

Realizing the Benefits of Biosimilars: PART B PAYMENT APPROACHES

Originator Biologics and Biosimilars: Payment Policy Solutions to Increase Price Competition While Maintaining Market Sustainability in Medicare Part B

Nitzan Arad, Derick Rapista, Marianne Hamilton Lopez, Mark McClellan

Executive Summary

Issue: Biosimilars present a unique opportunity to decrease drug spending while maintaining parity of clinical outcomes. However, providers generally have limited financial incentives under Medicare Part B's existing policies to use less costly biologics when biosimilars are available, reducing competitive pressures from biosimilars. Payment reforms are needed to increase price competition between originators and biosimilars, resulting in lower costs for beneficiaries and the Medicare program.

Potential policy reforms include consolidated billing codes with shared reimbursement rates and least costly alternative (LCA) payment policies. In a fully consolidated billing code system, both innovator biologics and their biosimilars would be reimbursed at the same 106% "blended" average sales price (ASP) rate, which is the volume-weighted average of the ASPs of all products of the same molecule (originator and biosimilar[s]). In an LCA or reference price system, the payment rate for every product within that group is set at the payment level of the lowest-cost alternative. Such payment reforms could spur head-to-head price competition between biologics and their clinically similar, lower-priced biosimilars. However, concerns have been raised that such reforms could compromise access and beneficiary quality of care.

Key Findings and Recommendations: To promote more price competition while minimizing concerns that these policies might result in adverse effects that would negate the potential cost savings of increased biosimilar utilization and could lead to worse patient outcomes, we propose a stepwise approach to biosimilar payment reform that permits assessment and adjustment of the proposed shift from the current product-specific reimbursement approach toward a shared payment amount for the originator and its biosimilars. The shared blended payment rate would be phased in, allowing an assessment of the consequences for price competition, access, and beneficiary spending. The initial payment rate for a biologic or biosimilar product could be partly (e.g., two-thirds) based on a product's own ASP and partly (remaining one-third) blended with the ASPs of the other products in that group, culminating in a fully blended reimbursement rate over time. This approach could result in significant savings while mitigating extreme adjustments in price and provide an opportunity

to assess the consequences of the policy change, while giving providers an opportunity and motivation to develop practices that optimize the use of biosimilars.

To implement the novel payment policy as described in this brief, legislative action is needed to give CMS authority to modify reimbursement methodologies away from individual products' ASPs for originator biologics. Alternatively, CMMI could use its authority to test and refine such a model in order to reduce Part B drug spending while improving beneficiary access and affordability of biosimilars.

Policymakers could also consider other approaches that extend beyond these proposed changes to encourage the use of biosimilars to improve access and lower costs. CMS could depart from the existing "buy-and-bill" payment system in favor of market-based reforms such as competitive bidding, using contractors like those in Medicare Part D to negotiate lower prices and benefit designs to provide lower copays and encourage uptake of less costly but effective biologics, especially when biosimilars or multiple therapeutic options are available for a condition. Lastly, increasing the uptake of value-based care models that include accountability for drug costs and outcomes can reward prescribers with more successful financial outcomes when they increase biosimilar utilization and offer another effective way to lower Part B spending on biologics and other costs of care.

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Introduction

As a growing number of biologic drugs and their corresponding biosimilars continue to be introduced to the U.S. pharmaceutical market, policy approaches that ensure access to novel breakthrough treatments, foster drug innovation, and promote product competition are increasingly important, especially in Medicare Part B. A previous Duke-Margolis issue brief examined policies that have contributed to slower biosimilar uptake in the U.S. than in European countries, highlighting several regulatory and payment policy lessons that could encourage greater use of lower cost biosimilars domestically.¹

Biologics, drug products derived from living organisms, include pharmaceuticals ranging from small-molecule insulins to monoclonal antibodies to gene therapies. Because biologics and their biosimilars – follow-on products to the original biologic innovator – are complex products that are typically physician-administered, they are covered primarily within payers' medical rather than pharmacy benefits. In Medicare, this means most biologics and biosimilars are covered under the Part B benefit, which pays for drugs that are normally given in a physician's office, clinic, or hospital outpatient department using "buy-and-bill". Under a "buy-and-bill" system, providers first purchase the drug and then bill Medicare once the product is administered and are reimbursed under a statutory fee schedule.

