

A White Paper

Biosimilars: Who Saves?

How similar molecules may mean
similar cost-sharing for patients



Introduction

As the U.S. faces record high spending on healthcare, public attention has shifted to the cost of pharmaceuticals more than ever – especially biologics. In recent years, drug spending has transitioned from traditional, retail therapies to specialty drugs, which today account for 36% of drug spending. This compares to less than 24% in 2010¹.

As part of healthcare reform, the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) provides an abbreviated approval pathway for biologics that have proven to be highly similar to or interchangeable with an FDA-approved biologic. Due to the lower barriers of entry and increased competition fostered by the new legislation, the U.S. Congressional Budget Office expects biosimilar savings to reach a cumulative \$25 billion by 2018². Although saving is expected, it is difficult to quantify the total savings from biosimilars given the uncertainty surrounding regulatory guidance, exclusivity, access, and uptake among physicians and patients. This report does not seek to further estimate these savings. Rather, the purpose of the study is to investigate how potential savings will be distributed among stakeholders who share in the final cost of biologic therapy.

To our knowledge, this is the first study that seeks to determine how savings will be distributed to each stakeholder (e.g., patient, payer) in the U.S. and assesses the conditions under which the savings for each group change. Our expertise in managed markets and patient access lends a unique perspective on savings. It brings the relationships between patients, their insurers, and pharmacy benefit managers (PBMs) to the forefront of the biosimilar savings discussion in order to accurately represent the way savings will affect the industry and not simply how sizable the savings will be.

Understanding who will realize savings from biosimilars is a necessary piece of the public's understanding of the value these treatments provide. Treatment decisions will likely be influenced by each stakeholder's perception of these savings. Transparency of how much each party (e.g., employers, patients, federal government, etc.) will benefit from the expected lower cost of biosimilars is critical. This report seeks to simplify these dynamics and clearly represent the reality of biosimilar savings.

This study was produced independently by the Amundsen Consulting division of IMS Health as a public service. The contributions to this report of Kyle Crowell, Stephen Prager, and Marcella Vokey at IMS Health are gratefully acknowledged.

— **David MacDougall, Practice Lead, Amundsen Consulting, a division of IMS Health**

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Executive Summary

Biosimilars are expected to stimulate saving in U.S. healthcare market: Because of the lower barriers of entry and increased competition fostered by the new legislation, the U.S. Congressional Budget Office expects biosimilar savings to reach a cumulative \$25 billion by 2018.

Payers (insurance companies, employers, federal government, etc.) will realize the vast majority of savings from biosimilars; patients will realize only a very small proportion of these savings at the point of sale (<5%): Many patients have low cost-sharing requirements for biologics due to generous and oftentimes widespread patient assistance programs, supplemental drug coverage provided by private plans or employers for Medicare patients, and government programs such as Medicaid, Medicare Savings Programs, and the Low Income Subsidy (LIS). Furthermore, most patients' out-of-pocket costs are not dependent on the list price of the product and thus will not change if prices decline.

Patients will realize a smaller proportion of direct savings when it manifests through non-list price discounts: There is a group of patients that pay a percentage of drug costs and actually benefit from list price decline. However, most of these patients will not benefit from non-list price discounts such as rebates.

The biosimilar mode of administration and its interchangeability status with the reference product will impact the savings beneficiaries: Different stakeholders are responsible for the payment of biologics when they are administered by patients (e.g., subcutaneously) versus administered by physicians (e.g., intravenously). Thus, savings from reduced net prices will impact different parties depending on the products' mode of administration. Moreover, patients will realize more saving from interchangeable biosimilars, as these products have a greater chance of moving to generic (or generic-like) formulary tiers.

It will be the responsibility of payers to deliver tangible benefits to patients: Payers may deliver savings from biosimilars to patients through reductions in insurance premiums or other mechanisms of improved access. However, the lack of net price transparency in the U.S. market will likely impede efficient redistribution of savings from one stakeholder to another, leading to a suboptimal outcome. Even an efficient reallocation of savings may not be noticed by patients. Reductions in insurance premiums are distributed across all enrollees (not just those treated with biologics), and for many patients the government or employers are picking up most of their costs.

It may be difficult for patients, physicians, and advocates to understand the value of biosimilar therapies: Because patient costs are not likely to decline, use of biosimilars may be especially difficult to rationalize for those patients who are already gaining clinical benefits from innovator therapies. Without the realization and effective communication of how payers will use savings to support patient care or reduce cost, the value of biosimilars to the U.S. healthcare system will be limited.

Objectives, methods, results

Study Objective

As a result of increased competition and a potentially abbreviated pathway to approval, the healthcare industry expects lower net prices for biologic products upon biosimilar entry into the U.S. market. If net prices decline (or increase less) as expected, various stakeholders will benefit from the reduced costs of biologic pharmaceuticals. This study establishes which stakeholders will benefit and the proportion of savings that each will receive.

Methods

The report only considers potential savings for stakeholders reflected at the final point of sale. Savings to stakeholders at the final point of sale can manifest through lower list prices and/or deeper discounts (e.g., rebates) provided to the final payer(s). The authors acknowledge that savings before the final point of sale—within the supply chain or distribution channels—may translate to profits for various channel intermediaries (e.g., wholesalers, pharmacies, hospitals, etc.) and not into direct savings for the final payers. As such, potential profits for various channel intermediaries are not evaluated.

Several stakeholders share in the final payment responsibility for biologic products. These include: patients, PBMs, employers, insurers, and state and federal government organizations (e.g., Medicaid and Medicare). As it is traditionally structured in the U.S. healthcare system, more than one stakeholder may be responsible for the final payment of the biologic product (like other prescription pharmaceutical products) when it is dispensed for a patient (i.e., coordination of benefits). Thus, it is these stakeholders – parties who share in biologic costs at the final point of sale – that are considered when determining the allocation of savings from lower cost biosimilar treatments.

