IQVIA INSTITUTE FOR HUMAN DATA SCIENCE

Policy Proposals to Achieve Long-term Sustainability of Infused Biosimilars in the U.S.

Summary Highlights from a Multi-Stakeholder Virtual Roundtable Held on May 6, 2024

OCTOBER
2024

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REFERENCING THIS REPORT

Please use this format when referencing content from this report:

Source: IQVIA Institute for Human Data Science. Policy Proposals to Achieve Long-term Sustainability of Infused Biosimilars in the U.S., October 2024. Available from www.iqviainstitute.org

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The panel discussion included one additional participant from a payer perspective who provided input during the roundtable. While their input has been reflected in this document, they wish to remain anonymous.

The views of speakers do not necessarily represent those of their organizations.

Introduction

While biosimilars in the U.S. have brought savings for the healthcare system by reducing the cost of biologics, a recent IQVIA Institute report titled *Long-term Market Sustainability for Infused Biosimilars in the U.S.* highlighted issues within the current system that can lead to sub-optimal uptake of infused biosimilars and put their long-term sustainability at risk. Building on this report, a closed-door expert roundtable was organized by the IQVIA Institute on May 6, 2024, to review and discuss potential policy proposals for overcoming the challenges to the long-term sustainability of infused biosimilars. This discussion took place with a multi-stakeholder panel representing key interest groups. This proceedings document provides a brief background of the issues facing infused biosimilars along with a review of the policy proposals discussed. Pfizer provided funding for this roundtable and a Pfizer representative participated in the roundtable.

"As ASPs decline, reimbursements decline as well, so [providers] struggle to recover costs in these markets."

Jeff Patton, One Oncology

Long-term sustainability challenges

The long-term sustainability of infused biosimilars faces several challenges which need to be understood and addressed to ensure gains from these biosimilars are not lost in the future.

Biosimilars of infused biologics have played a crucial role in ensuring the financial sustainability of the healthcare system by stimulating competition within an established therapy area, which has had the impact of reducing prices, generating savings for additional services, and reinvestment in future innovative medicines. In January 2024, The IQVIA Institute published a report on the current state of infused biosimilar sustainability in the U.S . that highlighted current dynamics and challenges that exist within this space. This report highlighted issues that limit the optimal use of infused biosimilars and threaten the long-term sustainability of the overall system. Biosimilars are expensive to develop, with costs estimated to be between $100 million and $300 million, and if biosimilars leave the market, originators can return to a monopoly-like situation where there are regular price increases thereby reversing the savings biosimilars have created. Issues that threaten the long-term sustainability of the system need to be understood and addressed.[1]

Challenges to infused biosimilar sustainability identified in the research include rebating and access, net cost recovery dynamics for providers, average sales price (ASP) dynamics and impact on manufacturer economic viability, and lack of benefit for patient out-of-pocket costs. A summary of these dynamics and the stakeholders impacted are given in Table 1.

"Patients are the ones that benefit the least from biosimilars, and we should try to come up with a solution that weaves in financial benefit to patients as well, not just the healthcare system."

Ken Komorny, Moffitt Cancer Center

Given the challenges to the long-term sustainability in the current infused biosimilar system, all participants agreed that there is a pressing need to consider policy solutions which can overcome these issues and create incentives for all stakeholders to continue to participate in this system.

Table 1: Summary of key challenges to long-term sustainability of infused biosimilars

ISSUE AREA	CHALLENGES	IMPACT
REBATING AND ACCESS	**Summary:** • Rebate walls and expected concessions can limit the uptake of biosimilars as they act as entry barriers and limit future competition. • In the infliximab market, for example, this dynamic was apparent as the originator Remicade held higher preferred formulary status, and consequently market share, compared to biosimilars for up to 5 years after biosimilars entered the market. • Rebate and discount expectations contribute to the acceleration of ASP declines as these concessions are included in quarterly ASP calculations.	• **Primary Impact:** Biosimilar manufacturers, as biosimilar uptake is limited until access improves and rebates add to ASP declines (See Issue Area on ASP dynamics) • **Secondary Impact:** Providers, healthcare systems, due to limited choice, and a portion of the savings that biosimilars may create for overall healthcare spend may not be realized
NET COST RECOVERY DYNAMICS FOR PROVIDERS	**Summary:** • Provider net cost recovery is the difference between the amount reimbursed to a provider and the amount paid by them to purchase a treatment for administration for administration to patients • The amount reimbursed in Medicare Part B is based on the ASP, which CMS publishes quarterly after assessing net costs (sans discounts to payers, providers, and other stakeholders) for a given product from two quarters prior. • In reality, provider net cost recovery can vary, and reimbursements are generally more robust in the commercial channel; however, using ASP-based reimbursements and net cost recovery estimates provide a simplified view of system-wide dynamics and are helpful to identify challenges and solutions to ensure appropriate reimbursement levels for providers. • As ASP declines for both biosimilars and the originator, the current system can result in higher net cost recoveries for the more expensive product. This dynamic is driven by the high initial ASP of the originator and the two-quarter lag in updating the ASP. As the initial high ASP of the originator falls in parallel to the biosimilar ASP, the reimbursement payment allowance is still based on values from two quarters ago while the actual purchasing cost for providers has gone down. • Additionally, the inclusion of rebates to different stakeholders as part of the ASP calculation can lead to situations where provider reimbursement is lower than acquisition cost, leaving providers incurring a loss when administering a treatment.	• **Primary Impact:** Providers, as their net cost recovery for infused treatments may not be favorable for cost recovery associated with biosimilars • **Secondary Impact:** Biosimilar manufacturers, as their biosimilar uptake may be limited if providers are not reimbursed well enough for their product

