER CURRENT PART D BENEFIT



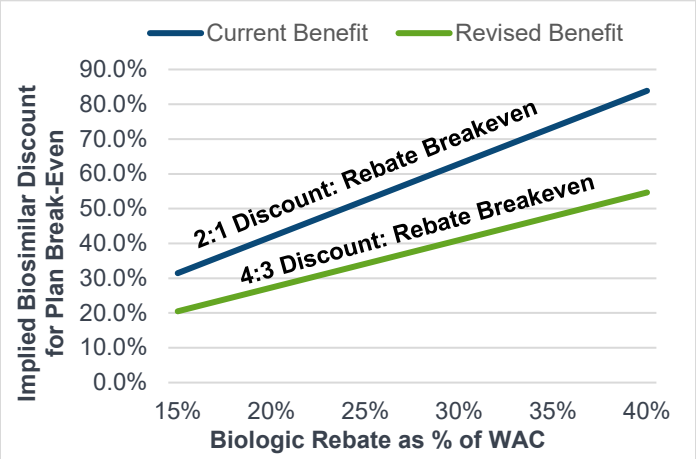
To put this into context, consider the scenario where the biologic offers a 30% rebate, a typical rebate percentage. A biosimilar manufacturer offering no rebate would need to price its product at least 60% lower than the reference biologic price (before rebate) to be at parity from the plan cost perspective – a net discount that is double the brand product rebate. Biosimilars offering 10% and 20% rebates would need to offer a gross cost at least 50% and 30% lower than the reference biologic, respectively.

PART D BENEFIT REDESIGN

The BBB Act proposed by the House of Representatives would modify the Part D benefit materially. The redesign would introduce a new member maximum out-of-pocket (MOOP) of $2,000 per year, eliminate the coverage gap, reduce federal reinsurance from 80% to 20% of gross drug costs above the MOOP, and introduce a new pharma discount program both above the MOOP and above the deductible but below the MOOP.

Figure 3, similar to Figure 2, illustrates the breakeven discount for a biosimilar with no rebate compared to a biologic with varying rebate levels. Additionally, Figure 3 compares the breakeven discount under the current benefit design to the revised Part D benefit design under the BBB. Under the revised benefit design, a 15% rebate is comparable to a 20% discount from a plan sponsor perspective (4:3 discount to rebate ratio). This is less pronounced than under the current Part D benefit design, where a 15% rebate is comparable to a 30% discount (2:1 discount to rebate ratio).

FIGURE 3: IMPLIED BIOSIMILAR DISCOUNT WITH 0% REBATE FOR PLAN BREAK-EVEN WITH $6,000 PER MONTH BIOLOGIC, CURRENT VS. REVISED BENEFIT



How might these dynamics affect Humira's upcoming biosimilars?

Humira is a biologic product that was approved to treat rheumatoid arthritis in December of 2002 by the FDA and became available to the US market in January 2003. Over the past 17 years, Humira has gained approval of 9 additional indications, increasing its market access.

Humira is expected to face biosimilar competition in 2023, with several biosimilars already approved by the FDA. Humira has the highest spend of any drug to face biosimilar competition in the Part D market to date, with $14.9 billion in Part D spend in 2019. Figure 4 summarizes Humira spend in Medicare Part D from 2015-2019.[9]

FIGURE 4: HUMIRA MEDICARE PART D METRICS (2015-2019)

	2015	2016	2017	2018	2019
Total Cost ($ millions)	$1,660	$2,200	$2,640	$3,170	$3,720
Cost per Rx	$4,100	$4,900	$5,500	$6,200	$6,600
Total Utilizers	65,000	70,000	73,000	82,000	96,000
% Total Part D Cost	1.2%	1.5%	1.7%	1.9%	2.0%

One of Humira's biosimilars – Cyltezo – is also one of the two biosimilars to be approved as interchangeable with its reference product.[10] This interchangeability allows a pharmacist to substitute Humira for Cyltezo at the point-of-sale, similar to pharmacist flexibilities available for traditional brand and generic drugs. This aspect, along with the Humira's current Part D spend, make Humira's biosimilar launches the most impactful in the Part D market to date.

Figures 1, 2, and 3 illustrate pricing dynamics for a biologic with a gross cost similar to the most common dose of Humira. These figures highlight the rebate dynamics affecting biosimilars under the current Part D benefit design and the revised Part D benefit design from the BBB.

For biosimilar manufacturers, our analysis indicates that manufacturers will need to carefully consider their pricing and rebate strategy to compete with Humira. Rebates may be an important part of that decision – with 25% of rebates being equivalent to a 50% list price discount under the current Part D benefit design. This relationship moderates under the revised benefit design, which would go into effect in 2024 (if approved).

What should stakeholders consider?

Biosimilar uptake has been limited in Medicare Part D to date primarily because most available biosimilars are covered under Medicare Part B. The pricing dynamics introduced above also create barriers for biosimilars to compete with biologics. We summarize some additional considerations by stakeholder below.