The proportion of the realized savings for each stakeholder will vary, and will be influenced by several factors investigated as part of the evaluation. These factors include but are not limited to:

- Method of discount (i.e., list price discount or discount through purchasing contracts such as rebates)
- Place of service or dispensing location of the product
- Interchangeability status of the molecule
- Provider of insurance coverage for the product
- Formulary design structure for the patient
- Presence of supplemental insurance coverage or a manufacturer coupon for the patient (which offsets patient final cost)

Because only one biosimilar has launched into the U.S. market at the time of this study (filgrastim- [Zarxio]), the allocation of cost savings are determined using analog biologic products. Analog products that capture different channel and payment dynamics are chosen (for more information on analog selection, see Appendix 1: Analog Selection). The impact of a net price reduction for each product is quantified by: identifying the parties responsible for payment today; determining how much of the payment each party is responsible for; and establishing how each party's payment responsibility changes as the products' net prices change (for more information on quantification of net price impact see Appendix 2: Net Price Impact).

Structure of Results

There are several factors, some of which are mentioned above, that will have an influence on the allocation of savings amongst stakeholders. However, for each potential biosimilar molecule, two key dynamics—product place of service and interchangeability status— will have a major impact on the potential savings beneficiaries. In consideration of these key influences, the study examines analog products that represent the following key dynamics.

Mode of administration – The report examines analog products primarily self-administered by patients and dispensed at retail or specialty pharmacies and compares them to products primarily administered by physicians in either private offices or the outpatient hospital setting. Patient-administered biologics are typically covered by a patient's pharmacy benefit while those administered by physicians are typically covered by a patient's medical benefit (the same benefit that covers other services and procedures). Cost-sharing structure, payment dynamics, and stakeholders are considerably different for drugs covered by the pharmacy and medical benefit.

Interchangeability status of the molecule – The report also examines the impact that a biosimilar's interchangeability status will have on the distribution of savings. Biosimilar products deemed "interchangeable" with the reference product may be substituted by the dispensing location in place of the reference product (final substitution laws for interchangeable products will vary by state). As a result, cost-sharing dynamics for interchangeable biosimilars are expected to more closely resemble dynamics of therapeutically equivalent (AB-rated) generics.

Furthermore, results are reported separately for savings that manifest through list price reductions or increased rebates to payers and other non-list price discounts. While these are not mutually exclusive scenarios, results are presented in this manner due to the complexity of pricing and rebating scenarios that may exist.

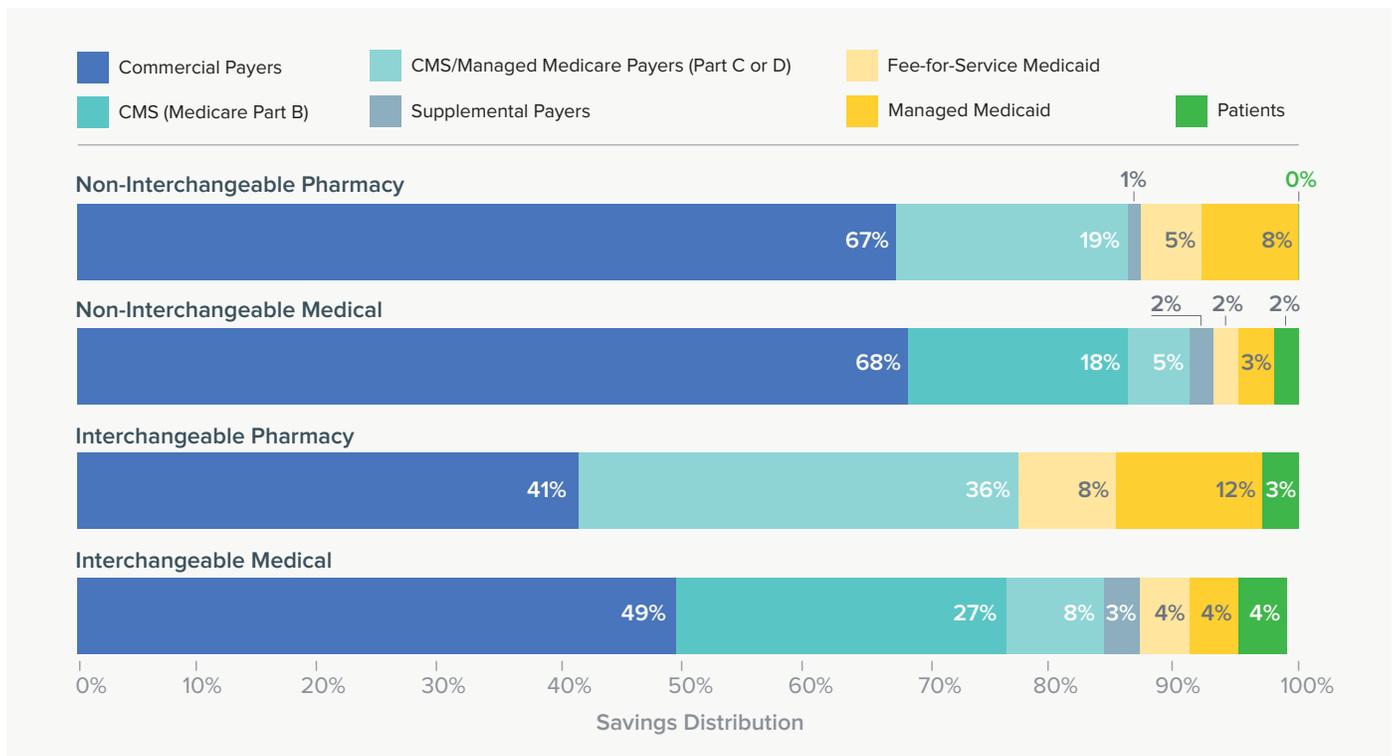
Results

If savings manifest through list price reductions, patients will share in less than 5% of every dollar saved in each of the four researched biosimilar scenarios—non-interchangeable pharmacy products, non-interchangeable medical products, interchangeable pharmacy products, and interchangeable medical products. Most of the patient savings can be attributed to patients who pay (non-capped) coinsurance, a fixed percentage of drug costs, for biologic products. When list prices change, these patients are directly

impacted if they are not using a manufacturer coupon or supplemental insurance to reduce their out-of-pocket spending (explained in more detail below [Patient Assistance Programs; Supplemental Drug Coverage]). Commercial payers (e.g., managed care plans, employers, and PBMs), CMS (Medicare), and Medicaid programs share in the remainder of the savings from list prices (>95% of savings).