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Table 1: Summary of key challenges to long-term sustainability of infused biosimilars *continued*

ASP DYNAMICS AND IMPACT ON MANUFACTURER FINANCIAL VIABILITY	**Summary:** • As infused biosimilars begin to enter a given market, their manufacturers begin to compete on discounts and rebates given to various stakeholders to vie for uptake and share, which continuously causes their ASPs to decline. • Payer rebates are included in the ASP computation, which is subsequently used for calculating provider reimbursement, but these do not flow down to the provider. Thus, further discounts on the acquisition costs are needed to ensure providers have a meaningful net cost recovery. • As ASP continue to decline, they may eventually decrease below the point where revenue and profitability are possible for the manufacturer. • In this situation, products may be withdrawn from the market and discontinued. • If biosimilars withdraw from the market or do not enter markets altogether, this would reduce competition and potentially reverse the healthcare savings gains made from the biosimilars up until now and threaten future advances as it can lead to withdrawal of biosimilars and subsequent increases in prices and/or lower investment in biosimilars. • Furthermore, in the long run biosimilar manufacturers may not find it financially viable to invest in developing biosimilars for biologics that will go off patent soon.	• **Primary Impact:** Biosimilar manufacturers, as discounts given out to remain competitive continue rising due the dynamics of ASP calculation, this puts financial viability at risk. • **Secondary Impact:** Healthcare system, as biosimilar savings will decline if manufacturers discontinue and leave their markets. In the long run, this can pose risks of shortages as has been seen in the generic market.
PATIENT OUT-OF-POCKET COSTS	• For most patients, out-of-pocket costs are not substantially different between infused originators and biosimilars, leading to a lack of incentives for patients to switch to the more cost-effective products. • This may be related to patient assistance programs in the commercial channel, as well as supplemental insurance (Medigap) in Medicare, buying most patients down to $0-$10 for originators and biosimilars. • Some patients without assistance or supplemental insurance do face higher costs for the use of an originator, but across the markets studied, an equivalent or similar proportion of patients faced $0-$10 for both originators and biosimilars across payer channels.	• **Primary Impact:** Patients, as the potential savings of using the more cost-effective biosimilars are not being translated to their lower out-of-pocket costs. • **Secondary Impact:** Healthcare system, as the recipients of treatment have no incentives to switch to the lower-cost alternatives entering the market in order to generate more healthcare system savings.

"The current state of biosimilars is near catastrophic… We need a radical approach to address this issue at this point."

Ken Komorny, Moffitt Cancer Center

Policy approaches for long-term sustainability of infused biosimilars

Any policy reform to improve the long-term sustainability of infused biosimilars needs to consider the needs of all stakeholders.

The long-term sustainability of infused biosimilars, particularly their financial sustainability, is at risk. Roundtable participants agreed that a new set of policy levers needs to be developed that consider the needs of all stakeholders while ensuring the biosimilar markets are sustainable in the short and long run. Some key principles that can be used to drive these policy levers are –

Healthcare system and payers:

- Optimize savings over the long run and ensure incentives exist for all stakeholders to participate and all stakeholder's finances are considered.

CMS:

- Be logistically executable by CMS.
- Be transparent and easy to understand by all stakeholders.

Providers:

- Provide appropriate reimbursement for biosimilars such that the net cost recovery can cover the practice costs and ensures uptake and continued use of biosimilars.
- Ensure sufficient supply of biologics and a mix of options through coverage of multiple biosimilars.

Biosimilar Manufacturers:

- Ensure that incentives exist for stakeholders (providers and patients) to switch to a lower cost infused biosimilar over a higher cost originator in a timely manner.
- Ensure that the system does not lead to negative economic consequences, and sufficient economic incentives exist for continued participation, especially given the high cost of developing biosimilars.

Patients:

- Ensure the lowest possible out-of-pocket costs.

These principles would apply to only markets where a biosimilar is available (i.e., the biosimilars and associated originator biologics) and policy recommendations that follow are not intended to be for buy-and-bill products without biosimilar entrants.

The current ASP based reimbursement system is seen as the main driver of the challenges for infused biosimilars and there is a need to evolve this system to overcome the challenges

The roundtable participants noted that the key challenges to the long-term sustainability of infused biosimilars stem from the ASP based reimbursement system. Provider reimbursement amounts are based on ASPs in Medicare (generally, ASP+6% or 8%). As ASP calculations consider both discounts on acquisition costs to providers and rebates to payers, the reimbursement amount may not be adequate for providers to use biosimilars. This can lead to pressure on biosimilar manufacturers to continuously lower their acquisition price for providers. All stakeholders at the discussion agreed that while this ASP model may be suitable for innovative drugs, it does not work for biosimilars in competitive markets. This ASP model for biosimilars violates several principles noted above and needs to evolve to ensure the long-term sustainability of infused biosimilars.

"The ASP erosion for infused biosimilars is the most concerning thing in the long run. The ASP system was not designed for biosimilars/ generics, and ASP erosion also actually contributes to drug shortages."

