



Shared Savings Demonstration for Biosimilars in Medicare:

An Opportunity to Promote
Biologic Drug Competition

BY ALEX BRILL

May 2020

EXECUTIVE SUMMARY

Biologic drugs are the driver behind increasing per-capita drug spending in the United States, and biosimilar competition offers a critical market-based strategy to curb overall drug costs. A unique opportunity exists in Medicare Part B to boost biosimilar utilization through the establishment of a shared savings demonstration model administered by the Centers for Medicare & Medicaid Services (CMS) Innovation Center. Such a program, squarely within the mission of the Innovation Center and straightforward to evaluate, has the potential to drive billions of dollars of new

healthcare savings. It would also foster greater competition and signal to future market participants the viability of the US biosimilars market.

Current Medicare Part B reimbursement establishes a uniform payment amount to physicians in excess of the average sales prices for both a biosimilar and its reference biologic. As a result, physicians are not incentivized to utilize lower-cost drugs. A shared savings program would align physician incentives with the objective of reducing overall Medicare program expenditures while preserving the quality of care.

A successful Innovation Center shared savings model for biosimilars should be designed with four principles in mind:

1 Voluntary

Consistent with recent CMS practice, a shared savings model for biosimilars should be constructed to permit providers to opt in, as opposed to mandating participation. Voluntary participation is easy to implement and will not jeopardize any aspects of program evaluation as long as there is a reasonably sized control group to which participants in the demonstration can be compared.

3 Optimized for fiscal responsibility

As a responsible steward of taxpayer funds, the Innovation Center should parameterize models to minimize the risk of loss for taxpayers, ensure sufficient reward to providers who achieve program savings, and strive for large-scale net program savings. Given the significant potential for cost savings of a shared savings demonstration for biosimilars, proper program stewardship is all the more important, and can easily be ensured. With a low barrier to enter and the opportunity for additional reimbursement with only moderate changes, it is reasonable to expect high participation among providers.

2 Simple and broad-based

Sizeable fixed costs can impede participation by smaller providers and, because many rural providers are smaller, limit opportunity for participation outside of urban and suburban settings. In the case of a shared savings demonstration for biosimilars, existing infrastructure for billing of Part B drugs can easily accommodate the necessary changes to be able to monitor biosimilar utilization and award payments.

4 Broad stakeholder appeal

Critical to promptly establishing an Innovation Center demonstration program is the involvement of a range of stakeholders, including biosimilar manufacturers, physicians who would be eligible for participation, and advocacy organizations representing patients who may be treated with biosimilar products subject to this program.

INTRODUCTION

The growth in inflation-adjusted per-capita pharmaceutical spending since 2014 has been wholly driven by an increase in spending on biologic drugs. Per-capita spending on small-molecule drugs has actually been declining in real terms. Biosimilars, approved by the Food and Drug Administration (FDA) through an abbreviated approval pathway, act as competitors to reference biologics and offer the opportunity to lower average costs for biologic products.

The long-run outlook for competition in biologics is positive. For example, the FDA is currently coordinating with biosimilar manufacturers interested in 76 biosimilar projects. However, due to a variety of market and nonmarket barriers inhibiting biosimilar entry and uptake, the short- and medium-term outlooks are more tepid, and the savings from

biosimilars has been slow to materialize. A unique opportunity exists in Medicare Part B to boost biosimilar utilization through the establishment of a shared savings demonstration model administered through the Centers for Medicare & Medicaid Services (CMS) Innovation Center.

A shared savings model for biosimilars is consistent with the Innovation Center's stated mission to "improve care, lower costs, and better align payment systems to support patient-centered practices." It also would be relatively easy to administer and evaluate, would not conflict with existing demonstrations, can be designed without downside risk so to attract widespread participation, and could yield significant savings not just for Medicare but for the entire healthcare system.

BACKGROUND

Biosimilars in the United States

The legal pathway for biologic drug competition was established in statute in 2010. Contrary to initial expectations (for example, *CBO (2008)*), the biosimilars market has been slow to develop in the United States. The first biosimilar, a competitor to the blockbuster biologic Neupogen, did not launch until 2015. Since then, the FDA has significantly increased the number of biosimilar approvals, but out of the 26 approvals to date, 17 were approved in the last two years (*FDA, 2020*).