Patients will inherit a greater proportion of potential list price savings in scenarios where the biosimilar product is interchangeable with the reference product – but only 1–2 percentage points more. Generic tier placement for interchangeable biosimilars is a reasonable expectation (thus greater savings for patients) due to similar substitution dynamics that exist for traditional generic molecules (explained in more detail below [Reduction in Preferred and Non-Preferred Co-Pays]).

Figure 1: Distribution of Direct Biosimilar Savings from List Price across Stakeholders



Source: IMS Health Longitudinal Access and Adjudication Data, Amundsen Consulting Analysis

Chart Notes: Commercial payers include private payers (such as Anthem, United, etc.), employers, and pharmacy benefit managers (PBMs) when they are at risk for drug costs.

Medicare Part B covers medical drugs and services for Medicare and is fully sponsored by CMS.

CMS/Managed Medicare Payers (Part C or D) includes the partnerships between the Centers for Medicare and Medicaid Services (CMS) and private payers that manage Medicare Part A, Part B, and typically Part D benefits.

Managed Medicaid is also a partnership between private payers/PBMs and the government – this time CMS and the state.

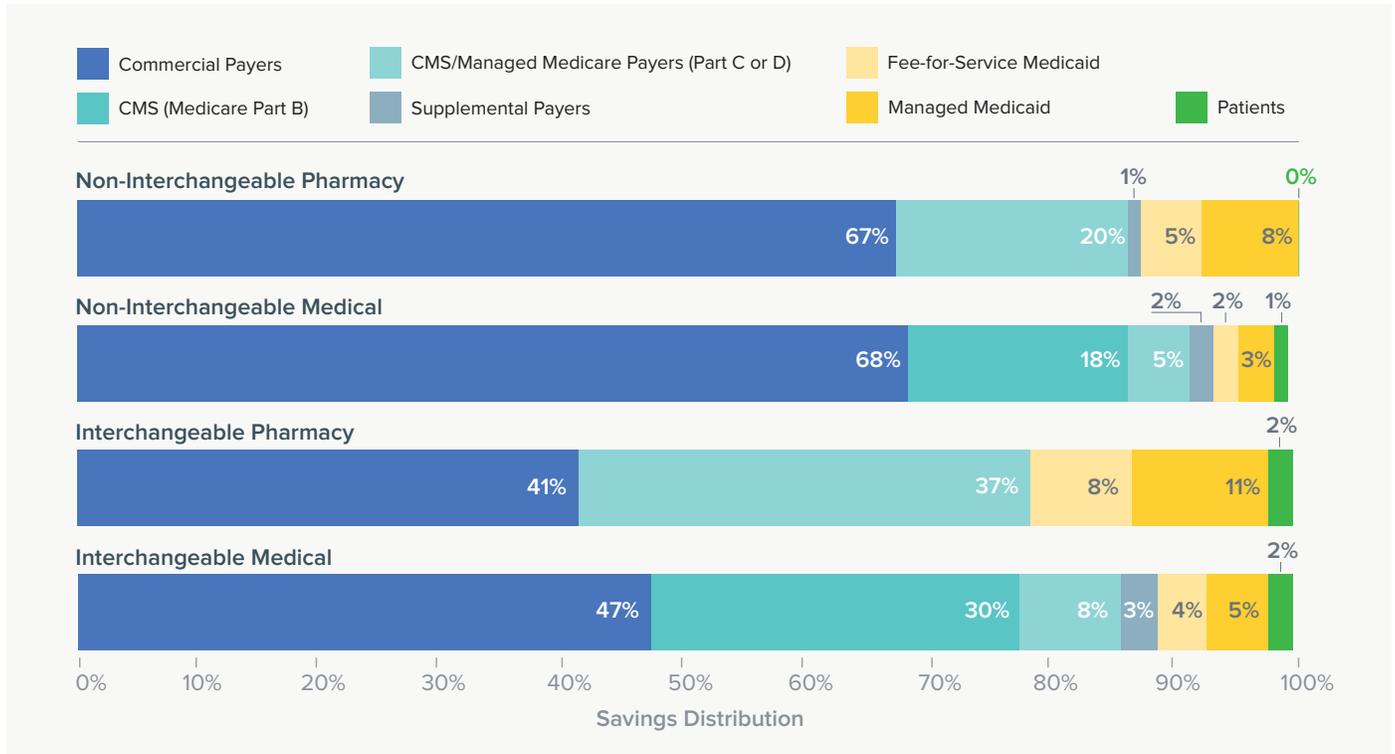
Fee-for-service Medicaid (FFS) is entirely government-funded (CMS and state governments).

Supplemental insurers provide coverage (in addition to a patient’s primary coverage) which offsets patients’ out-of-pocket costs.

Assuming that savings from biosimilars come in the form of rebates or non-list price discounts, a smaller proportion of the savings get passed through to patients (<2%). Patients benefit less from non-list price discounts because most coinsurance patients are not directly impacted. For pharmacy prod-

ucts, deeper discounts will benefit PBMs and other private payers who extract net price concessions from pharmaceutical manufacturers in exchange for formulary coverage. Similar to scenarios for list price discounts, patients benefit more from overall savings when biosimilars are interchangeable with their reference product.