Juliana Reed, Biosimilar Forum

Exhibit 1: Policy proposals discussed at multi-stakeholder roundtable discussion

POLICY PROPOSAL 1	POLICY PROPOSAL 2	POLICY PROPOSAL 3	POLICY PROPOSAL 4	POLICY PROPOSAL 5
Enhance reimbursement percentage	Utilization-based enhancement	Shared savings model	Implement a Provider Reimbursement Floor for Biosimilars	Adjust incorporation of rebates in ASP calculation
Evolve the ASP-based reimbursement beyond +8%	Incorporate utilization metrics that measure the use of infused biosimilars (in cases where infused biosimilar ASP is lower than originator ASP) and provide financial incentives for high performance on these metrics for providers	By using infused biosimilars, providers would receive a portion of the savings realized to Medicare. Specifically, providers that administer infused biosimilars would share in a portion of the difference between the ASP of the infused biosimilar and that of its reference product in the form of an additional add-on payment	Set a minimum provider reimbursement for biosimilars to ensure providers' financial viability through stable reimbursement, and overcome the impact of competitive discounts resulting in unsustainable ASP trends and market exits	Limit or weight payer rebates when calculating ASPs for biosimilars. Given that incorporation of rebates into the ASP calculation, provider reimbursements can be lower than their acquisition costs. This would result in considering reimbursement based on average provider acquisition costs to ensure provider financial viability and the impact of rebates on ASP

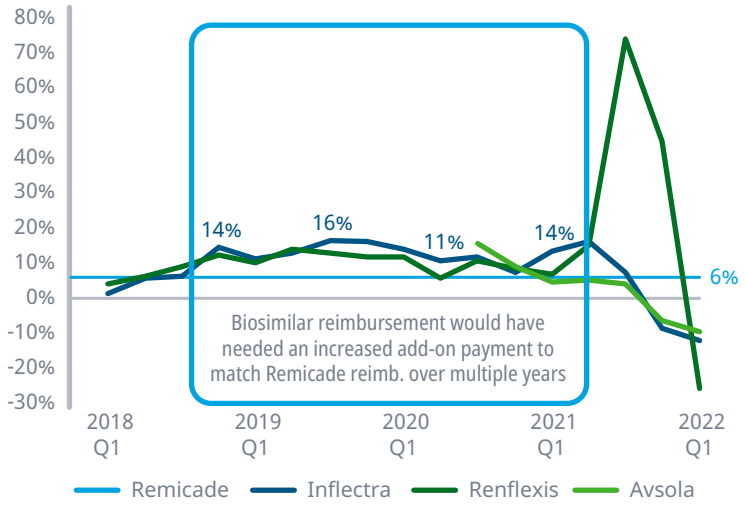
In the multi-stakeholder discussion, several potential policy proposals were considered and discussed to evolve the current ASP system (Exhibit 1). These included policies to increase the ASP-based reimbursement percentage beyond 8%, adding in utilization-based incentives, shared savings models, provider reimbursement floor and adjusting the incorporation of rebates in ASP calculation.

Out of the policy proposals discussed, implementing a provider reimbursement floor was viewed as the best approach to directly address current challenges with asp-based reimbursement

POLICY PROPOSAL 1: Increase ASP-based reimbursement percentage beyond 8%

The amount reimbursed, i.e., the payment allowance, to the provider in Medicare Part B is based on average sales price (ASP), either the biosimilar's ASP plus 6% of the reference biological's ASP, or the biosimilar's ASP plus 8% of the reference biological's ASP temporarily for certain biosimilars as described in section 1847A(b)(8) (B) of the Act.[2] The amount reimbursed for the originator is 106% of their ASP. The goal of this difference in calculation between originator and biosimilars is to incentivize biosimilar use by providers. Recently, recognizing the issue with the current ASP system of reimbursement which provides 106% of the ASP, CMS was granted new authority under section 11403 of the Inflation Reduction Act (IRA) to increase Medicare add on payment to providers for certain qualifying biosimilar products from 6% to 8% for a five-year period beginning on October 1st, 2022. However, this increase to 8% may not be sufficient for incentivizing biosimilar use. While biosimilars in the infliximab and pegfilgrastim markets launched well before late 2022 (when the ASP + 8% provision went into effect), using ASP-based net cost recovery shows that this add-on increase from +6% to +8% would not have been enough to fill the gap between biosimilar net cost recovery and originator net cost recovery for multiple years after biosimilar launches. In the example for infliximab, the average necessary reimbursement add-on from 2019 Q1 to 2021 Q1 for Inflectra and Renflexis to match Remicade's net cost recovery was 13% and 16%, respectively. This add-on payment amount can vary depending on the product and initial prices. Additionally, it does not address the fundamental issues in the ASP system that lead to a continuous cycle of declining ASPs (Exhibits 2 and 3).

