
Patient Out-of-Pocket Costs for Biosimilars in Medicare Part D

Avalere Health | April 2016



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INTRODUCTION

In March 2015, the Food and Drug Administration (FDA) approved Zarxio®(filgrastim-sndz) as the first biosimilar in the United States and, more than one year later, on April 5, 2016, FDA approved the second biosimilar, Inflectra™(infliximab-dyyb). As more biosimilars come to market, these products are expected to be priced lower than existing biologics, and therefore reduce costs for consumers and payers. However, because of particular policies for self-administered products within Medicare Part D, patients may pay more out-of-pocket for the biosimilar than the higher-cost, innovator reference product. Higher patient out-of-pocket costs may discourage use of biosimilars in Part D, reducing overall savings to the Medicare program. In this paper, Avalere reviews beneficiary out-of-pocket costs for biosimilars in Part D compared to the reference product. We then examine two potential policy solutions that could reduce patient out-of-pocket costs for biosimilars:

1. Requiring manufacturer discounts to close the coverage gap for biosimilars, consistent with current law for branded drugs; and
2. Creating a biosimilar tier that would reduce beneficiary costs for the biosimilar to the same level as the reference product.

For each of these proposals, we estimate the financial impact on the federal government, patients, drug manufacturers, and health plans.

BACKGROUND

Biosimilar Pathway

The Biologics Price Competition and Innovation Act¹ (BPCIA) was passed by Congress in 2010 as part of the Affordable Care Act (ACA) and created a “biosimilar pathway” for the FDA to approve both biosimilars and interchangeable biologics.² Prior to BPCIA, there was no abbreviated pathway for FDA to approve biosimilars, which prevented market entry for these products. To date, only two biosimilar products have been approved by the FDA for the U.S. market. The first approval, Zarxio®³, is a biosimilar of Neupogen® (filgrastim) and both are used to

¹ TITLE VII: IMPROVING ACCESS TO INNOVATIVE MEDICAL THERAPIES. Subtitle A: Biologic Price Competition and Innovation (BPCI Act) provisions of the Patient Protection and Affordable Care Act (PPACA), (2010) Pub.L.111-148, 124 Stat. 817. Available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM216146.pdf> (Accessed April 8, 2016).

² To date no interchangeable biologics have been approved. For the purposes of this paper, we assume all products will be biosimilars and none designated as interchangeable by FDA; thus, they will not be substitutable by a pharmacist.

³ FDA Media Briefing “First Biosimilar Approval in the United States” March 6, 2015. Available at: <http://www.fda.gov/downloads/newsevents/newsroom/mediatranscripts/ucm437548.pdf> (Accessed April 8,

stimulate the generation of white blood cells necessary in a variety of settings to prevent infections. Zarxio[®] was priced about 15 percent below the list price for Neupogen at launch, not taking into account any discounts or rebates provided for either product. Inflectra[™], is a biosimilar for Remicade[®], an immunologic agent used to treat a range of conditions including rheumatoid arthritis and Crohn's disease.⁴ At this time, the product has not launched in the United States and no list price has been announced. Meanwhile, in Europe, there are 21 biosimilars approved (including one awaiting full market authorization), and for those on the market the average price discount is 25 percent off the price of the reference product,⁵ albeit this varies widely for different biosimilars in different countries.

The launch of biosimilars into the market has the potential to generate savings to patients and the healthcare system at large. The Congressional Budget Office (CBO) estimates that introduction of biosimilar medications would generate \$25 billion in total savings over 10 years (with \$6 billion in savings accruing to the federal government)⁶, while the RAND Corporation estimated 10 years total direct cost savings of \$44 billion between 2014 and 2024.⁷

Medicare Part D Coverage

In 2016, 40.7 million Medicare beneficiaries receive pharmacy benefit drug coverage through Medicare Part D plans.⁸ This includes coverage for typically self-administered drugs received through retail, mail-order, or specialty pharmacies, and includes both small molecule and biologic drugs. The Part D benefit is divided into four distinct phases of coverage based on different measures of drug spending. The four phases are the deductible, initial coverage, coverage gap, and catastrophic phases. Beneficiary cost-sharing amounts vary across the different phases of the benefit.