Figure 2: Distribution of Direct Biosimilar Savings from Rebates across Stakeholders



Source: IMS Health Longitudinal Access and Adjudication Data, Amundsen Consulting Analysis

Chart Notes: Commercial payers include private payers (such as Anthem, United, etc.), employers, and pharmacy benefit managers (PBMs) when they are at risk for drug costs.

Medicare Part B covers medical drugs and services for Medicare and is fully sponsored by CMS.

CMS/Managed Medicare Payers (Part C or D) includes the partnerships between the Centers for Medicare and Medicaid Services (CMS) and private payers that manage Medicare Part A, Part B, and typically Part D benefits.

Managed Medicaid is also a partnership between private payers/PBMs and the government – this time CMS and the state.

Fee-for-service Medicaid (FFS) is entirely government-funded (CMS and state governments).

Supplemental insurers provide coverage (in addition to a patient’s primary coverage) which offsets patients’ out-of-pocket costs.

Understanding several market dynamics helps explain why patients stand to benefit far less than other payers from direct savings due to biosimilars. These include:

- Patients have low cost-sharing currently
 - Patients’ out-of-pocket costs are not necessarily dependent on the net price of the product
 - Patient assistance programs for current biologics offset patient costs (in commercially insured patients)

- Supplemental drug coverage provided by private plans or employers (e.g., Employer Group Waiver Plans [EGWP]) also offset patient costs for many Medicare patients
- Patients face minimal cost-sharing for biologics under traditional Medicaid and both dual eligible and LIS Medicare
- Manufacturer payment responsibility in the Part D coverage gap (50% of costs) will not be required for biosimilar agents
- For non-interchangeable biosimilars, a lack of incentive for formulary managers to reduce fixed co-pays for biosimilars

Each market dynamic is explained in more detail below.

Patient Cost-Sharing Structure

Most patients pay fixed co-pays for their medications. These patients' cost-sharing responsibilities are not impacted when a product's price changes unless the payer changes the plan's benefit design or moves the product to a lower tier. Conversely, patients paying non-capped coinsurance are affected by price changes since their cost is a proportion of the total drug cost (before rebates and discounts).

Furthermore, there may be little incentive for pharmacy benefit managers to treat non-interchangeable biosimilars like traditional generics on their formularies. In fact, CMS has already established that for Part D, biosimilars "do not meet the CMS definition of a generic drug" and will be treated like branded agents for which patients will be responsible for paying branded product cost-sharing requirements³. Biosimilar prices are not expected to reach the depths of traditional generic prices, and unlike traditional generics, non-interchangeable biosimilars, by definition, will not be eligible for automatic pharmacist substitution. Therefore, it is a more reasonable expectation that biosimilars will resemble branded products on commercial formularies and establish coverage on the same tiers used today for other biologic products.

Reductions in fixed co-pays are expected and taken into account for the interchangeable product scenarios. And while the upside observed for patients is limited (no more than 2 percentage points more savings), patients will benefit from a greater proportion of savings when fixed co-pays are reduced. As discussed below, the prevalence of patient assistance programs and supplemental drug coverage mitigate the opportunity for patient savings generated by a change in co-pay structure.

Patient Assistance Programs

Most patients without government-sponsored insurance (e.g., Medicare, Medicaid, etc.) are eligible to use manufacturer-sponsored assistance programs which help patients with their out-of-pocket costs. For many biologic products, these programs are generous and widespread. As a result, a substantial proportion of patients without government sponsored insurance already have low out-of-pocket cost burdens for biologic products. A number of biologic products treating multiple sclerosis, immunology, oncology, diabetes, etc. have patient assistance programs which help cover all but \$5-15 of a patient's out-of-pocket costs. Therefore, it would require highly generous out-of-pocket support from biosimilar

manufacturers to provide incremental out-of-pocket relief for patients with eligibility and access to current programs.

Supplemental Drug Coverage

Employer groups, government organizations, or private insurers may subsidize patient cost-sharing for pharmaceuticals under Medicare (as well as premiums and other services in some cases). Patients may have supplemental coverage for drugs covered by Medicare Part B and/or drugs covered by Medicare Part D plans. Medigap coverage is one such example of supplemental coverage that helps offset cost-sharing for Medicare Part B covered drugs and services. Approximately 76%⁴ of patients covered by Part B have Medigap or another form of supplemental coverage for their Part B benefit. As a result, these patients have low cost-sharing responsibility for their biologic medicines. For many of these patients, it's unlikely that their out-of-pocket costs will decrease as a result of lower priced biosimilars.

Medicaid, Dual Eligible, and LIS

Patients who are eligible and enrolled in Medicaid have low cost-sharing requirements for biologics covered by the medical and pharmacy benefit (typically < \$10). Similarly, patients covered by both Medicare and Medicaid (dual eligibles) are also eligible for extra help through the Low Income Subsidy (LIS), which pays for Part D covered drugs. These patients pay a range of co-pays less than \$10 for their biologic medicines. Medicare patients with limited incomes and resources who do not qualify for their state Medicaid programs but who qualify for Medicare Savings Programs (QMB, SLMB, QI, and QDWI) are also eligible for LIS. LIS patients represent approximately 30% of all Medicare Part D patients⁵, and for some biologic products, represent the vast majority of their Medicare patient population.