PLAN SPONSOR

- **Plan cost**: As highlighted in Figures 1 and 2, biosimilars with no or limited rebates would need to offer significant price discounts to produce the same net plan cost as biologics offering a rebate under the current benefit design. Plan sponsors may need to increase premiums to offer biosimilars based on existing market dynamics. Under the revised Part D benefit design, the net cost difference between biosimilars and biologics may be more subdued (as illustrated in Figure 3).
- **Adverse selection**: Members taking biologic products tend to have higher costs than the average member, and the risk-adjusted Part D direct subsidy may not be sufficient to cover claim costs. Offering lower cost alternatives for members may drive adverse selection if other carriers do not cover biosimilars. This may result in a financial loss for plan sponsors if more biosimilar users enroll in the plan than were accounted for in the pricing.
- **Formulary strategy**: Biologics may offer higher rebates if the biosimilar is not covered on the formulary. Plan sponsors may estimate the expected shift from the biologic to the biosimilar to evaluate rebate contracts, which may be materially lower than a typical generic launch. This may lead to covering both the biosimilar and the original biologic, or just the original biologic, if the anticipated shift is low. Beneficiary education may help increase the shift to biosimilars and limit member dissatisfaction.

BIOSIMILAR DRUG MANUFACTURERS

- **Pricing and rebate strategy**: As highlighted in Figures 1, 2, and 3, pricing and rebate strategies for both biologic and biosimilar manufacturers can have a large impact on Part D plan sponsor costs. Analyzing the impact of pricing and rebate decisions on Part D stakeholders may be important to set pricing strategies, especially in the context of the revised Part D benefit. This dynamic may have influenced Viatris' Semglee,

an interchangeable insulin product to Lantus, which has two different price tags (and likely different rebates).[11]

- **Accessibility**: With traditional brand drugs, pharmacists may be able to swap a member's prescription for an approved interchangeable drug. The BPCIA includes a clause allowing biosimilars to be approved as interchangeable with the reference biologic. To date, two biosimilars have received the interchangeable status - Semglee (biosimilar of Lantus) and Cyltezo (biosimilar of Humira).[12] Receiving approval for this status may be critical for manufacturers to ensure accessibility to the biosimilars. Utilization management (UM) programs also affect accessibility. Working with Pharmacy Benefit Managers (PBMs) and carefully considering rebate strategies may help mitigate the risk of UM programs reducing accessibility.
- **Education**: Biosimilar manufacturers may consider emphasizing education to increase adoption of their products. This education may focus on two groups: providers and consumers. If providers do not view biosimilars as a direct substitute for biologic products, or are simply not as familiar with them, then they may not prescribe the biosimilar products. Highlighting research and information on interchangeability or cross-over studies and sharing with providers may lead to changes in prescribing patterns. Educating members on their options is also important to ensure success. This education may also come through providers and insurers to gain one-on-one access to members.

REGULATORY

- **Benefit redesign**: The BBB Act proposed changes to the Medicare Part D benefit design that would materially affect costs by stakeholder. As presented in Figure 3, this revised design reduces the disincentive for plan sponsors to favor biologics with rebates over biosimilars with no rebates. This also caps member cost-sharing at $2,000 for all beneficiaries, which may limit the adverse selection risk noted above.
- **Point-of-sale rebates**: This white paper does not reflect the impact of removing safe harbor protection for manufacturer rebates under the federal anti-kickback statute. This rule would eliminate many of the pricing dynamics outlined in this white paper. The BBB Act would delay this rule indefinitely, so we did not explore these dynamics further.
- **Drug price negotiation**: The BBB Act also allows the Secretary of the Department of Health and Human Services (HHS) to negotiate prices directly with manufacturers for a limited number of drugs under certain conditions. After 13 years, biologic reference products such as Humira may be eligible for drug price negotiation. This could reset the market pricing for the reference biologic, forcing associated biosimilars to follow if intending to compete with the reference product.
- **Coverage requirement**: To create widespread biosimilar adoption, the Centers for Medicare and Medicaid Services (CMS) could consider a mandatory biosimilar coverage requirement if reference biologics are covered. This approach may address the anti-selection issue for plan sponsors evaluating their formulary strategy. This requirement may still face resistance from plan sponsors if the requirement is anticipated to increase plan costs.
- **Other lines of business**: The strategies plans use in Medicare Part D are often adopted by other lines of business, such as the adoption of multi-tier formularies and specialty drug tiers in the commercial market. This creates the potential to generate widespread adoption of biosimilars if CMS develops strong policies in support of biosimilars for the Medicare Part D market. That said, incentives to adopt biosimilars may already exist in the commercial market, where the rebate dynamics discussed above are dampened.

Methodology

We estimated stakeholder costs in Figure 1 and biosimilar equivalent discounts in Figure 2 based on the 2022 defined standard benefit parameters for a non-low-income member. This approach reflects a deductible of $480 and specialty coinsurance of 25% between the deductible and the initial coverage limit. It also reflects the defined standard gap coverage, with CGDP covering 70% of the brand drug cost, and reinsurance of 80% in the catastrophic phase.