From 2006-2010, Part D beneficiaries were responsible for 100 percent of costs during the coverage gap—otherwise known as the “donut hole”. Beneficiaries reach the coverage gap once they incur a certain amount of total drug spending. In 2016, the coverage gap begins after a beneficiary has incurred \$3,310 in total drug costs (including plan and beneficiary contributions). On the other hand, determining when a beneficiary exits the coverage gap and enters the catastrophic phase is based on when a measure of beneficiaries’ out-of-pocket drug spending known as “true out-of-pocket,” or TrOOP, has reached a specific threshold. Beneficiary cost sharing is capped at five percent in the catastrophic phase. In 2016, beneficiaries must reach \$4,850 in TrOOP to exit the coverage gap.

2016); FDA press release “FDA approves first biosimilar product Zarxio” March 6, 2015. Available at: <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm436648.htm> (accessed April 8, 2016).

⁴ FDA News Release: FDA approves Inflectra, a biosimilar to Remicade. Available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm494227.htm> (accessed April 8, 2016)

⁵ Robert Wood Johnson Foundation, “Health Policy Brief: Biosimilars,” Health Affairs, October 10, 2013.

⁶ Ibid.

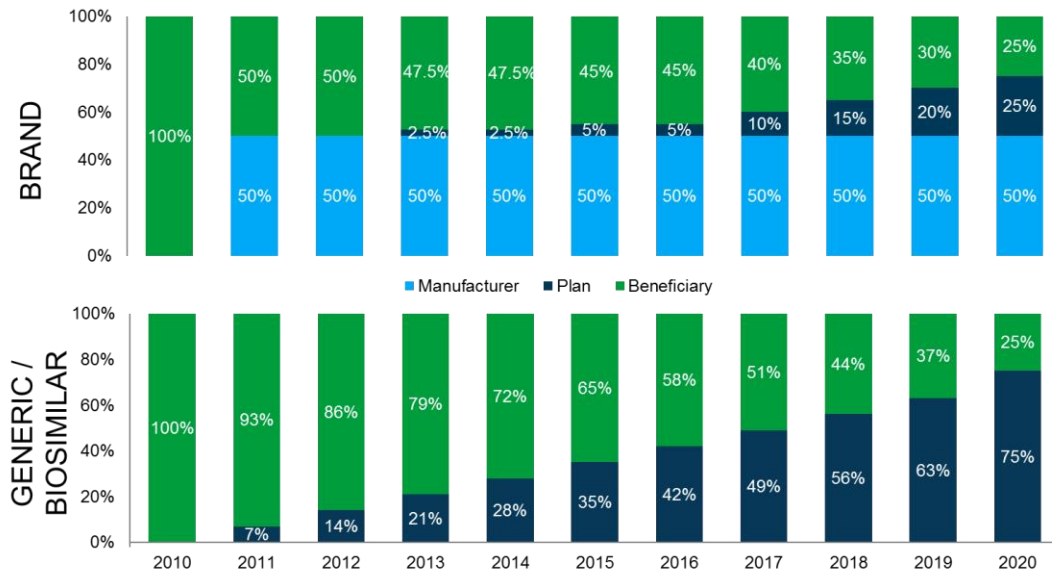
⁷ Mulcahy, Andrew W; Predmore, Zachary; Mattke, Soeren, “The Cost Savings Potential of Biosimilar Drugs in the United States,” RAND Corporation, 2014.

⁸ Avalere Health analysis of Medicare Part D enrollment data released by CMS in February 2016.