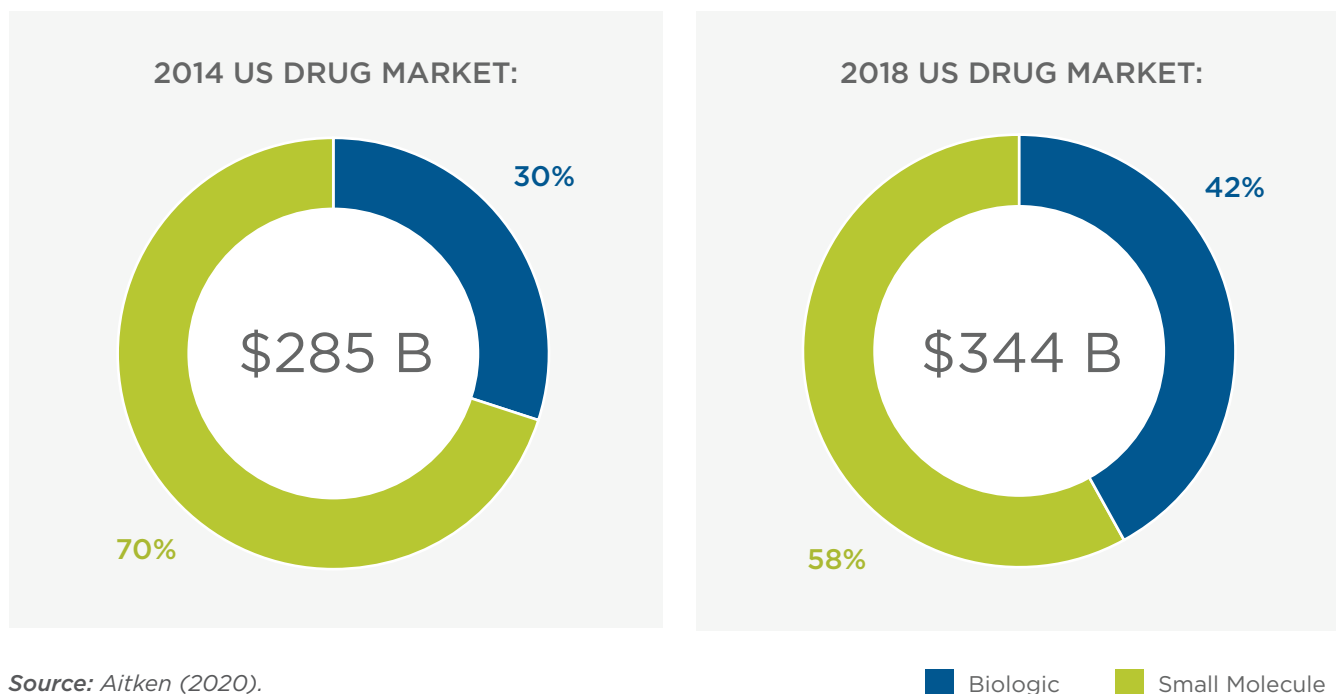
Not all approved biosimilars have launched, and most of the available biosimilars have been on the market for less than two years. At present, 16 biosimilars are marketed, and they provide competition for seven reference biologics. According to recent data from IQVIA, biosimilars have achieved 20 percent market

share within the markets in which they compete (*Aitken, 2020*). Moreover, the majority of the brand biologic market – 83 percent, according to IQVIA – is without a biosimilar competitor.

Biologics Drive Rising National Drug Spending

Biologics are an increasing share of total drug spending in the United States. Spending on biologics grew from 30 percent to 42 percent of total drug spending from 2014 to 2018 (see **Figure 1**). In inflation-adjusted terms, biologic drug spending increased from \$291 to \$435 per capita, while small-molecule drug spending fell from \$689 to \$610 per capita during this period (*IQVIA, 2019*).