For Figure 3, we relied on the revised Part D benefit design from the BBB Act. This approach reflects a deductible of $480, followed by member coinsurance of 23% up to a MOOP of $2,000. This also reflects a 10% manufacturer discount above the deductible and below the MOOP, a 20% manufacturer discount above the MOOP, and 20% federal reinsurance above the MOOP.

These estimates exclude utilization for other medications for the purpose of these comparisons. The values presented are illustrative and do not reflect the impact of anti-selection and member behavior.

Caveats and limitations

This report summarizes biosimilar considerations in Medicare Part D. This information may not be appropriate and should not be used for other purposes. Milliman does not intend to benefit, and assumes no duty or liability to, third parties who receive this work product. Any third party recipient of this work product who desires professional guidance should not rely upon Milliman's work product, but should engage qualified professionals for advice appropriate to its own specific needs. Any releases of this report to a third party should be in its entirety. Milliman does not endorse any public policy or advocacy position on matters discussed in this report.

The results presented herein are estimates based on carefully constructed actuarial models. Differences between our estimates and actual amounts depend on the extent to which future experience conforms to the assumptions made for this analysis. It is certain that actual experience will not conform exactly to the assumptions used in this analysis. Actual amounts will differ from projected amounts to the extent that actual experience deviates from expected experience.

Models used in the preparation of our analysis were applied consistently with their intended use. We have reviewed the models, including their inputs, calculations, and outputs for consistency, reasonableness, and appropriateness to the intended purpose and in compliance with generally accepted actuarial practice and relevant actuarial standards of practice (ASOP). The models, including all input, calculations, and output may not be appropriate for any other purpose. Where we relied on models developed by others, we have made a reasonable effort to understand the intended purpose, general operation, dependencies and sensitivities of those models. We relied on input, review, and validation by other experts in the development of our models.

We do not provide legal advice and recommend that readers consult with legal advisors regarding legal matters. This report provides objective quantification of program dynamics and is not advocating for any viewpoint. This report represents the opinion of the author and is not representative of the views of Milliman.

In summarizing Figure 4, we relied on data and other information from CMS' "Medicare Part D Drug Spending Dashboard." In performing the analyses and forming the conclusion presented in this report, we relied on information from CMS and other publicly available information. We have not audited or verified this data and other information but reviewed it for general reasonableness. If the underlying data or information is inaccurate or incomplete, the results of our analysis may likewise be inaccurate or incomplete.

Kevin Pierce is a Consulting Actuary at Milliman. He is a member of the American Academy of Actuaries and meets the Qualification Standards of the American Academy of Actuaries to render the actuarial opinion contained herein.

[1] Committee on the Budget (November 3, 2021), H.R. 5376, Build Back Better Act, Retrieved November 2021, from https://rules.house.gov/sites/democrats.rules.house.gov/files/BILLS-117HR5376RH-RCP117-18.pdf}
[2] Ibid.
[3] Bell, Deana, et al., (November 25, 2020), November 2020 Medicare drug pricing rules: What do you need to know?, Retrieved November 2021, from https://us.milliman.com/en/insight/november-2020-medicare-drug-pricing-rules-what-do-you-need-to-know
[4] U.S. Food and Drug Administration, (October, 23, 2017), Biosimilar and Interchangeable Products, Retrieved November 2021, from https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products
[5] Ibid.
[6] Patient Protection and Affordable Care Act (March 23, 20210), H. R. 3590, Retrieved November 2021, from https://www.fda.gov/media/78946/download
[7] U.S. Food and Drug Administration, (September, 20, 2017), Biosimilar Product Information, Retrieved November 2021, from https://www.fda.gov/drugs/biosimilars/biosimilar-product-information
[8] Barnhart, Adam, et al.,(February 16, 2018), How will the Bipartisan Budget Act of 2018 impact Part D in 2019 and beyond?, Retrieved November 2021, from https://www.milliman.com/en/insight/how-will-the-bipartisan-budget-act-of-2018-impact-part-d-in-2019-and-beyond
[9] Centers for Medicare & Medicaid Services, (December 1, 2021), Medicare Part D Drug Spending Dashboard & Data?, Retrieved November 2021, from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD
[10] U.S. Food and Drug Administration, (October, 18, 2021), FDA Approves Cyltezo, the First Interchangeable Biosimilar to Humira, Retrieved November 2021, from https://www.fda.gov/news-events/press-announcements/fda-approves-cyltezo-first-interchangeable-biosimilar-humira
[11] Kansteiner, Fraiser, (November, 16, 2021), Viatris launched 2 versions of its interchangeable insulin biosimilar. Why?, Retrieved November 2021, from https://www.fiercepharma.com/pharma/viatris-launches-two-versions-its-interchangeable-biosimilar-semglee-bid-to-tackle-pricing
[12] Silver, Khadijah M. (October, 20, 2021), FDA approves Humira biosimilar as first-ever interchangeable monoclonal antibody, Retrieved November 2021, from https://medcitynews.com/2021/10/fda-approves-humira-biosimilar-as-first-ever-interchangeable-monoclonal-antibody/