Because of the high cost sharing to beneficiaries in the coverage gap, the ACA included a provision to begin closing the gap by gradually reducing beneficiary cost-sharing to 25 percent by 2020.⁹ One part of this effort is the creation of the Coverage Gap Discount Program (CGDP), through which manufacturers are required to provide a 50 percent discount on brand drugs dispensed during the coverage gap. This discount is provided to the beneficiary at the point of sale. The CGDP took effect in 2011. By 2020, the Part D benefit will cover an additional 25 percent of the cost of branded drugs dispensed in the coverage gap (Figure 1). As a result of this change, in 2016, beneficiaries are responsible for paying 45 percent of costs associated with branded medications while in the coverage gap. Importantly, both the manufacturer discount as well as the beneficiary out-of-pocket costs will count toward TrOOP.

By contrast, the coverage gap for generic and biosimilar medications will also be phased out by 2020, but there is no cost sharing contribution by manufactures in the coverage gap.¹⁰ As such, in 2016 beneficiaries are responsible for 58 percent of costs associated with generic and biosimilar medications and the plan is responsible for all remaining spending in the gap. As a result, no other stakeholder is contributing to beneficiary TrOOP. This policy can result in patients paying more for a biosimilar product than for the innovator biologic product.

Figure 1. ACA Closure of the Part D Coverage Gap



⁹ Patient Protection and Affordable Care Act of 2010. <http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>.

¹⁰ Notably, current law likely prevents biosimilar manufacturers from voluntarily providing a point-of-sale discounts in the coverage gap to match those required for brand drugs as part of the CGDP due to the anti-kickback statute. Even if discounts were provided voluntarily, it is not certain that such discounts would be eligible to be counted as TrOOP.

To demonstrate these dynamics, Avalere constructed a spending model focusing on Medicare beneficiary out-of-pocket costs for biosimilars covered in Medicare Part D.

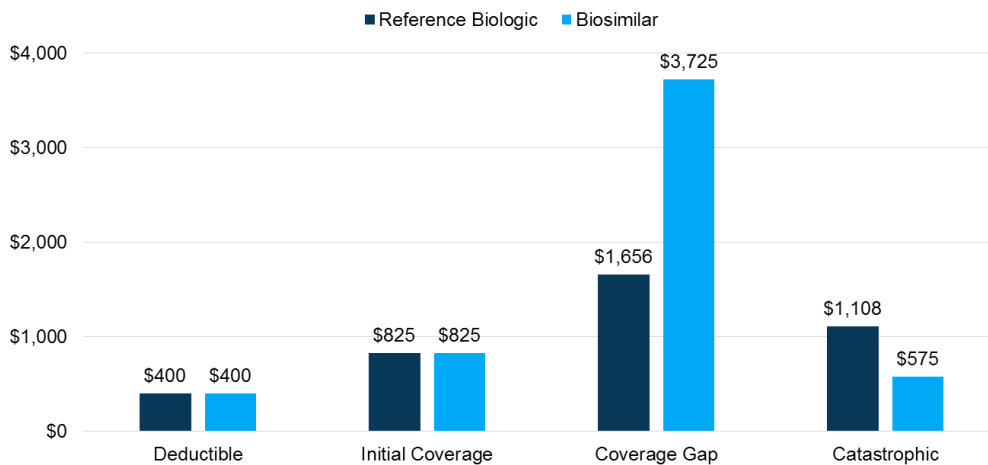
Illustrative Example of Consumer Out-of-Pocket Costs

To illustrate cost sharing differences between the reference product and the biosimilar under the current law, we developed an example where a typical Part D beneficiary¹¹ with a 2017 standard benefit design takes a single biologic medication while another beneficiary takes the biosimilar. We assume the Part D innovator biologic has an annual treatment cost of \$30,000 and the biosimilar is discounted by 25 percent. We assume each patient takes only one product and continues treatment throughout the entire year. In this example, we found that a Part D beneficiary will pay approximately \$1,536 more per year in out-of-pocket costs for a lower-cost biosimilar product than for the reference product—a 39 percent increase in the patient’s annual cost (Figure 2).