Part D Coverage Gap Requirements

The Medicare coverage gap for pharmacy-reimbursed drugs is a phase of coverage that requires higher cost-sharing by patients than other coverage phases (i.e., 45% in 2016). Many patients with Part D drug coverage face high costs upon reaching the coverage gap due to the high cost of some biologics. As a result of the Health Care and Education Reconciliation Act of 2010, patient cost-sharing requirements in the coverage gap are slated to decrease⁶. However, it will remain at 25% even after the reductions are completed in 2020. In 2016, brand drug manufacturers are required to pay 50% of brand drug costs in the coverage gap. Plan sponsors are required to contribute 5% of drug costs, a proportion that will increase steadily until it reaches 25% in 2020. CMS announced that biosimilars will be covered like brands in the coverage gap. However, unlike reference product manufacturers, biosimilar manufacturers will not be required to pay 50% of the costs in the coverage gap. Patients may face greater cost-sharing requirements for biosimilars than the reference product counterpart as a result of this dynamic (*for more detail refer to Appendix 3: Standard Medicare Coverage*).

Discussion

As a result of the access that patients have today, only a small proportion of patients stand to directly benefit from the savings potential of biosimilars. Instead, the vast majority of potential savings will be allocated to other healthcare stakeholders such as PBMs, employers, insurers, and state and federal

government organizations. It will be the responsibility of these stakeholders to deliver benefits to patients and thus, demonstrate the value of biosimilars.

One mechanism that may be leveraged to deliver savings to patients is a reduction in insurance premiums. Stakeholders may take the savings afforded from biosimilars and reallocate them in the form of premium reductions. However, U.S. market dynamics make an efficient reallocation of funds unrealistic. Above all, the lack of net price transparency in the U.S. market will likely impede efficient redistribution of savings by those parties negotiating discounts from pharmaceutical manufacturers. Even today, the magnitude of savings from negotiated discounts (non-list price) is unknown, and the portion of these savings passed through to other stakeholders is unclear and may vary depending on the situation.

Even if savings are efficiently translated into premium reductions, it may not translate into meaningful or noticeable reductions on a patient's health insurance bill. Less than 30% of the average insurance premium is the responsibility of the patient, and biologic spending is only a fraction of healthcare spending as a whole. As a result, very little premium reduction can be realized by the patient. For patients with employer-based coverage, every 10% reduction in total U.S. biologic spending may reduce premiums by an average of approximately \$0.21 per month (\$0.29 in Medicare). A 50% reduction may translate to premium savings of \$1.05 per month in commercial and \$1.46 in Medicare (*refer to Appendix 4: Premium Savings*).

If meaningful reductions in premiums are unrealistic, it becomes critical that the savings are used to improve patient care and/or access. As discussed earlier in the report, many of today's patients have excellent access to biologic drugs as a result of generous formulary designs, widespread patient assistance programs, and other forms of supplemental insurance coverage. Still, there remains a group of patients, namely those covered by Medicare Part D, that has poor access (i.e., high costs) to biologics today and will likely have poor access to biosimilars. Access to biologics could be improved for these patients by reducing overall cost-sharing requirements (i.e., deductibles, coinsurance, and fixed co-payments). In Part D specifically, closing the coverage gap for biosimilars would improve access to biologics substantially. As it stands today, Part D may require patients to pay a higher percentage of drug costs for biosimilars in the coverage gap than for reference biologics depending on the list price of the biosimilar.

Conclusion

The U.S. healthcare system is expected to save billions of dollars⁷ due to the lower barriers of entry and increased competition fostered by biosimilar legislation (BPCI Act). However, because few patients will benefit directly from the savings, it will be difficult for patients, physicians, and advocates to understand the value of biosimilar therapies. As a result, treatment with biosimilars may be difficult to rationalize for patients and providers. Biosimilar therapies may be especially difficult to justify for those patients who are already gaining clinical benefits from innovator therapies. Therefore, it is critical that the savings recognized by other parties translate into meaningful improvements in access or new programs/initiatives that advance patient care. Moreover, they need to be communicated to patients and plan sponsors effectively. Without the realization of these improvements, the value of biosimilars to the U.S. healthcare system will be limited.

Appendix

Appendix 1: Analog Selection

Analog products are selected to represent different potential biosimilar launch scenarios. More specifically, analog biologics are chosen that represent a specific dispensing channel and likelihood of facing interchangeable or non-interchangeable competitors. The dispensing channel of a biologic will partially dictate stakeholders involved and the reimbursement dynamics. In addition, the economics of biosimilars that are interchangeable versus those that are not interchangeable with the reference product can have a substantial impact on potential savings distributions.

For this study, a product is chosen to represent its primary dispensing channel as represented in IMS NSP data. It represents an interchangeability status based on its complexity. While no interchangeable biosimilars currently exist, we assume that less complex innovator biologics are more likely to face interchangeable biosimilar competition in the future.

Humira is chosen to represent a pharmacy product which is less likely to face interchangeable competition. Remicade is chosen as a medical product which is less likely to face interchangeable competition. Lantus is chosen as a pharmacy product which is more likely to face interchangeable competition. Finally, Neupogen is chosen as a medical product which is more likely to face interchangeable competition (although current biosimilar versions of Neupogen are not interchangeable).