FIGURE 1. SHARE OF US DRUG SPENDING BY CATEGORY, 2014 AND 2018



The growth in US biologic spending is attributable to three factors: 1) availability of new and costly innovative biologics, 2) rising prices of existing biologics, and 3) increased utilization of biologics as the US population ages.

In Medicare Part B, the medical insurance component of Medicare, the trends in drug spending have been the same as the larger US market: biologics are single-handedly driving total drug spending higher. Since 2005, Part B spending on biologics has seen a cumulative *increase* of 42 percent while spending on nonbiologics has *declined* by 20 percent (*MedPAC, 2019*). As MedPAC (2019) notes, “The downward price trend for nonbiologics in part reflects patent expiration and generic entry for some of these products.” Unfortunately, the experience of competition among biologics is thus far vastly more limited. While there are more than 700 unique Part B drug codes, the top 10 products represent 43 percent of total drug spending (*MedPAC, 2019*). All 10 of these products are biologics. Half of them have biosimilars on the market, but four only began facing biosimilar competition last year.

Most biologics are administered by a physician and, therefore, are reimbursed through a payor’s medical benefit – Part B in Medicare. All available biosimilars in the United States are covered under Medicare Part B, and most future biosimilars will be reimbursed through Part B, rather than Medicare’s prescription drug benefit, Part D. This makes the biosimilars market ripe for a Part B demonstration, which the CMS Innovation Center is already equipped to run.

CMS Innovation Center Models

The Center for Medicare & Medicaid Innovation (CMMI), also known as the CMS Innovation Center, exists to test “innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care” (*42 USC 1315a(a)(1)*). The Innovation Center has organized its efforts around seven types of innovation model: 1) accountable care, 2) episode-based payment, 3) primary care, 4) Medicaid and CHIP, 5) Medicare-Medicaid enrollees, 6) development and testing of new payment and service delivery, and 7) best practices.

CMMI is very active in Innovation Programs focused on Type 6 models, for new payment and service delivery. More than two dozen such models are active or in development, though there is no ongoing CMMI demonstration in Medicare Part B at present. While lower-cost biosimilars can contribute to the success of models currently in operation or under consideration by CMS, the Innovation Center has yet to formally pursue an innovation model centrally focused on payment reforms necessary to unleash the significant savings opportunities from biosimilars.¹ Such a model, if properly designed to share biosimilar savings, would offer the opportunity to transform the biosimilars marketplace in the United States for all payor types.

¹ For example, the Oncology Care Model may lead to increased utilization of biosimilars through the episode-based payment model for certain cancer care. The recently proposed Oncology Care First Model may also offer opportunities to encourage the utilization of certain biosimilars.

RATIONALE FOR A BIOSIMILARS SHARED SAVINGS MODEL

Payment Incentives Affect Provider Behavior

A biosimilars payment model would allow physicians, hospitals, and drug manufacturers to harness the potential from competitive forces to increase utilization of lower-cost biosimilars, a process that is already occurring but at a relatively slow pace. Current reimbursement policy for Part B drugs can create perverse incentives to use more costly drugs, and insights from a biosimilars payment model may inform broader payment reforms across Part B in the future.

CMS recently expressed its view that reimbursement policy for Part B drugs may lead to certain prescribing patterns. “[The current ASP+6%] drug add-on payment may encourage increased utilization, particularly of higher-cost drugs, since doing so increases revenue for the physician or hospital when the add-on is higher than drug acquisition-related costs” (CMS, 2018). Moreover, there is a sizeable academic literature providing evidence that provider reimbursement can affect patterns of care, including the quantity and composition of medical goods (such as drugs) and services. For example, a recent literature review in *JAMA Oncology* identified 15 studies that find that physician practice patterns in oncology are influenced by financial reimbursement arrangements (Mitchell et al., 2019). With respect to prescribing patterns, physician payments, and drugs, multiple studies indicate that the Medicare Part B reimbursement structure encourages the use of higher-priced medicines. Epstein and Johnson (2012), for example, demonstrate that physician prescribing for the treatment of metastatic breast cancer is influenced by differences in reimbursement across drug treatment options. Conti et al. (2012) estimate that prescriptions for a particular Part B oncologic, irinotecan, declined significantly relative to a close

therapeutic substitute, oxaliplatin, when Medicare reimbursement for irinotecan declined following generic entry.