Within Medicare Part B, biologics account for a significant and growing share of drug spending costs. All ten highest expenditure drugs under Medicare Part B are biologics.² In addition, biologics equal 43% of all drug expenditures³ and 90% of growth in net drug spending since 2014⁴ in the U.S. overall. Domestically, biosimilars, on average, cost 10-37% less than their reference product biologic,⁵ while in some developed European countries, biosimilars have achieved up to an 80% discount off of the originator's list price⁶ (although biosimilar market penetration and their impact on costs vary by country⁷). Biosimilars present an increasingly important opportunity to significantly decrease pharmaceutical spending while maintaining clinical outcomes and encouraging further new product innovation.

Biosimilars in the U.S. have demonstrated mixed results in terms of their ability to penetrate the healthcare market and generate meaningful cost savings. For example, according to a recent MedPAC report,⁸ while both Neupogen (filgrastim) and Remicade (infliximab) first encountered biosimilar competition in the third quarter of 2015 and fourth quarter of 2016, respectively, by the third quarter of 2020, filgrastim biosimilars had acquired 77% market share while infliximab biosimilars had acquired only 16% market share. Additionally, the change in the list price of a given reference biologic in response to biosimilar entry has also varied.⁹ Payment

policy reform that increases price competition between biosimilars and their innovator biologics and incentivizes use of the lower cost option (typically the biosimilar), especially within Medicare Part B, could decrease total drug spending.

The most recent Congressional proposal¹⁰ from House Democrats to control drug prices includes regulatory authority for Medicare to impose significant discounts relative to the overall U.S. market for a subset of the highest gross spending single source drugs in Part B and D. This authority would not apply to new drugs: the new Medicare discount price negotiations for some originator biologics only begin 10 years after their approval by FDA, protecting them from these price reductions for 13 years from their FDA approval. While some of the highest-cost biologics in Medicare have had long periods of exclusivity, the potential imposition of required discounts at that stage could be a source of uncertainty for biosimilar manufacturers, possibly impacting their investment in biosimilar development programs. To reduce this uncertainty, Congress could consider alternative approaches to reduce biologic prices through more competition and more financial incentives for biosimilars, such as those that have been adopted in other countries.¹¹ If this proposal or a similar one is adopted, its implementation should seek to provide more certainty about the circumstances and conditions when it would be applied. For example, implementation could focus on situations where biosimilar entry is not expected to occur in the near-term, and could be coupled with steps to encourage savings from biosimilars.

This issue brief examines current biologic and biosimilar reimbursement under Medicare Part B, with the goal of supporting a more robust and competitive biologic market. We focus on policy changes that can generally be facilitated within the existing Medicare fee-for-service (FFS) Part B payment methods (although some legislative changes may be required for their implementation) and have the potential to directly impact over 60% of Medicare beneficiaries that receive their benefits through traditional Medicare.¹² We describe an incremental path toward substantial payment reforms and discuss legislative implications. Additionally, we provide recommendations for how this biologic payment model can be potentially tested and implemented. Finally, we describe other potential policies that extend beyond the current system and could help spur greater price competition between originators and biosimilars in Part B.

Biologic and Biosimilar Payment in Medicare Part B

Medicare Part B bases its payment for pharmaceuticals on manufacturer-reported average sales price (ASP).¹³ In particular, Medicare reimburses providers for single-source drugs (i.e., without generic competition) and biologics at 100% of their ASP plus a 6% ASP add-on payment, which has effectively been reduced to 4.3% due to budget sequestration legislation. ASP is the weighted average of all of a manufacturer's market prices inclusive of rebates, discounts, and other price concessions. The add-on payment aims to account for costs of administration, product handling expenses, and differential acquisition costs experienced between providers.¹⁴ Biosimilars are currently reimbursed at their own ASP but receive the same add-on payment as

the innovator biologic to limit provider financial incentives to pick the higher-cost originator product.

Between 2016 and 2018, the Center for Medicare and Medicaid Services (CMS) grouped biosimilars that relied upon the same reference product under the same health care common procedure coding system (HCPCS) billing code. Each group of biosimilars was given the same payment rate under a common HCPCS code, using a volume-weighted average ASP calculation of all biosimilars in that group. In contrast, originator biologics separately maintained unique HCPCS codes and were paid based on their individual ASP payment rates.¹⁵

While the goal of this policy was to lower biologic drug spending for the Part B program, it also generated some concern that biosimilars would be unequally subjected to downward price competition when compared with the original reference biologics that maintained their own reimbursement levels, resulting in inadequate financial incentives for providers to use biosimilars,¹⁶ impaired biosimilar uptake and market development, and sustained high market share and price for the originator. In response to these concerns, CMS changed its payment policy in 2018 as part of the Physician Fee Schedule Final Rule¹⁷ such that each product (innovator and biosimilar) receives its own HCPCS billing code and reimbursement rate based on its own ASP (biosimilars still receive the originator's 6% ASP add-on).¹⁸