Figure 3: Biologic Therapy Characteristics of Analog Products

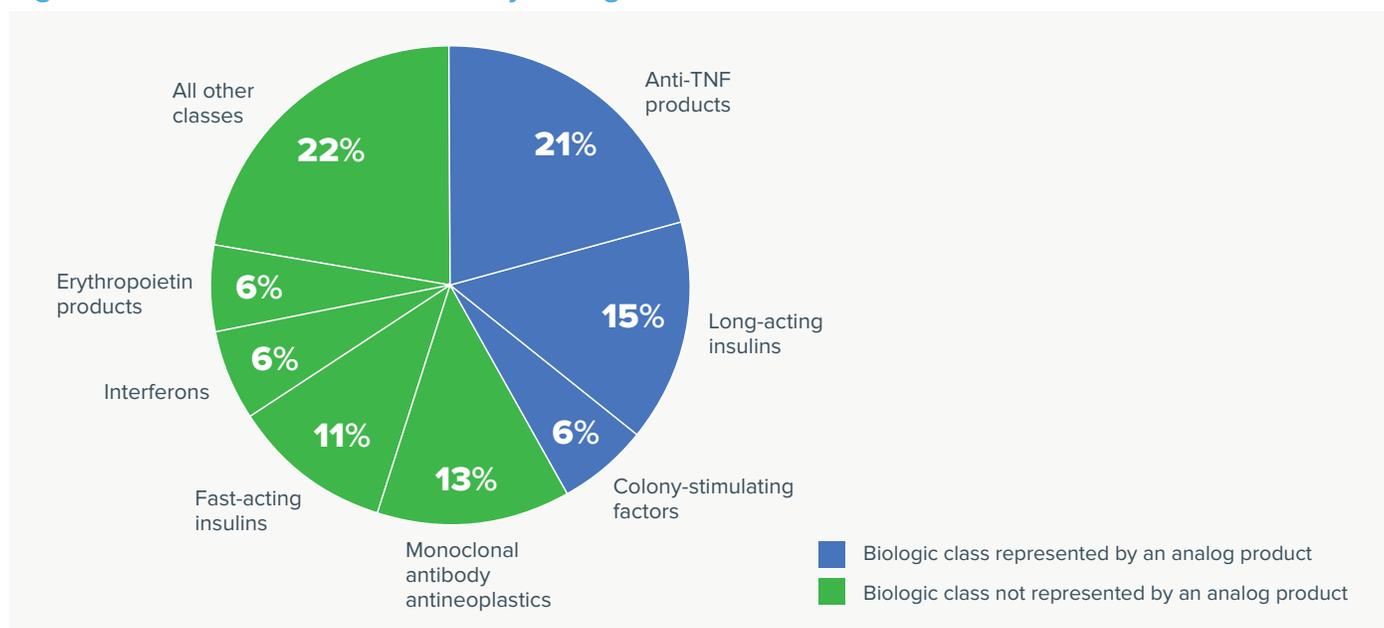
Analog Category	Biologic	Molecule Complexity		2015 Volume By Dispensing Channel		
		Size	Naturally Occurring	Pharmacy	Physicians Office (clinic)	Hospital
Non-interchangeable Pharmacy	Humira	150 kDa	No	91%	2%	3%
Non-interchangeable Medical	Remicade	149 kDa	No	6%	73%	17%
Interchangeable Pharmacy	Lantus	6 kDa	Yes	87%	3%	4%
Interchangeable Medical	Neupogen	20 kDa	Yes	24%	43%	29%

Source: IMS Health National Sales Perspective (NSP) data; Amundsen Consulting Analysis

Chart Notes: Molecular size is measured in atomic mass units (kDa) and represents complexity – the larger the molecule, the more complex its structure. Naturally occurring molecules are easier to reproduce and are more likely to be considered interchangeable by FDA.

The four products selected are key members of biologic classes (e.g., anti-TNF alpha products) that together account for over 42% of 2013 U.S. biologic sales [see figure 4 below].

Figure 4: Distribution of U.S. Sales by Biologic Class



Source: Mulcahy et al. The Cost Savings Potential of Biosimilar Drugs in the United States. 2013

Appendix 2: Net Price Impact

For the purposes of this study, total direct savings are defined as the reduction in a biologic’s net (final) price. These reductions are measured in two different forms:

- a) the lower list price from substituting less expensive biosimilar products for a reference product; and/or
- b) the lower net price from manufacturer rebates to payers

Appendix 3: Standard Medicare Coverage

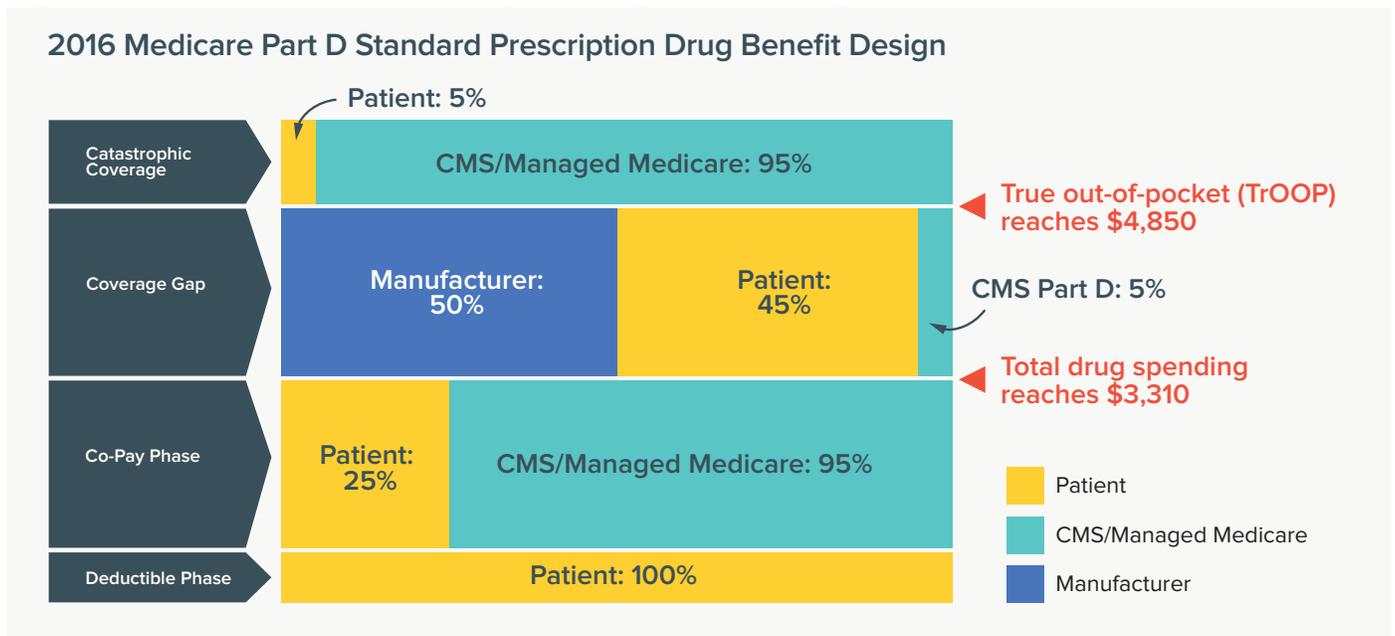
Medicare Part D patients may progress through four phases of coverage: Deductible, Initial Coverage Period, Coverage Gap, and Catastrophic Coverage. During the deductible phase, standard (non-subsidy) patients pay full price for a therapy. After paying a deductible (if required), standard Medicare patients pay 25%-33% coinsurance on specialty treatments during the initial coverage period. Once total drug costs exceed \$3,310 (in 2016), patients enter the coverage gap, which expects patients to pay 45% of brand drug costs. Brand manufacturers are responsible for paying 50% towards the costs of branded prescriptions during this phase and payers the remaining 5%. Patients do not exit the coverage gap phase until their true out-of-pocket (TrOOP), which includes the manufacturer’s portion (50%), reaches \$4,850. Surpassing the TrOOP threshold pushes patients into the catastrophic phase of coverage under which standard patients pay 5% of specialty drug costs. It is important to note that biosimilar products will not be required to pay 50% of coverage gap drug costs. Since this payment from traditional brand drugs lowers patient cost, it may be more expensive for non-LIS patients to be treated with a biosimilar agent⁸. It is also important to note that in June 2016, the Medicare Payment Advisory Committee (MED-