This evidence, along with broader research into the impact of incentives on the delivery of care (Clemens and Gottlieb (2014), for example), offers important support for the potential value of a shared savings biosimilars model, as it indicates that prescribing patterns will likely change significantly if incentives for biosimilars are established. This offers not only the potential for significant savings to Medicare and patients, but also valuable assistance to the burgeoning biosimilars market.

Benefits of Establishing a Shared Savings Model for Biosimilars

An Innovation Center shared savings demonstration in Medicare Part B would test the potential for payment reform to encourage use of lower-cost biosimilar drugs. If properly structured, such a program could yield significant savings to the Medicare program and establish valuable insights into the impact of pharmaceutical reimbursement on physician prescribing patterns among physician-administered drugs. Moreover, this can be achieved through the use of an incentive structure as opposed to a cut in physician reimbursement.

Now is the appropriate time for a biosimilars innovation model because a sufficient number of products are available today, and more are expected on the market soon. Given the nature of existing payment policies and reporting requirements for Part B drugs, a biosimilars payment model would entail few, if any, additional reporting burdens on physicians and hospitals, while offering the Innovation Center valuable data on the effectiveness of payment alternatives for driving savings related to high-cost drugs.

SPECIFICS OF A BIOSIMILAR SHARED SAVINGS MODEL

Reimbursement Design

Current Reimbursement of Biosimilars and Biologics in Part B

At present, physicians administering reference biologics in Part B are reimbursed at the average sales price (ASP) of that drug plus 6 percent. Biosimilars are reimbursed at the ASP of the biosimilar plus 6 percent of the reference biologic's ASP. For example, a physician administering a reference biologic with an ASP of \$1,000 would be reimbursed \$1,060. A biosimilar that references that \$1,000 biologic, but costs \$700, would be reimbursed at \$760. As a result of the Budget Control Act of 2011, reimbursement for Part B has been subject to Medicare mandatory sequestration. Though temporarily suspended for 2020 as a result of the CARES Act, sequestration reduces Medicare payments by 2 percent and establishes a *de facto* Part B reimbursement of ASP+4.3%, given that the cut is only applicable to the 80 percent of reimbursement that is payable by CMS (Brill and Leitner, 2012). As such, the physician's share of the Part B payment in these examples would, according to current reimbursement rules, be \$43.

This reimbursement structure for reference biologics and biosimilars establishes a constant add-on payment for both products, making the physician no better or worse off for using one product over another. But in this example, the Medicare program would save \$300 if the physician chose the biosimilar. In other words, physician incentives are not aligned with Medicare's objective of financial prudence. The physician is neither encouraged nor discouraged from using the lower-cost biosimilar, while Medicare (and, ultimately, taxpayers) face significant additional costs from the utilization of the equivalent, but more costly, biologic.

Align Reimbursement Incentive for Cost Savings

The purpose of a biosimilars shared savings model is to align the incentives of the physician with the objective of Medicare to reduce unnecessary spending. In the above example, if physicians were able to share a portion of the \$300 in Medicare savings, they would have an incentive to increase biosimilar utilization, yielding significant potential cost savings to the Medicare program.

There are a number of ways such an incentive could be designed. Physicians prescribing a lower-cost biosimilar could receive a fixed dollar amount or an add-on payment equal to a share of the difference in ASP between the biosimilar and the reference product. The incentive could be paid starting with the first biosimilar administered during the demonstration period, or it could be paid periodically and only to the extent that biosimilar utilization exceeds a simple, fixed, and established threshold or baseline. However, such thresholds create both complexity and uncertainty for physicians and, while intended to target incentives more efficiently, may create disincentives for participation and other burdens.