While the equal add-on payment to both innovator and biosimilar reimbursement aims to ensure that providers are not encouraged to utilize the more expensive product (typically the originator), it does not create much incentive for providers to switch to the biosimilar. The use of unique billing codes and reimbursement rates means that the differences in ASP do not translate into a difference in net provider reimbursement, so price competition between the biologic reference products and their biosimilars is blunted in the "buy-and-bill" process.¹⁹ At the same time, because of a 20% Part B coinsurance based on the ASP of a given biologic, Medicare beneficiaries without supplemental coverage (10% of overall Medicare patients and 17% of patients with traditional Medicare²⁰) are subject to higher out-of-pocket costs with higher originator biologic prices. Beneficiaries that are enrolled in Medicare Advantage (MA) plans typically face a 20% coinsurance for Part B drugs but only up to their plan's out-of-pocket cap, known as the Maximum Out-of-Pocket (MOOP) limit. Moreover, since 2019, CMS has allowed the usage of step therapy by MA plans for Part B drugs, and in 2021 nearly all MA enrollees are in plans that require prior authorization for these drugs,²¹ unlike traditional Medicare that does not impose such step therapy requirements. These utilization management tools help reduce MA plan and beneficiary costs and allow beneficiaries to directly share in savings arising from lower cost drug utilization.²²

Fee-for-Service Payment Reforms of Biologics and Biosimilars in Part B

Further payment reforms within the Part B FFS payment structure could increase biosimilar utilization and lower biologic drug costs. Some previously proposed reforms include, for example, increasing the biosimilar's ASP add-on percent²³ or creating biosimilar shared savings

programs,²⁴ where physicians directly share in the savings from biosimilar use, as has been done successfully in some European countries. To support a more robust and competitive biosimilar market, Part B payment reforms could create more price competition by transmitting more of the savings from biosimilars (and, conversely, the higher prices of originator products) to the prescribers.²⁵ Previously suggested alternative payment policies such as consolidated billing codes and least costly alternative (LCA) payment models set single payment rates for groups of biosimilars and their reference product.

In a consolidated billing code and “blended” payment rate system, all related biologic products (biosimilar[s] and the biologic innovator reference product) are grouped under the same billing code and reimbursed at the same volume-weighted average ASP for the originator and all biosimilars of that reference biologic, plus an add-on payment of 6% of this volume-weighted amount.²⁶ This approach would be expected to enhance price competition for products within the group similar to how branded small-molecule drugs and their generics fall into the same payment code and share the same payment rate in Medicare Part B.²⁷ Manufacturers would face more pressure to lower their prices to match or beat their competitors’ prices to encourage providers to utilize their product and capture market share. Providers would have a stronger incentive to only prescribe the originator product if there were clear and compelling clinical reasons to do so – with the European experience suggesting that is generally not the case.

LCA payment policies provide even stronger provider incentives to increase lower-cost biosimilar utilization. In general, an LCA policy sets the payment for a group of clinically similar HCPCS codes at the “reference price” of the least costly alternative within that group and was previously implemented by CMS in the context of Part B therapeutically equivalent branded drugs (i.e., outside the biosimilar context) in oncology and was proposed for two inhalation drugs.²⁸ However, CMS discontinued this policy after it was successfully challenged in federal courts as a result of statutory limitations.²⁹

LCA payment policy could take two approaches: a unique ASP approach and a common ASP approach.³⁰ In a unique ASP approach, each product keeps its own unique code and ASP. The total payment (i.e., from Medicare and the patient) for any drug within the group would be set at 106% of the unique ASP for that drug with Medicare paying 80% of the cost of the LCA within the group and the beneficiary accounting for the remaining balance. If the LCA is administered, the beneficiary would be responsible for the standard 20% share. If there is utilization of a more expensive product, then the patient would be accountable for the difference.³¹ In this approach, providers are at no financial risk for utilizing a costlier option, placing the burden on beneficiaries in the form of increased out-of-pocket costs. This approach would depend on beneficiary price sensitivity to encourage manufacturers to reduce their prices to remain competitive; however, it is unlikely to be implemented given Medicare’s prohibition of balance billing³² and could be viewed as inequitable and burdensome on Medicare beneficiaries.

In a common ASP approach, all drugs within an LCA category would be paid at the same rate (106% of the ASP of the least expensive drug). Medicare would continue to pay 80% of the cost, and the patient would cover the remaining 20%. Similar to shared coding and blended reimbursement payment policies, a common ASP LCA approach would create financial pressure for providers to use the lower-cost option as the mechanism for increasing manufacturer price competition. This approach would also increase financial risk for providers who choose to persist in prescribing relatively high-priced products.