Figure 2. Annual Impact on Patient Costs of Switching to a Biosimilar, Based on a Hypothetical Innovator Biologic with \$30,000 Annual Cost in 2017

	Reference Product	Biosimilar	Difference	Percent Difference
Patient Cost	\$3,989	\$5,525	+\$1,536	+39%

Figure 3. Beneficiary Costs for Hypothetical \$30,000 Biologic and 25% Discounted Biosimilar by Part D Benefit Phase, 2017



Thus, while the government and the plan may realize savings from biosimilar substitution, the patient actually incurs higher out-of-pocket costs. Over time reduced costs for the plan from biosimilars may result in lower premiums that benefit all enrollees, but these savings would not be expected to offset the cost

¹¹ A beneficiary not eligible for low-income subsidies.

increase for an individual beneficiary switching to a biosimilar product. It is important to note that this issue does not impact low-income subsidy (LIS) beneficiaries, who comprise approximately one-quarter of all Part D enrollees and have fixed cost sharing with no coverage gap.

POLICY OPTIONS TO REDUCE PATIENT COSTS FOR BIOSIMILARS IN PART D

Although biosimilars have the potential to save billions of dollars in system-wide healthcare spending, the ACA has the unintended consequence of potentially increasing out-of-pocket costs for consumers who switch to biosimilar products. We evaluated two policy options to address the Part D cost-sharing issue for biosimilars:

1. **Biosimilar Coverage Gap Discounts:** The ACA directed the Centers for Medicare & Medicaid Services (CMS) to treat biosimilars like generics for the purposes of the manufacturer discount in the Part D coverage gap. Changing the statutory language to direct biosimilar manufacturers to pay 50 percent of drug costs in the coverage gap would result in lower out-of-pocket costs for patients, as well as additional savings to the federal government. If biosimilars were to be treated like branded products, the additional manufacturer contribution would count towards beneficiaries' progression toward the TrOOP threshold, leading beneficiaries to reach the catastrophic phase more quickly and lowering patient out-of-pocket. With the additional contribution from biosimilar manufacturers, the program costs in the coverage gap would also be reduced.
2. **Create a Biosimilar Tier:** While biosimilars are generally less expensive than innovator products, we anticipate that they will usually be subject to the same cost sharing applied to branded products on the specialty tier. Under this option, Part D plans would create a "biosimilar tier" that would lower patient cost-sharing for a biosimilar such that total out-of-pocket costs would not exceed those for the reference product. This would result in the Part D benefit paying more to cover the lower cost sharing associated with a "biosimilar tier".

It is likely that both of these policy options would require legislative action. The model methodology and projected financial impact of these two policy proposals is presented below.

METHODOLOGY

This paper models the 10-year costs and savings between 2016 and 2025 to patients, the federal government, health plans, and manufacturers associated with

the biosimilars covered under Medicare Part D. In addition to the baseline projection in which biosimilars are treated like generics for the purposes of the manufacturer discount in the Part D coverage gap, we modeled the impact under the two alternative policy options described earlier.

Avalere analyzed the universe of Part D biologic medications across several dimensions:

- Annual Medicare Part D costs for existing biologics;
- Biologic loss of exclusivity (LOE) dates;
- Currently-known U.S. biosimilar pipeline¹²; and
- Biosimilar approvals in the European Union (EU).¹³

Based on this assessment we selected Part D biologics with the highest annual Part D costs¹⁴ that have either already lost exclusivity and have biosimilars in development or that will lose exclusivity within the 10-year projection window, which will enable biosimilar launch. For products that have already passed their LOE date, we estimated biosimilar market entry date based on the stage of clinical development of known publicly disclosed candidates. For products with future LOE dates, we assumed biosimilar entry one year after LOE. Figure 4 lists the reference products included in the analysis, their costs, LOE date, and assumed market entry date of a biosimilar:

Figure 4. Part D-Covered Biologics Included in the Biosimilar Impact Model

Drug	Total Medicare Spending, 2013, in Millions¹⁵	LOE Date	Assumed Biosimilar Market Entry
Enbrel[®]	\$977	2010	2017
Humira[®]	\$955	2014	2017
Betaseron[®]	\$199	2005	2018
Cimzia[®]	\$77	2020	2021
Orencia^{®16}	\$75	2017	2018
Simponi^{®16}	\$69	2021	2022

To construct the model, we made several key assumptions about product pricing, utilization, and the Medicare Part D market, including:

¹² The U.S. Biosimilar Pipeline, Pink Sheet, June 2015 based on the public statements of biosimilar products filed at FDA or in development.