For instance, in the example above with a \$1,000 reference product and \$700 biosimilar, if the shared savings to the physician was 10 percent of the \$300 savings (\$30), the physician's share of the Part B payment would rise from \$43 to \$73 (assuming sequestration) and the government's share of the savings would be \$270. To the extent that policymakers are concerned about the impact of unnecessarily large incentive payments, the per-payment incentive could be capped at a maximum dollar amount. A downside of a cap is that it may mitigate the incentive among manufacturers of biosimilars to the same reference product to engage in price competition beyond the point at which physician reimbursement is maximized.

Model Design

In addition to ensuring that physician incentives are aligned with the objective of cost savings for Medicare, a successful Innovation Center shared savings model for biosimilars should be designed with four principles in mind:

1

Voluntary

Consistent with recent CMS practice, Innovation Center demonstrations should, to the extent possible, be constructed to permit providers to opt in, as opposed to mandating participation. In the case

of a shared savings demonstration for biosimilars, voluntary participation is easy to implement and will not jeopardize any aspects of program evaluation as long as there is a reasonably sized control group to which participants in the demonstration can be compared, as discussed below.

2

Simple and broad-based

Many of the other Innovation Center demonstrations have required participants to incur significant startup costs, as well as considerable ongoing costs for staff to monitor and administer the demonstration. Such sizeable fixed costs can impede participation by smaller providers and, because many rural providers

are smaller, limit opportunity for participation outside of urban and suburban settings. In the case of a shared savings demonstration for biosimilars, both enrollment costs and ongoing participation costs could be minimal. Existing infrastructure for billing of Part B drugs can easily accommodate the necessary changes to be able to monitor biosimilar utilization and award payments.

3

Optimized for fiscal responsibility

Setting up and administering an Innovation Center demonstration requires federal resources, and an unsuccessful demonstration risks raising overall program costs. As a responsible steward of taxpayer funds, the Innovation Center should parameterize models to minimize the risk of loss for taxpayers, ensure sufficient reward to providers who achieve program savings, and strive for large-scale net program savings.

In the case of a shared savings demonstration for biosimilars, Innovation Center administration costs

(implementation and evaluation) will likely be on par with other low-cost demonstrations.² But, given the significant potential for cost savings (easily in the billions of dollars annually) and relatively small share of the savings likely necessary to properly align incentives, proper program stewardship can easily be ensured. With a low barrier to enter (i.e., minimal burden on physicians to enroll) and the opportunity for additional reimbursement with only moderate changes, it is reasonable to expect high participation among providers.

4

Broad stakeholder appeal

Critical to promptly establishing an Innovation Center demonstration program is broad stakeholder appeal. With respect to a Part B shared savings demonstration for biosimilars, this support should include biosimilar manufacturers, physicians who would be eligible for participation, and advocacy organizations representing patients who may be treated with biosimilar products subject to this program.

A shared savings biosimilars model is highly likely to have broad stakeholder appeal, as physicians need not face downside risk (as is the case in other models) or new compliance burdens, and patients can expect reduced out-of-pocket expenses without any risk of adverse clinical outcome. Other payors, including commercial plans, would likely look favorably on the development of a new reimbursement structure that motivates physicians to utilize lower-cost biosimilars over higher-priced reference biologics.

² For example, GAO (2018) reports that the Part D Enhanced Medication Therapy Management model obligated \$8.4 million in funds, which covered implementation and evaluation costs.

Measuring the Success of a Shared Savings Model

At the completion of an Innovation Center demonstration, it should be evident if the model was successful in generating overall cost savings. In the case of a shared savings demonstration for biosimilars, validation can be achieved without the need for projecting a baseline upon which to judge success. A number of current and recent shared savings models rely on complex calculations of historical baselines and trend forecasting projections to judge a demonstration participant's behavioral response and to calculate generated savings and ultimately determine shared savings. In addition, multiple models require a risk-adjustment factor to compensate for differences and changes in patient population over time and across practices. Such elements, while perhaps necessary to ensure savings targets are set efficiently in those models, can also impose uncertainty and risk for providers for whom the baseline against which savings are measured is opaque or unpredictable. Such shortcomings discourage participation, impose unnecessary costs on providers, and increase the potential for errors in program administration.