Policy Concerns and Proposed Middle Ground Payment Approach

In contrast to the pre-2018 biosimilar reimbursement policy with shared payment rates between biosimilars, the aforementioned alternative payment policies include both innovator biologic and biosimilar(s), thus creating much stronger pressure to switch from the originator product. However, some of the same previous concerns of price erosion, market instability, and resulting access problems could recur. In comparison to generic drugs, biosimilars have significantly higher development costs and time and require additional studies for their approval.³³ Strong short-term price competition has resulted in less competition in relatively fragile markets for generic drugs;³⁴ such risks seem higher for aggressive pricing in biologics markets, where the significant costs of entry and limited financial rewards could reduce incentives for biosimilar introduction, effectively negating the desired cost savings of a robust biosimilar market.³⁵ Consequently, as the biosimilar market continues to grow, payment reforms should aim for an appropriate balance between competitive biologic pricing and incentives for continued entry and participation in a robust market.

A potential “middle ground” approach between the extremes of no pass-through of price signals and full pass-through is a gradual implementation of a shared payment rate. Paying all products in a given group based on the same reimbursement amount could be phased-in gradually to generate price competition without discouraging the market from developing. For example, payment rate for a biologic or biosimilar product could initially be partly (e.g., two-thirds) based on a product’s own ASP and partly (the remaining one-third) blended with the ASPs of the other products in that group, increasing annually and culminating in a fully blended reimbursement rate if market participation and access remain robust while greater price competition phases in. CMS could assess the evolving reimbursement policy and slow down if needed, aiming for a sustainable combination of access and price competition that limits spending.

A phased-in payment approach would also address provider concerns with a single blended payment rate, allowing prescribers more time to become comfortable with switching to biosimilars, especially for chronic conditions,³⁶ and for further real-world evidence on switching from the innovator to the biosimilar to be developed as new biosimilars enter the market.

Legislative Implications of Part B Reimbursement Reforms to Increase Competition

By statute, biologics and single-source drugs must be paid based on their ASP and not averaged or otherwise mixed with other products' ASPs.³⁷ Because the approaches described above may require that the originator biologic is not (fully) paid based on its own ASP but also based on the ASPs of its biosimilar counterparts, a legislative change would be necessary for implementing these alternatives. For example, the aforementioned LCA policy precedent around branded inhalation and oncology products was later terminated by CMS after a court ruled that it was inconsistent with relevant law, which requires the payment rate for Part B single-source drugs to be based on their own ASPs.³⁸

Since the passage of the biosimilar approval pathway under the Biologics Price Competition and Innovation Act (BPCIA) in 2010, both Congress and the executive branch have been interested in promoting increased biosimilar adoption levels. A statutory change specifying that originator biologics are not required to be paid based on their own ASPs and providing guidance to CMS for assessing the impact of the incremental pricing changes and adjusting accordingly would enable the proposed reform described above, achieve beneficiary and Medicare program savings, and align with bipartisan interest in promoting biosimilar competition.³⁹

In the absence of legislation, or to provide further evidence to guide it, the Center for Medicare and Medicaid Services Innovation Center's (CMMI) authority could potentially be used to pilot such a model. CMMI has the authority to implement such pilot payment reforms to test their ability to reduce Medicare spending and improve access, quality, and outcomes for Medicare beneficiaries. CMMI's innovation models are organized into seven categories, one of which is initiatives to accelerate the development and testing of new payment and service delivery models. However, CMMI has not yet successfully implemented a drug payment reform pilot. On August 10, CMMI proposed to rescind the Trump administration's most favored nation (MFN) model, which has been facing legal barriers to implementation. The MFN model sought to test a new way to lower drug costs by paying no more for high-cost Medicare Part B drugs and biologics than the lowest price that drug manufacturers receive in other similar Organization for Economic Cooperation and Development (OECD) countries.

With the withdrawal of the MFN model, absent other CMMI models related to Medicare Part B drugs, and given the prominent role that biologics play in Part B's drug spending, testing a model that is directly focused on realizing savings from biosimilars would allow CMMI to explore how Medicare could remove incentives to use higher-cost drugs and help reduce growth in Part B spending without adversely affecting quality of care for beneficiaries while lowering their out-of-pocket cost and increasing their access to important biologic therapies. Testing ways to reduce program and beneficiary spending on drugs and supporting increased biosimilar utilization are listed as goals for CMMI in the recent Department of Health and Human Services report to the White House Competition Council.⁴⁰

Alternative Payment Models for Part B Drugs to Promote Biosimilar Competition

Modifying Part B “buy-and-bill” reimbursements based on originator and biosimilar ASPs offer policymakers a pathway to create more price competition between originators and biosimilars within CMS’s existing payment methods for pharmaceutical products. However, there are additional ways to lower biologic drug spending in Part B that extend beyond these proposals. As the growth in Medicare FFS Part B drug spending per enrollee is more than twice as high as Part D and nearly three times as high as the nation overall,⁴¹ CMS and Congress could implement more significant structural changes in Part B payment that could create greater price competition and opportunities for beneficiary savings through biosimilars.