¹³ European Medicines Agency, <http://www.ema.europa.eu/ema/>

¹⁴ We included biologic drugs with 2013 annual Part D spending above \$50 million per year for which biosimilar launch is likely during the period of analysis. We excluded products for which beneficiaries do not reach the coverage gap, since they would not impact the model.

¹⁵ Medicare Part D spending obtained from the Prescription Drug Event (PDE) data and does not include reconciliation of capitation and various subsidy payments that happen at the end of the benefit year. In addition, the spending figures do not reflect any manufacturers' rebates or other price concessions. Lastly, the data for drugs filled 10 or fewer times is not captured. As a result, the estimates do not reflect the total drug payments made by Medicare program. Source: Medicare Fee-For Service Provider Utilization & Payment Data Part D Prescriber Public Use File: A Methodological Overview, April 7 2015, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Downloads/Prescriber_Methods.pdf

¹⁶ We excluded spending on the intravenous formulation of the drug from the analysis even though it is covered under Part D benefit in certain circumstances.

- Baseline spending and utilization of the reference product is based on 2013 Medicare Part D data¹⁷;
- The number of treated patients for each product increases at the same rate as Part D population growth;
- A biosimilar will be approved for all indications of the reference product and no additional, future indications¹⁸;
- Biosimilars will have a list price 25 percent below the price of the reference product based on the current average cost per patient. The model does not account for discounts or rebates on either the reference product or the biosimilars¹⁹;
- Until the biosimilar launch, list prices for reference products increase consistent with historical average growth among the analyzed products;
- The year of the biosimilar launch and thereafter, all products (reference and biologic) will increase 3 percent annually based on the historical inflation of prescription drug prices;²⁰
- Under the baseline, adoption of the biosimilar product begins at 5 percent of the utilization for reference product and increases to a ceiling of 50 percent by year 6; We do not assume any therapeutic switching from other competitor biologics to the biosimilar;
 - Under Option 1 policy, where the biosimilar is treated like a brand in the coverage gap, we assumed increased adoption by 10 percent on the top of the baseline adoption assumption due to lower consumer out-of-pocket costs. This results in 15 percent adoption in the first year growing to 60 percent by year 6;
 - Under Option 2 policy, where the biosimilar is placed on the special tier with lower patient cost-sharing, we assumed increased adoption by 5 percent on the top of the baseline adoption assumption due to consumer out-of-pocket costs that are lower than baseline but higher than Option 2. This results in 10 percent adoption in the first year growing to 55 percent by year 6;
- Launch of multiple biosimilars does not create any additional effects on price, adoption, and utilization due to the launch of multiple biosimilars for the same reference product;
- Patients use a single product and remain on a particular course of treatment for the entire year rather than switching between innovator biologic and biosimilar mid-year;

¹⁷ CMS Part D Prescriber Public Use File, http://download.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Downloads/PartD_Prescriber_PUF_Drug_Ntl_13.zip

¹⁸ While some products examined have orphan indications with outstanding exclusivity, these do not represent the main uses of the products and are not considered in this analysis.

¹⁹ Discount assumption is based on the EU experience, IMS Institute for Healthcare Informatics, Delivering on the Potential of Biosimilar Medicines, March 2016, http://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/Documents/IMS_Institute_Biosimilar_Brief_March_2016.pdf

²⁰ Customer Price Index, Urban (CPI-U), Prescription Drugs, U.S. city average, the U.S. Bureau of Labor Statistics, <http://www.bls.gov/cpi/#tables>

- Patient out-of-pocket exposure assumes the defined standard benefit design with 25 percent coinsurance for all drugs and use of the largest allowable deductible²¹; standard benefit design also assumed for government, plan, and manufacturer contributions through various parts of the Part D benefit; and
- Low-income subsidy beneficiaries are excluded from the model.