Exhibit 2: Infliximab reimbursement add-on (ASP+X%) required to match originator over time by product (CMS data, 100mg, Q1 2016 – Q3 2023)



Product	Remicade	Inflectra	Renflexis	Avsola
2019 Q1	6%	14%	13%	-
Q2	6%	11%	10%	-
Q3	6%	13%	14%	-
Q4	6%	16%	13%	-
2020 Q1	6%	16%	12%	-
Q2	6%	14%	12%	-
Q3	6%	11%	6%	-
Q4	6%	12%	11%	16%
2021 Q1	6%	8%	9%	9%
Q2	6%	14%	7%	5%
Q3	6%	16%	15%	5%
Q4	6%	8%	74%	4%

"The +8% reimbursement for biosimilars is somewhat helpful, but not really sustainable in the long term." *Juliana Reed, Biosimilar Forum*

Exhibit 3: Assessment of ASP-based reimbursement percentage increase based on key policy principles

POLICY PROPOSAL 1		HEALTHCARE SYSTEM
Enhance Reimbursement Percentage	✖	Ensure that incentives exist for all stakeholders to participate, and all stakeholder's finances are considered to optimize savings and support a competitive market
Evolve the ASP-based reimbursement beyond +8%		**CMS**
	✔	Be logistically executable by CMS.
	✔	Be transparent and easy to understand by all stakeholders.
		PAYERS
	✖	Optimize savings over the long term
	✖	Provide access and choice without burdensome administrative processes
		PROVIDERS
	✔	Provide appropriate reimbursement for biosimilars such that the net cost recovery can cover the practice costs and ensures uptake and continued use of biosimilars.
	✔	Ensure sufficient supply of biologics and a mix of options through coverage of multiple biosimilars.
		MANUFACTURERS
	✔	Ensure that incentives exist for stakeholders (providers and patients) to switch to a lower cost infused biosimilar over a higher cost originator in a timely manner.
	✖	Ensure that the system does not lead to negative economic consequences, and sufficient economic incentives exist for continued participation, especially given the high cost of developing biosimilars.
		PATIENTS
	✖	It should ensure the lowest possible out-of-pocket costs.

POLICY PROPOSAL 2 AND 3: Utilization-based enhancement and shared savings model

Both policies were viewed as important to incentivizing the use of lower cost biosimilars. However, like the earlier policy discussed, these ones do not address the main ASP issue. Thus, even though they would increase the cost recovery for providers in the short run, the declining ASPs would still lead to challenges to economic viability (Exhibit 4).

Exhibit 4: Assessment of Utilization-based enhancement and Shared Savings Model based on key policy principles

POLICY PROPOSAL 2	POLICY PROPOSAL 3		
Utilization-Based Enhancement	Shared Savings Model		
Incorporate utilization metrics that measure the use of infused biosimilars (in cases where infused biosimilar ASP is lower than originator ASP) and provide financial incentives for high performance on these metrics	By using infused biosimilars, providers would **receive a portion of the savings** realized to Medicare. Specifically, providers that administer infused biosimilars would share in a portion of the difference between the ASP of the infused biosimilar and that of its reference product in the form of an additional add-on payment	**HEALTHCARE SYSTEM**	
		✖	Ensure that incentives exist for all stakeholders to participate, and all stakeholder's finances are considered to optimize savings and support a competitive market
		CMS	
		✔	Be logistically executable by CMS.
		✔	Be transparent and easy to understand by all stakeholders.
		PAYERS	
		✖	Optimize savings over the long term
		✔	Provide access and choice without burdensome administrative processes
		PROVIDERS	
		✔	Provide appropriate reimbursement for biosimilars such that the net cost recovery can cover the practice costs and ensures uptake and continued use of biosimilars.
		✔	Ensure sufficient supply of biologics and a mix of options through coverage of multiple biosimilars.
		MANUFACTURERS	
		✔	Ensure that incentives exist for stakeholders (providers and patients) to switch to a lower cost infused biosimilar over a higher cost originator in a timely manner.
		✖	Ensure that the system does not lead to negative economic consequences, and sufficient economic incentives exist for continued participation, especially given the high cost of developing biosimilars.
		PATIENTS	
		✖	Ensure the lowest possible out-of-pocket costs.

RECOMMENDED POLICY PROPOSAL 4: Implementing a provider reimbursement floor

In the current "Buy and Bill" system, providers acquire biosimilars at their cost and are then reimbursed for treating Medicare beneficiaries based on a Medicare part B Allowable for each specific biosimilar. The biosimilar product part B allowable is calculated using a combination of the Biosimilar manufacturer reported quarterly ASP and 6% (or, for eligible biosimilars, 8%) of innovator ASP. As the Biosimilar ASP calculation includes discounts to providers, payers and distributors, and as biosimilars pay rebates and lower cost to compete for uptake, the combination of all these discounts can result in Medicare reimbursement to fall below the provider's acquisition price for the product. This can lead to an untenable situation in which physicians are forced to take a loss if they use a biosimilar to provide care for their patients.

One proposed approach to this issue is to create a floor on the Part B allowable calculation as a certain percentage below the innovator allowable at a selected time point. This could be achieved by either creating a lower limit for the part B allowable, i.e., the provider reimbursement, for each biosimilar (and associated originator). The floor would only apply to the provider reimbursement, while manufacturers can continue to react to competitive pressures in a biosimilar market.

"It's time to think about a floor for reimbursement for biosimilars and generics. We've demonstrated that there is a competitive market driving prices down, but if we don't do something with regards to a floor for reimbursement, then we will continue to see products drop off the market and crash."