In other parts of the U.S. healthcare system, including Medicare Part D, Medicaid, and commercial insurance programs, plans and their benefit managers negotiate with drug manufacturers to influence their drugs’ placement on plan formularies in exchange for price concessions such as rebates that can be substantial in classes where strong competition exists. Furthermore, these plans have a range of additional utilization management tools at their disposal to affect physician and patient drug utilization choices and steer them towards more cost-effective options, including prior authorization, step therapy and tiered cost-sharing. As mentioned earlier, since 2019, CMS has allowed Medicare Advantage (MA) plans to implement step therapy for Part B drugs which can support lower prices as drug manufacturers are incentivized to negotiate with MA plans so that their drugs are selected by the plans as the first step in a therapy. However, FFS Medicare has no such mechanism.

Proposals such as MedPAC’s Drug Vendor Program (DVP)⁴² would bring such approaches to Medicare Part B as an alternative to the “buy-and-bill” ASP payment method. Under such a proposal, CMS would contract with a set of competing third party intermediaries authorized to negotiate lower drug prices from manufacturers by using formularies, benefit design adjustments to lower copays for beneficiaries, and other utilization management tools. This more comprehensive set of tools could have larger effects on biosimilar use: beneficiaries would have significantly lower cost-sharing amounts for less costly but effective treatments like biosimilars, and providers would also have financial and non-financial incentives to use them. This reform would be substantially different from CMS’s earlier Competitive Acquisition Program (CAP), which did not enable such tools to negotiate lower prices and shift utilization. It could also be coupled with limits on subsequent price increases as proposed in recent Congressional bills.

Lastly, CMS could also continue to encourage providers to use lower-cost but equally effective biosimilars as part of its support for more comprehensive patient-centered care models by including the use of biologics and biosimilars in its future value-based payment reforms. Accountable care organizations (ACOs) and episode-based payment models such as the Oncology Care Model (OCM) provide prescribers with incentives to use lower-cost biosimilars by sharing in some of the savings generated from more efficient management of patients’

health, aligning incentives to control total cost of care. Providers in advanced alternative payment models could be given more flexibility to give beneficiaries lower copays or other benefits when they switch to more cost-effective biosimilars, much as advanced ACOs have more flexibility to cover home-based and digital services, since these providers are more accountable for total costs of care. CMMI has recently highlighted its interest in piloting value-based insurance design models to encourage use of higher-value services.⁴³ Biosimilars could be included in such models. Increasing the uptake of these models and expanding them to other disease areas where biologic interventions have the potential to play an important role could help increase the use of biosimilars by improving participating providers' financial outcomes and generate cost-savings to Medicare and enrollees.

Conclusion

As more and more biosimilars continue to be approved and introduced into the vibrant U.S. biologics market, payment reforms to encourage their utilization will be increasingly important for Medicare to achieve both financial sustainability and continued robust innovation for new biologics. Current Medicare policies do not do much to engage providers in adopting and utilizing less costly biosimilar alternatives over their more expensive originator biologics despite strong evidence of the equivalence of clinical outcomes. As a result, price competition is less intense in these markets, and biosimilar markets are less robust than they could be.

The payment reforms we have described here have the potential to decrease Part B drug spending by increasing the effectiveness of head-to-head price competition between originator biologics and their biosimilars. Moreover, payment policy shifts for biosimilar reimbursement under Medicare Part B could have implications for the greater payer market as many commercial insurers follow Medicare reimbursement regulations for physician-administered drugs.⁴⁴ Finally, there are options for more significant reforms to the way Medicare pays for drugs covered under Part B, including shifting to an approach with greater use of tools that enable effective price negotiations and engaging biologic and biosimilar manufacturers in the patient-centered, value-based payment reforms that are a high priority for CMS. All of these steps could help CMS address the rapidly increasing spending on physician-administered drugs while continuing to provide strong support for new innovative products for Medicare beneficiaries.

Disclosures

Mark B. McClellan, MD, PhD, is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and receives fees for serving as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.

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