Biosimilar Inclusion in Manufacturer Coverage Gap Discount Program:

Fiscal Implications

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The Fiscal Implications of Including Biosimilars in the Manufacturer Coverage Gap Program

The Medicare Modernization Act of 2003 created a drug benefit in Medicare (Part D) designed to provide drug coverage after a relatively modest deductible, while also providing catastrophic coverage for patients with high levels of drug spending. In order to achieve these goals within the budget available for the benefit, the legislation included a coverage gap, commonly known as "the donut hole," where beneficiaries would be responsible for 100% of the negotiated price for the drugs and biologics they received under the drug benefit.[1] In 2010, the Affordable Care Act (ACA) included provisions that, over time, will have the effect of eliminating the coverage gap and setting effective cost-sharing levels equal to the 25% level that applies up to the initial coverage limit.

One part of the ACA's effort to close the donut hole is a coverage gap discount program, under which manufacturers of brand-name drugs and biologics provide a 50% discount on their products for beneficiaries in the coverage gap. These discounts count toward a beneficiary's out-of-pocket costs, allowing affected beneficiaries to reach the threshold for catastrophic coverage as if they were still paying 100% of the costs of the drugs in question.[2]

The ACA also included a framework for approval of biosimilars to compete with brand-name biologics. However, the Act excluded biosimilar manufacturers from the coverage gap discount program, meaning that Medicare beneficiaries using biosimilars would not receive the benefit of the program.

We were asked by our client, the Association for Accessible Medicines (AAM), to analyze how the Congressional Budget Office (CBO) might "score" the budgetary implications of a policy that would apply the manufacturer coverage gap discount program to biosimilars.

Highlights of Our Findings:

- In a discussion of the use of generics and biosimilars, CBO notes that under current law beneficiaries with a choice between a Part D biologic and a biosimilar competitor may have strong incentives to use the branded product, since biosimilars are not subject to the discount program.[3]
- Even after the coverage gap is closed in 2020, more of the costs of branded biologic products will be counted toward patient "True Out-of-Pocket" Costs (TrOOP)—allowing them to reach catastrophic coverage more quickly. CBO may believe that this will provide continuing incentives for patients to choose branded biologics over biosimilars.
- Part D plans arguably have similar incentives to encourage beneficiaries to use branded biologics instead of biosimilars, since by 2020 the plans will be responsible for 75% of

[1] These provisions are included in section 1860D-2 of the Social Security Act (SSA).
[2] SSA §1860D-14A.
[3] *Effects of Using Generic Drugs on Medicare's Prescription Drug Spending: A CBO Study*. CBO (September 2010). https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/118xx/doc11838/09-15-prescriptiondrugs.pdf

the cost of a biosimilar in the coverage gap—whereas 75% of the cost of a branded biologic will be covered by manufacturer discounts or beneficiary cost-sharing.

- Consequently, CBO may assume that the current structure of the manufacturer discount program would significantly limit penetration of biosimilars in Medicare Part D for beneficiaries who reach the coverage gap.
- If so, we would expect CBO to conclude that a policy to include biosimilars in the coverage gap discount program would increase use of biosimilars and provide budgetary savings in Part D.
- Using a model that adopts these assumptions, we estimate that biosimilar inclusion in the discount program would result in $1 billion in savings to the federal government over the 2018 to 2027 budget scoring window.
- Based on the current structure of the Part D program, we believe it would be reasonable for CBO to assume that there are limited incentives for plans or beneficiaries to use biosimilars. As such, our scoring model assumes de minimis biosimilar spending in the current law baseline. If CBO adopts different assumptions about the role of biosimilars in Part D under current law, their findings about the policy would vary from the estimates we have presented.

The balance of this paper provides more details on our findings.

Methodology

We constructed a baseline for biologic pharmaceutical spending in Part D of the Medicare Program using the 2015 Medicare Provider Utilization and Payment Part D Public Use File, in conjunction with the Food and Drug Administration's (FDA) release of the "Purple Book."[4] We estimate total spending for Part D biologic branded prescriptions to be $95.8 billion during the scoring window. Note, the development of this score was based on top biological products, or products with Part D spending above $50 million in 2015, because we believe that smaller products are unlikely to justify the level of investment necessary for biosimilar competition.

We used our baseline to score the impact of the policy, using the following assumptions:

- We applied the annual growth rate from CBO's June 2017 baseline for drug spending for Medicare Part D to update our baseline amounts through the scoring window.
- We then modeled savings to the government based on the penetration of biosimilars under Part D resulting from the proposed policy.
- We aligned with CBO's assumptions from its 2008 score of legislation designed to create a pathway for biosimilar approvals, similar to the language that was ultimately adopted in the ACA.

[4] The Purple Book is reference to FDA's "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity of Interchangeability Evaluations". This book identifies whether a particular biological product has been determined by the FDA to be a reference biologic, a biosimilar, or to be interchangeable with a reference biological product.

    - We assumed an initial uptake rate of biosimilars of 0.10 in the beginning of the window, but increased this to 0.35 in later years.[5]
- Using this same CBO score, we applied an initial sales-weighted market average discount of 20% off the brand-named innovator products in the early years of the scoring window, but increased this discount to 40% by year 5.
- An additional offset was measured to account for costs shifting out of the catastrophic level of spending and into the coverage gap as a result of the adoption of biosimilars with lower costs than the branded biologics in our baseline.
- Lastly, we adjusted our estimates to account for Part D beneficiary premium and cost-sharing effects.

Results

The estimated direct federal savings of implementing this policy is $1 billion over ten years. Refer to Table A below for a summary of our analysis.

[5] Cost Estimate: S. 1695, Biologics Price Competition and Innovation Act of 2007. CBO (July 25, 2008). https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/costestimate/s16950.pdf

Table A: Scoring of Biosimilar Inclusion in Manufacturer Coverage Gap Discount Program

	Changes in Direct Federal Spending ($ in billions, by fiscal year)										
	2018	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2018-2027**
Biologic Spending Assuming No Biosimilar Entry	$6.0	$7.0	$7.5	$8.2	$9.6	$9.8	$9.8	$11.6	$12.6	$13.7	**$95.8**
Baseline Savings	-	-	-	-	-	-	-	-	-	-	**$0.0**
(Assumes Plans/Benes Disincentivized to use Biosimilars by Current Policy)											
Policy Savings	(0.0)	(0.0)	(0.1)	(0.1)	(0.1)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	**($1.4)**
Difference	(0.0)	(0.0)	(0.1)	(0.1)	(0.1)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	**($1.4)**
Offset for Cost Shift out of Catastrophic into Coverage Gap	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	**($0.2)**
(81.5% of Biologic Spending Above OOP Threshold)											
Subtotal	(0.0)	(0.0)	(0.1)	(0.1)	(0.2)	(0.2)	(0.2)	(0.2)	(0.3)	(0.3)	**($1.6)**
Demand Offset	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	**$0.5**
Subtotal	(0.0)	(0.0)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.2)	(0.2)	(0.2)	**($1.1)**
Adjusted for Beneficiary Share and Premiums	(0.0)	(0.0)	(0.0)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.2)	(0.2)	**($1.0)**
Net Change in Direct Federal Spending	(0.0)	(0.0)	(0.0)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.2)	(0.2)	**($1.0)**