Robert Popovian, Conquest Advisors and Global Healthy Living Foundation

Key considerations for implementation

However, there are multiple considerations that must be considered to successfully implement a floor for the Part B allowable for biosimilars. First, there is a need to establish: how the floor would be set, when would it be set, at what level would it be set, would it need to change over time with inflation, etc. For example, would the originator's ASP before biosimilar entry be used as a baseline upon which the floor would be estimated (e.g., 60% of the baseline)? Would the floor come into effect once the biosimilar or originator reaches the set limit?

There would also be a need to ensure that the baseline cannot be "gamed" by increasing prices prior to the floor being set. Finally, there may still be the need to incentivize the use of lower cost biosimilars in the short run while the floor has not been reached and the originator has a higher ASP. Additional policy considerations, such as shared savings models or incentive metrics, may be needed to ensure healthcare system savings and sustainability for biosimilars in addition to a provider reimbursement floor.

The reimbursement floor would be based on originator's cost to CMS and could no longer be linked to each biosimilar's reported ASP. This would give providers predictability on reimbursement, would lock in savings for CMS, and allow manufacturers to compete without prices going below cost to supply biosimilars to the market. Manufacturers can provide further discounts to providers and/or rebates to payers once the floor has been reached. This would also allow for competition amongst different manufacturers while providing predictability for providers specifically on the reimbursement side.

Impact

A floor limits the downward spiral of the ASP and can help ensure that there are economic incentives for all stakeholders to continue participating in this system (Exhibit 5). From CMS's perspective, this policy proposal will need logistical considerations as discussed above but would be executable and transparent for all stakeholders. For payers, there are likely to be some reduction in savings in the short run as ASPs may not fall at the current rate. However, in the current system, there are risks of biosimilars dropping out of existing markets and manufacturers reducing investments in future biosimilars. Some of these dynamics are already visible with many classes of biologics at risk of failing to attract biosimilar competition due to lack of investment in research and development. A recent IQVIA Institute report found that of the 26 high-sales products exposed to loss of exclusivity events in Europe in the next 10 years (by end of 2032), almost one in three (27%) does not yet have a biosimilar candidate in the pipeline. In the long-term (2027 and beyond), the average number of biosimilars in development is expected to decrease from 2.19 per molecule to 0.44.[3] This can lead to a reversal of savings in existing markets and limited savings in future biosimilar markets. If a provider reimbursement floor is implemented, it will help
ensure that savings continue in a predictable and consistent manner over the long run. Exhibit 6 shows illustrative dynamics for savings over the long run in the two scenarios.

Exhibit 5: Assessment of Provider reimbursement floor based on key policy principles

POLICY PROPOSAL 4		HEALTHCARE SYSTEM
Implement a Provider Reimbursement Floor for Biosimilars	✔	Ensure that incentives exist for all stakeholders to participate, and all stakeholder's finances are considered to optimize savings and support a competitive market
		CMS
Set a minimum provider reimbursement for biosimilars to ensure providers' financial viability through stable reimbursement, and overcome the impact of competitive discounts resulting in unsustainable ASP trends and market exits	✔	Be logistically executable by CMS.
	✔	Be transparent and easy to understand by all stakeholders.
		PAYERS
	✔	Optimize savings over the long term
	✔	Provide access and choice without burdensome administrative processes
		PROVIDERS
	✔	Provide appropriate reimbursement for biosimilars such that the net cost recovery can cover the practice costs and ensures uptake and continued use of biosimilars.
	✔	Ensure sufficient supply of biologics and a mix of options through coverage of multiple biosimilars.
		MANUFACTURERS
	✖	Ensure that incentives exist for stakeholders (providers and patients) to switch to a lower cost infused biosimilar over a higher cost originator in a timely manner.
	✔	Ensure that the system does not lead to negative economic consequences, and sufficient economic incentives exist for continued participation, especially given the high cost of developing biosimilars.
		PATIENTS
	✖	Ensure the lowest possible out-of-pocket costs.

A provider reimbursement floor policy may not solve for all potential issues (e.g., short-term incentives to use the higher cost originator due to the two-quarter lag in ASP based reimbursement before reaching the floor), but it would solve the two main issues of the current system: physician reimbursement for biosimilars and biosimilar market exits.

Even in a world with provider reimbursement floors for biosimilars implemented, there may be certain cases where providers might still be incentivized to use the higher price originator as reimbursement may still be more favorable. Additionally, patients still would not have an incentive to switch to lower cost biosimilars due to out-of-pocket cost dynamics with a provider reimbursement floor implemented. Added policy considerations mentioned below may be needed to ensure healthcare system savings and sustainability for biosimilars in addition to a provider reimbursement floor:

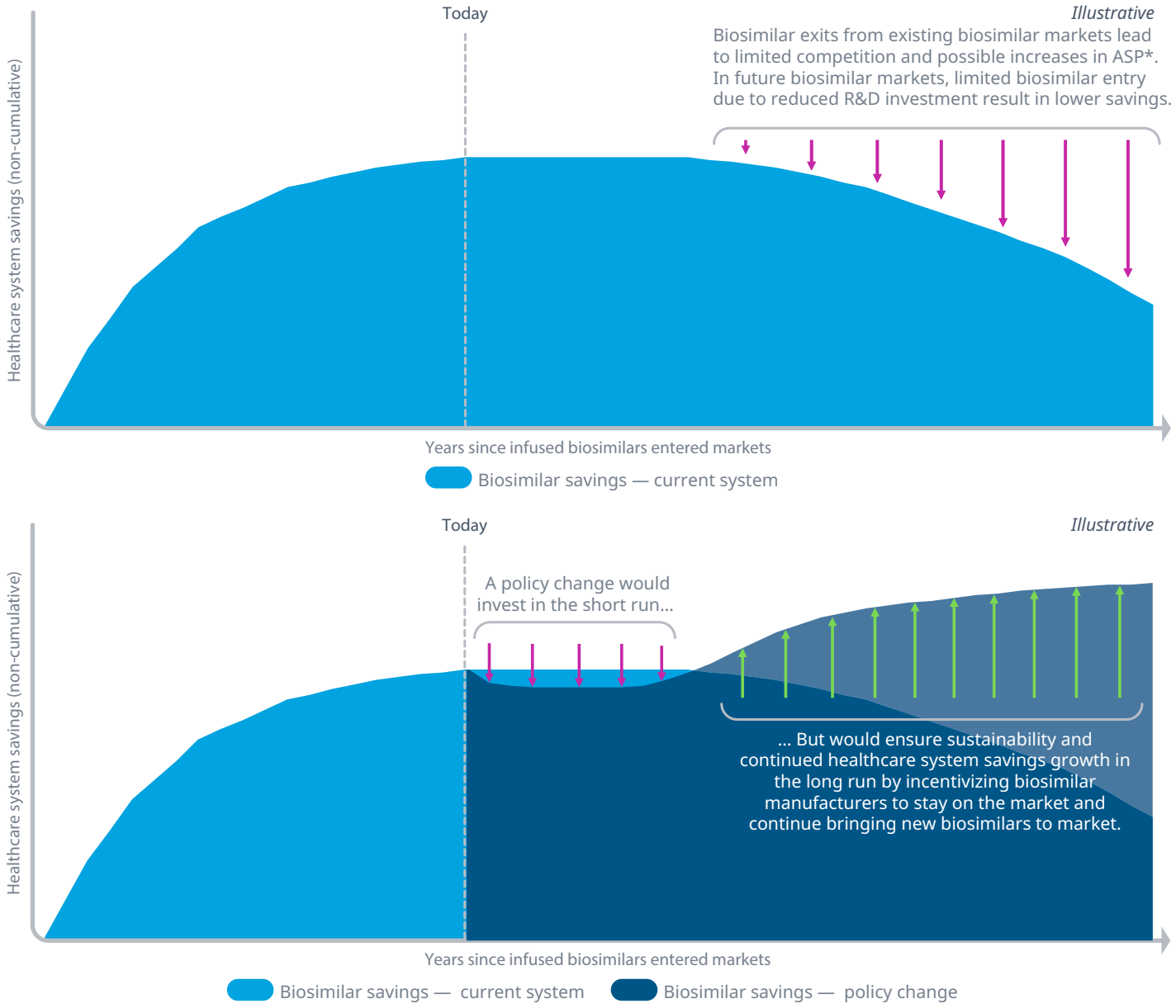
Utilization-based enhancements

- Incorporate utilization metrics that measure the use of infused biosimilars (in cases where infused biosimilar ASP is lower than originator ASP) and provide sufficient economic incentives to providers for high performance on these metrics.

Shared savings model

- By using infused biosimilars, providers would receive a portion of the savings realized to Medicare. Specifically, providers that administer infused biosimilars would share in a portion of the difference between the ASP of the infused biosimilar and that of its reference product in the form of an additional add-on payment.

Exhibit 6: Illustrative example of future savings in the current system and in a system with policy change



*As competition within a market is reduced due to biosimilar(s) exits, the remaining product(s) could increase prices despite inflation penalties.

POLICY PROPOSAL 5:
Adjust incorporation of rebates in ASP calculation

Given that the incorporation of rebates into the ASP calculation leads to challenges for providers in terms of net cost recovery, adjusting the weight given to rebates in the calculation of ASP or removal of rebates from the ASP calculation for biosimilars only may be an alternate policy to consider. This would result in considering reimbursement based on average provider acquisition costs which can help address provider cost recovery and economic viability concerns and reduce pressure on manufacturers to continuously provide increasing ASP discounts to address provider net cost recovery concerns (Exhibit 7). However, this policy may still face issues of a lack of predictability of reimbursement for providers as the acquisition costs vary across providers (Exhibit 8). While this policy was viewed favorably, it requires further discussion and consideration to ensure the key principles for a biosimilar market are being met.

Exhibit 7: Illustrative description of impact of removal of payer rebates into ASP calculation on provider net cost recovery