PAC) issued a recommendation to not include manufacturer payment as part of TrOOP. While this would remove the potential disadvantage for biosimilars it will increase costs for patients and reduce access⁹. Figure 5 below illustrates the payment responsibilities and coverage limits of the standard drug benefit design for Medicare Part D patients in 2016.

Appendix 4: ASP Reimbursement for Physician-Administered Products

The final reimbursement of a medical reimbursed biologic is oftentimes based on the average sales price (ASP) of the agent. Eligible non-list price discounts, including rebates, are factored into a product’s ASP and will therefore eventually impact the final reimbursement. Thus, stakeholders who do not directly command discounts or collect rebates will benefit from discounts and rebates to other eligible stakeholders. Furthermore, patients who pay coinsurance for their drugs will eventually benefit from a reduction in ASP if the final reimbursement of the product is, in fact, based on ASP. Still, not all final reimbursement is based on ASP for physician-administered products, and, moreover, not all patients have a costsharing design which exposes them to a portion of the final reimbursement.

Figure 5: Standard Medicare Prescription Drug Benefit Design for Brands, 2015



Source: Medicare.gov. Costs in the coverage gap. 2016; Amundsen Consulting Analysis

Appendix 5: Premium Savings

This assessment establishes a patient’s average monthly premium reduction given a certain reduction in payer biologic spending.

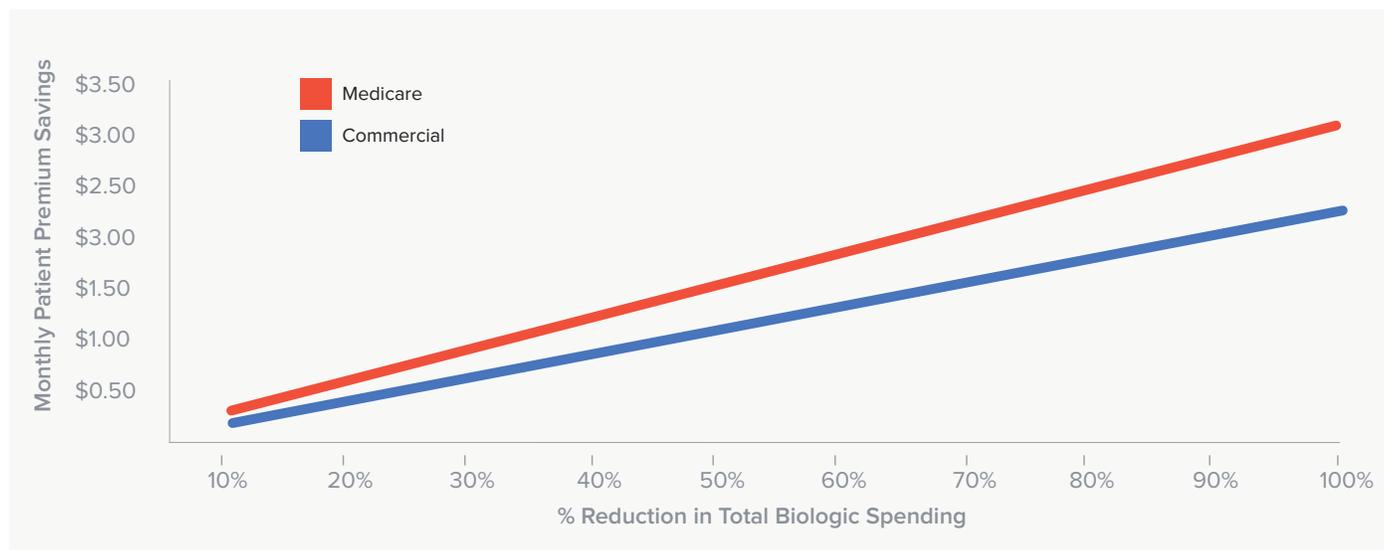
For the analysis, it is assumed that a reduction in overall healthcare spending would equal a proportional reduction in healthcare premiums. The analysis also assumes that all savings would be efficiently reallocated through premium reductions. While absolute efficiency is unrealistic, it provides insight into the maximum potential indirect saving for patients. This approach also excludes administrative costs, risk-sharing costs, and other factors which may prevent premium reductions, despite cost savings.