A shared savings program for biosimilars can establish a metric for program evaluation without imposing a complex and uncertain baseline. A control group can be established in various ways, but

one simple option is to randomly exclude all physicians in one of the 12 A/B Medicare Administrative Contractor (MAC) regions. The program would still be voluntary for physicians in the other 11 MAC regions, but any concern about sample selection bias would be overcome by the existence of prescribing data from physicians in the excluded MAC. This would permit analysts to compare utilization among three groups: those who opt into the demonstration, those who choose not to opt in, and those who are not permitted to opt in.

Patient Out-of-Pocket Costs

The Innovation Center could consider design elements in addition to those described above. For example, a portion of the savings accruing from this model could be used to reduce beneficiary cost-sharing obligations. This would be relatively straightforward for patients without Medicare supplemental insurance (Medigap) because the traditional copay associated with a Part B drug could be reduced for patients treated by physicians enrolled in the shared savings program. However, it may be infeasible to share savings with patients who have little or no coinsurance due to their Medigap coverage. Moreover, reducing patient out-of-pocket costs and increasing physician reimbursement simultaneously may complicate the analysis of the program's success.

Conclusion

As lower-cost versions of some of the most expensive prescription drugs on the market, biosimilars present a unique opportunity to deliver savings in a high-cost, rapidly growing segment of the healthcare system. A shared savings model for biosimilars organized by the CMS Innovation Center could achieve cost savings without reducing services or quality of care for patients. In doing so, a biosimilar shared savings model could clearly and effectively achieve the President's objective of addressing high drug costs.

REFERENCES

- Aitken, Murray. 2020. "Biologic Market Dynamics: Setting the Stage for Biosimilars." *FDA/FTC Workshop on Competitive Marketplace for Biosimilars*. (March 9).
- Brill, Alex, and Brett Leitner. 2013. "Sequestration's Uniform Medicare Cut Will Yield Disparate Impacts Across Providers." *The Health Lawyer*. June.
- Congressional Budget Office. 2008 "Cost Savings from Follow-on Biologics." June 25. www.cbo.gov/publication/24808 (Accessed May 6, 2020).
- Centers for Medicare & Medicaid Services (CMS). 2018. "ANPRM for Medicare Program; International Pricing Index Model for Medicare Part B Drugs," *Federal Register* 83, no. 210 (October 30).
- Clemens, Jeffrey, and Joshua Gottlieb. 2014. "Do Physicians' Financial Incentives Affect Medical Treatment and Patient Health?" *American Economic Review* 104, no. 4. (April).
- Conti, Rena M., Meredith B. Rosenthal, Blase N. Polite, Peter B. Bach, and Ya-Chen Tina Shih. 2012. "Infused Chemotherapy Use in the Elderly After Patent Expiration," *Journal of Oncology Practice* 8:3S, e18s-e23s.
- Epstein, Andrew, and Scott Johnson. 2012. "Physician Response to Financial Incentives When Choosing Drugs to Treat Breast Cancer," *International Journal of Health Care Finance and Economics* 12, no. 4: 285–302.
- Food and Drug Administration (FDA). 2020. "Biosimilar Product Information." February 24. www.fda.gov/drugs/biosimilars/biosimilar-product-information (Accessed May 7, 2020).
- Government Accountability Office (GAO). 2018. "CMS Innovation Center: Model Implementation and Center Performance." March.
- IQVIA. 2019. "Medicine Use and Spending in the U.S." May.
- MedPAC. 2019. "Report to Congress: Medicare and the Health Care Delivery System." June.
- Mitchell, Aaron, Jason Rotter, Esita Patel, Daniel Richardson, Stephanie Wheeler, Ethan Basch, and Daniel Goldstein. 2019. "Association Between Reimbursement Incentives and Physician Practice in Oncology: A Systematic Review." *JAMA Oncology*. June.

ABOUT THE AUTHOR

Alex Brill is the founder and CEO of Matrix Global Advisors, an economic policy consulting firm in Washington, DC. He served on the staff of the House Ways and Means Committee from 2002 to 2007 and the White House Council of Economic Advisers from 2001 to 2002.

This report was sponsored by the Biosimilars Forum. The author is solely responsible for the content. Any views expressed here represent only the views of the author.