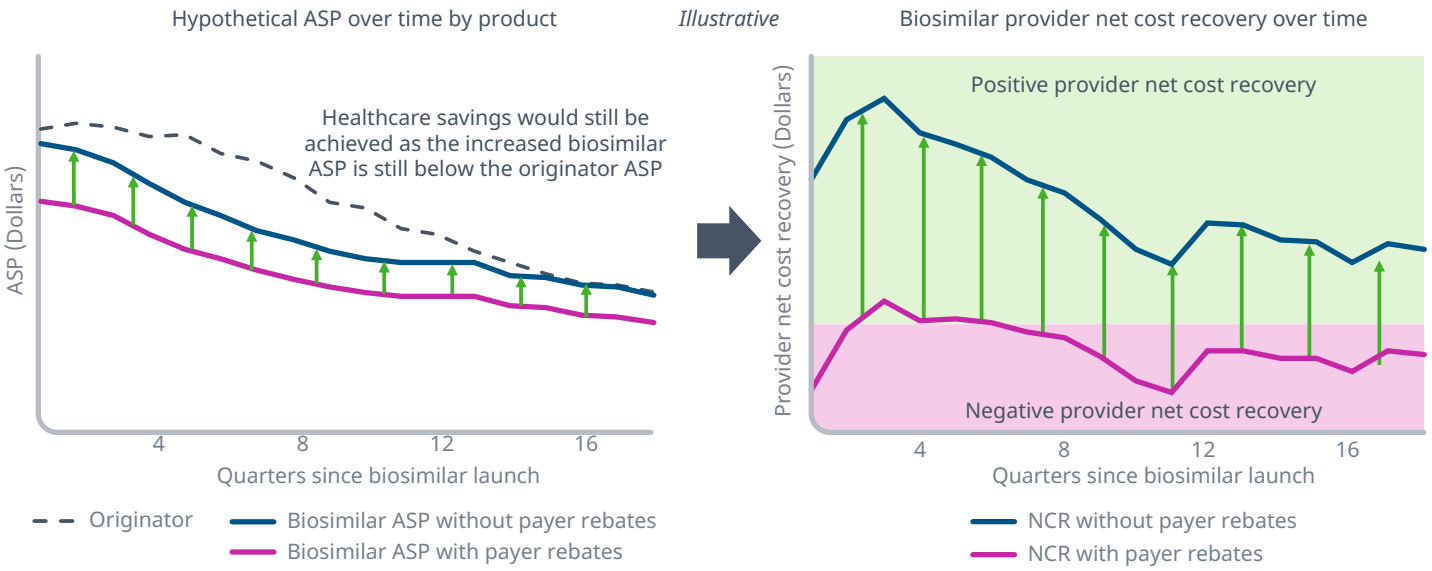


Exhibit 8:Assessment of adjusted incorporation of rebates in ASP calculation based on key policy principles

POLICY PROPOSAL 5		HEALTHCARE SYSTEM
Adjust incorporation of rebates in ASP calculation	✖	Ensure that incentives exist for all stakeholders to participate, and all stakeholder's finances are considered to optimize savings and support a competitive market
		CMS
Limit or weight payer rebates when calculating ASPs for biosimilars. Given that the incorporation of rebates into the ASP calculation, provider reimbursements can be lower than their acquisition costs. This would result in **considering reimbursement based on average provider acquisition costs** to ensure provider financial viability and the impact of rebates on ASP	✔	Be logistically executable by CMS.
	✔	Be transparent and easy to understand by all stakeholders.
		PAYERS
	✔	Optimize savings over the long term
	✔	Provide access and choice without burdensome administrative processes
		PROVIDERS
	✔	Provide appropriate reimbursement for biosimilars such that the net cost recovery can cover the practice costs and ensures uptake and continued use of biosimilars.
	✔	Ensure sufficient supply of biologics and a mix of options through coverage of multiple biosimilars.
		MANUFACTURERS
	✖	Ensure that incentives exist for stakeholders (providers and patients) to switch to a lower cost infused biosimilar over a higher cost originator in a timely manner.
	✖	Ensure that the system does not lead to negative economic consequences, and sufficient economic incentives exist for continued participation, especially given the high cost of developing biosimilars.
		PATIENTS
	✖	Ensure the lowest possible out-of-pocket costs.

Conclusion

Given the research and outcomes from the roundtable, the panelists believed a policy change by CMS for the ASP system as it pertains specifically to infused biosimilars is needed to ensure the long-term sustainability of the infused biosimilar ecosystem. An ASP floor emerged from the discussion as the best policy consideration to address the current challenges. Further research and evaluation are needed to understand the implementation of such a policy and potential benefits and system wide consequences. A key next step would be for policymakers to evaluate this potential policy in detail with the support of all involved stakeholders and assess how it could be implemented in a manner that allows for continuous assessment.

One of the considerations that was brought up in the multi-stakeholder discussion was on the lack of benefits for patients from the use of biosimilars. Currently, most patients do not directly benefit from savings through biosimilars. There is a need to evaluate how the benefits can be passed on to the patients. At this stage, policy considerations did not take this aspect into account; however, all stakeholders noted the importance of addressing this issue. Future policy discussions should carry this consideration forward and ensure that benefits for the patient are a part of policy discussions.

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2. Centres for Medicaid and Medicare Services (CMS). Part B Drug Payment Limits Overview. Available from https://www.cms.gov/files/document/part-b-drug-payment-limits-overview.pdf-0#:~:text=For%20biosimilars%2C%20the%20payment%20limit,(B)%20of%20the%20Act.

3. IQVIA Institute for Human Data Science. Assessing the Biosimilar Void. Achieving Sustainable Levels of Biosimilar Competition in Europe. October 2023. Available from www.iqviainstitute.org

About the Institute

The IQVIA Institute for Human Data Science contributes to the advancement of human health globally through timely research, insightful analysis and scientific expertise applied to granular non-identified patient-level data.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved human outcomes. With access to IQVIA's institutional knowledge, advanced analytics, technology and unparalleled data the Institute works in tandem with a broad set of healthcare stakeholders to drive a research agenda focused on Human Data Science including government agencies, academic institutions, the life sciences industry, and payers.