FINDINGS

In our analysis of the six biologic and biosimilar products, under the baseline scenario, we estimated, \$22.0 billion in overall costs from 2016 through 2025 for Medicare Part D beneficiaries accessing the six products (Figure 5). This translates into total patient out-of-pocket spending of \$3.6 billion, Part D plan contributions of \$16.9 billion, and branded manufacturer contributions of \$1.5 billion. The federal government subsidies to Part D plans will amount to approximately \$16.4 billion in total, which is 74.5 percent of overall Part D costs.

The two alternative policy options will both reduce beneficiary spending, but have different impacts on the federal government, manufacturers, and health plans. The impact of each of these options is summarized in the table below:

Figure 5. 10-Year Cost Estimate for Different Policy Options, 2016-2025

Stakeholder	Baseline Spending: Biosimilar Treated Like Generic	Option 1: Biosimilar Coverage Gap Discounts	Option 2: Create a Biosimilar Tier
Federal Government	\$16.4B	-\$0.8B	+\$0.3B
Patient	\$3.6B	-\$0.6B	-\$0.5B
Manufacturers	\$1.5B	+\$0.9B	-\$0.1B
Health Plans	\$16.9B	-\$0.8B	+\$0.3B
Total²²	\$22.0B	-\$0.5B	-\$0.3B

Both policy options result in savings to patients and overall savings to the system. Requiring manufacturers to pay coverage gap discounts for biosimilars under policy Option 1 shifts the costs away from the government, patients, and health plans to manufacturers. This policy, in addition to reducing the cost sharing percentage required of patients in the coverage gap, would allow patients to reach the catastrophic coverage phase sooner. Additionally, because of the lowered cost sharing associated with this policy option, we assume that some patients who might have previously purchased branded products would transition to using

²¹ Actual OOP costs may vary from this amount since most plans use formularies with different cost sharing amounts on each tier. Generally, plans place the analyzed products on specialty tiers with coinsurance ranging from 25 to 33 percent depending on the size of the plan deductible.

²² Total spending and savings do not add up across payers because of overlap between spending categories

biosimilars; thus, we used the higher rate of biosimilar adoption compared to the baseline (60 percent by year 6, compared to 50 percent under baseline).

In contrast, creating a separate biosimilar tier would shift costs to health plans and the federal government under policy Option 2, as patient cost sharing would be reduced and plans would be responsible for a greater share of costs without additional contributions from manufacturers. Again, because of the reduced cost sharing burden to patients from the creation of a biosimilar tier, we assumed that more patients previously using branded reference products would shift to using biosimilars compared to the baseline. While this does reduce plan and federal government costs, the reduction is not sufficient to offset the costs of reduce biosimilar cost sharing in the gap. The greater adoption of biosimilars leads to increased market share over what would otherwise be the case at baseline (55 percent by year 6, compared to 50 percent under baseline). However, the total system-wide savings from the creation of a biosimilar tier is about half the savings garnered from treating biosimilars as if they were branded drugs because we assume fewer consumers would switch to biosimilars under policy Option 2 compared to policy Option 1.

CONCLUSION

It is unlikely that the intent of the ACA was to increase cost sharing for patients using biosimilar products. However, because of the structure of the Part D program, Medicare beneficiaries may be subject to significantly higher out-of-pocket costs when taking biosimilars compared to their reference products. While there are still substantial savings to the government and other third party payers from the use of biosimilars, fewer Medicare beneficiaries are likely to start treatments with biosimilars, or to transition to biosimilars from other treatments, due to higher out-of-pocket costs. This paper introduces two policy options that would enable Medicare Part D enrollees to share in the savings that result from biosimilar product use when clinically appropriate, which in turn would lower overall drug spending.

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