First, the proportion of overall U.S. healthcare spending attributable to biologics is established. The study uses National Health Expenditures 2013 Highlights to determine total U.S. healthcare spending in 2013 and The Cost Savings Potential of Biosimilar Drugs in the United States¹⁰ to determine total U.S. biologic drug spending in 2013. Next, baseline premium costs are considered. Average patient premiums for commercial and Medicare patients obtained from Kaiser Family Foundation¹¹ are used for this purpose. For Medicare patients, both Part B and Part D premiums are included. Medicaid programs can only charge premiums for patients with incomes >150% of the federal poverty line (FPL), and federal law limits the amount states can charge for premiums for patients with incomes >150% of the FPL. Therefore, Medicaid patients are not expected to benefit from premium reductions.

The biologic spending reduction is considered as a reduction in the proportion of total biologic spending (e.g., 5% reduction, 15% reduction 50% reduction, etc.) in the US. The total savings on biologic spending is then recalculated as a proportion of total healthcare spending. The proportional reduction in healthcare spending reduction is applied to patient premiums to understand the potential impact of indirect savings.

Indirect savings are reported as the maximum potential monthly premium savings for patients driven by the reduction in total U.S. biologic spending (all biologic pharmaceuticals). Results are shown for patients with employer based insurance and for patients with Part B and Part D coverage through Medicare.

Figure 6: Patient Monthly Premium Savings by Reduction in National Biologic Spending



Source: Kaiser Family Foundation State Health Facts, 2013; U.S. Department of Health and Human Services, 2013; Amundsen Consulting Analysis

The opportunity for patients to save through premium reductions is tempered due to several factors, including but not limited to:

- **Small Footprint** – Biologics account for approximately 2% of all healthcare spending in the US
- **Employer Health Benefits** – Employers, on average, are responsible for 79% of premium costs for employer based coverage
- **Government Funding for Part B** – In Medicare Part B, general government revenues account for 75% of healthcare costs; beneficiary premiums fund remaining 25%
- **Government Funding for Part D** – In Medicare Part D, general revenues fund 73% of costs; state payments fund 13%; beneficiary premiums fund remaining 14%
- **Risk Pool** – Savings are distributed to all plan members, not specifically to patients using biologics

References

Notes

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⁴ Kaiser Family Foundation. Medigap Enrollment Among New Medicare Beneficiaries: How Many 65-Year-Olds Enroll in Plans with First-Dollar Coverage?, April 2015

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⁶ Office of the Legislative Counsel for the U.S. House of Representatives. Health Care and Education Reconciliation Act of 2010, Subtitle B, Section 1101: Closing the Medicare Prescription Drug “Donut Hole.” May 2010.

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⁸ Medicare.gov. Costs in the coverage gap. 2016

⁹ MEDPAC. Report to the Congress: Medicare and the Health Care Delivery System. June 2016

¹⁰ Mulcahy et al. The Cost Savings Potential of Biosimilar Drugs in the United States. 2013

¹¹ Kaiser Family Foundation. 2015 Employer Health Benefits Survey. September 2015

Data Sources

IMS Health National Sales Perspective (NSP):

NSP data is used to quantify historical unit sales across distribution channels (pharmacies, physician offices, hospitals) for the five analog biologics covered in this report. The NSP dataset is the industry standard for quantifying pharmaceutical spending, measuring sales at actual transactional prices instead of average wholesale prices with a 100% capture rate. This data monitors every major class of trade and channel of distribution for prescription pharmaceuticals, over-the-counter products, and select self-administered diagnostic products in the United States and measures volume of both dollars and units moving from manufacturers into various outlets within all 50 states.

The Centers for Medicare & Medicaid Services (CMS):

CMS.gov drug pricing files are used to quantify ASP (average sales price) information for the analog biologics covered in this report that are administered primarily by physicians. Within these files, CMS establishes maximum reimbursement rates for pharmaceutical products within a specified billing J-code. The maximum rate (typically ASP+6%) is based on sales data directly reported to CMS by manufacturers.

IMS Health Longitudinal Access and Adjudication Data (LAAD):

LAAD is an anonymized patient sample dataset that captures longitudinal pharmacy (both retail and specialty) and medical claims. LAAD was used to quantify payer channel distribution, co-pay card penetration, and LIS prevalence for these products. LAAD includes pharmacy data covering 40% of the market and is comprised of multiple sources, including national and regional chains, independent pharmacies, and a switch house for a comprehensive view into all types of retailers across all geographies.

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Dave MacDougall is responsible for leading the Amundsen Consulting division of IMS Health. With over twenty years of experience in the healthcare industry, Dave is a leading authority on patient access, managed markets strategy and public policy with extensive expertise in advanced analytics. His analytical focus includes longitudinal patient data assessments for medical and pharmacy-reimbursed therapies. Dave holds a B.S. in Biochemistry from Suffolk University and an M.B.A. from Babson College.



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About Amundsen Consulting

Amundsen Consulting is a strategy and analytics consulting division of IMS health, focused on the U.S. pharmaceutical industry. Founded in 2005, Amundsen Consulting helps companies address the challenges brought on by significant transformations in public policy, managed markets, or patient access facing the industry. The management team of Amundsen Consulting has served the industry for over 20 years, and continues to find new and innovative ways to meet the strategic needs of our clients.

Amundsen is at the forefront of data-driven insights primarily leveraging anonymous, longitudinal, patient-level data. With data, we measure real-world behaviors to understand and improve customer access to patients in the form of contracting, patient assistance programs, salesforce targeting, and other strategies in both retail and specialty pharmacy markets.