Research Agenda

The research agenda for the Institute centers on 5 areas considered vital to contributing to the advancement of human health globally:

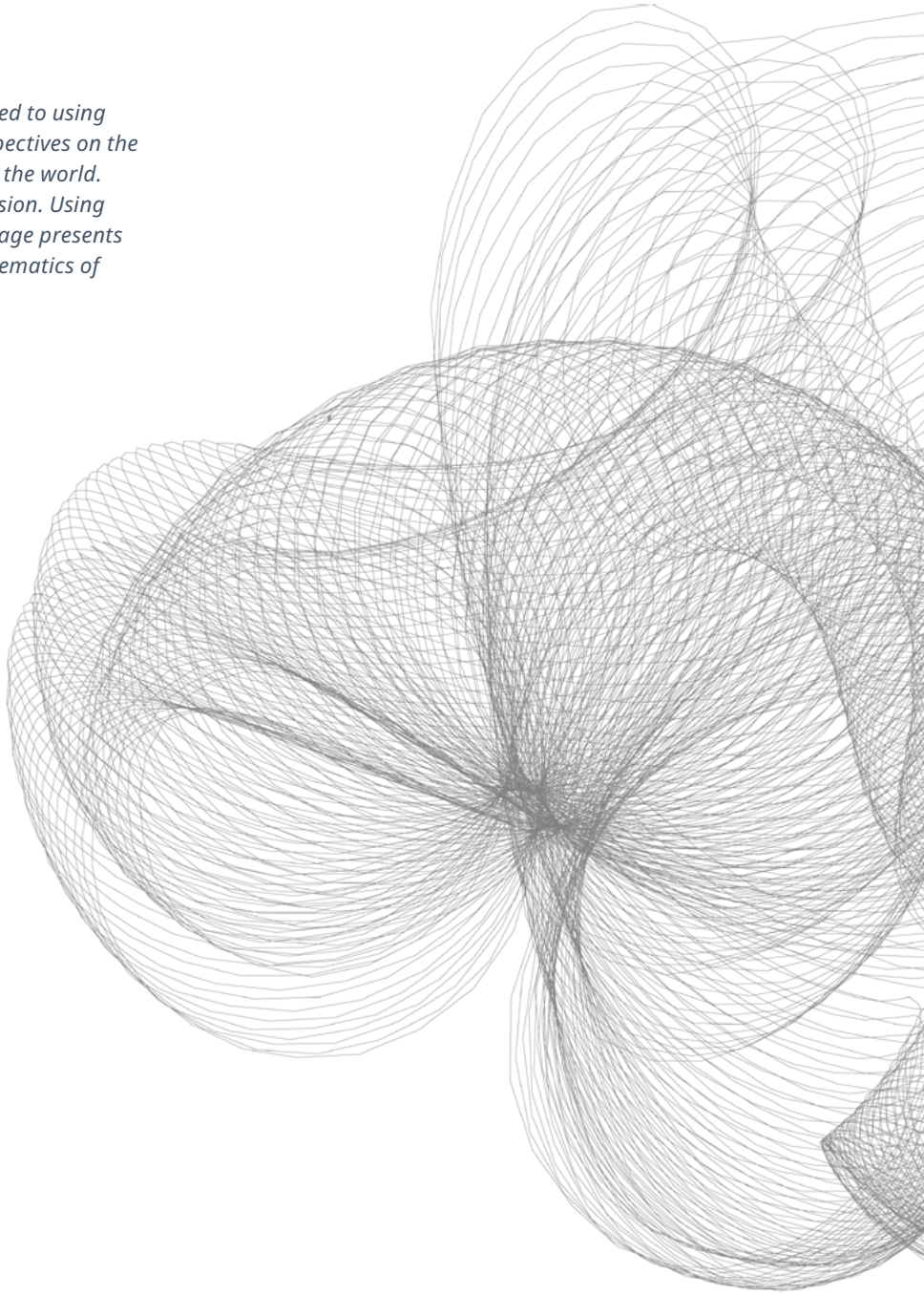
- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing the performance of health systems by focusing on patient centricity, precision medicine and better understanding disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.
- Understanding the future role for biopharmaceuticals in human health, market dynamics, and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.
- Researching the role of technology in health system products, processes and delivery systems and the business and policy systems that drive innovation.

Guiding Principles

The Institute operates from a set of guiding principles:

- Healthcare solutions of the future require fact based scientific evidence, expert analysis of information, technology, ingenuity and a focus on individuals.
- Rigorous analysis must be applied to vast amounts of timely, high quality and relevant data to provide value and move healthcare forward.
- Collaboration across all stakeholders in the public and private sectors is critical to advancing healthcare solutions.
- Insights gained from information and analysis should be made widely available to healthcare stakeholders.
- Protecting individual privacy is essential, so research will be based on the use of non-identified patient information and provider information will be aggregated.
- Information will be used responsibly to advance research, inform discourse, achieve better healthcare and improve the health of all people.

The IQVIA Institute for Human Data Science is committed to using human data science to provide timely, fact-based perspectives on the dynamics of health systems and human health around the world. The cover artwork is a visual representation of this mission. Using algorithms and data from the report itself, the final image presents a new perspective on the complexity, beauty and mathematics of human data science and the insights within the pages.



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