

Medi**impact**

One Source. Lower Cost. Better Care.™

Biosimilar Strategy

OPTIMIZING THE USE OF NEW BIOSIMILARS

Biosimilar Specialty Drugs: Largest Potential to Reduce Specialty Spend

In 2015, specialty drug spend exceeded \$120 billion. The majority of specialty medications are biologics. In 2010, with the passage of the Affordable Care Act, the Food and Drug Administration (FDA) was granted authority to approve biosimilars in the U.S. The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) created an abbreviated licensing pathway for biologic products. This biosimilar pathway is known as the 351(k) application/pathway.ⁱ

The existence of biosimilars provides a potential opportunity to significantly reduce the staggering specialty trend seen in

the U.S. over the past decade. Over the next 10 years, 60 biologic drugs worth \$100 billion in sales are estimated to lose their patent protection. Biosimilars entering the market are expected to be priced less than the reference branded agent, with most estimates quoting a 15% price reduction.ⁱⁱ

As a result, plan sponsor interest in biosimilar specialty drugs and the savings they can offer is intensifying. Currently, 1-2% of claims are driving more than 35% of total drug spend. This number is expected to increase 50% within the next three years.ⁱ

Managing Challenges with Specialty

There are several challenges associated with managing specialty drugs, from both a cost and utilization perspective. A significant portion of the drug pipeline is composed of drugs for orphan diseases for which there are no other effective treatments. There also are a large number of approvals for cancer treatments with dire prognoses. The newer therapies are given in combination with other specialty oncolytics which can double the cost of treatment. Unlike therapies that are non-specialty, patients for whom a biologic is prescribed cannot simply switch to a low-cost

generic medication.ⁱ

Coverage of these high-cost specialty medications is either mandated by law or must be provided because there are simply no other therapeutic options.

In the MedImpact Book of Business, 1% of claims are driving more than 35% of total drug spend. We estimate this will increase to 50% within three years.ⁱⁱⁱ Payers need effective strategies for managing utilization PRIOR to drug launch to mitigate budget impact.

MedImpact: Managing Trend Before It Happens™

MedImpact, an independent, trend-focused pharmacy benefit manager (PBM), is the nation's largest independent PBM, serving health plans, self-funded employers and government entities. Our business model is unique—avoiding conflicts by not owning a fulfillment pharmacy. Instead, we focus on effectively managing client pharmacy benefits to promote **Lower Cost** and **Better Care** through **One Source**. We work with clients to promote prescribing to the medically appropriate, lowest-net-cost drug. Our number one goal is client satisfaction by providing flexible solutions and patient-centric products with a focus on lowest net cost and quality outcomes.

Biologic Specialty Drugs are worth **\$120 BILLION** in the U.S.

How do we reduce this staggering trend?

Biosimilars: What Are They?

Biologics are drugs produced from living cells derived from a biological process. They are larger, complex proteins sensitive to manufacturing, storage and handling, and this renders biologics to higher immunogenic potential compared to small-molecule drugs. The manufacturing process directly determines the chemical

characteristics of the biologic. Identical copies of biologics cannot be ensured, unlike small molecules; therefore, biologics are not considered generics. Biosimilars are biologic products that are similar to their reference product but not guaranteed to be identical. In addition to submitting their product for approval as a “biosimilar,”

manufacturers also can apply to have their product approved as “interchangeable” with the reference biologic product. To date, there have been no biosimilar products approved that have also been approved as interchangeable with the reference product.

Biosimilars in the European Market: Key Takeaways

Biosimilar Savings Potential in the EU5 and U.S. for 8 Key Products in 2015-2020

The first biosimilar was approved in 2006 in the European Union. Because the European Union does not have a specific pathway for interchangeable status of biosimilars (interchangeable to the reference product), all agents that receive authorization are considered biosimilar.ⁱⁱⁱ The U.S. managed care market can benefit from the European Union experience with regard to the uptake of biosimilars.

The success of biosimilars in Europe has differed in each individual country depending on factors such as pharmaceutical manufacturing opposition, physician acceptance,

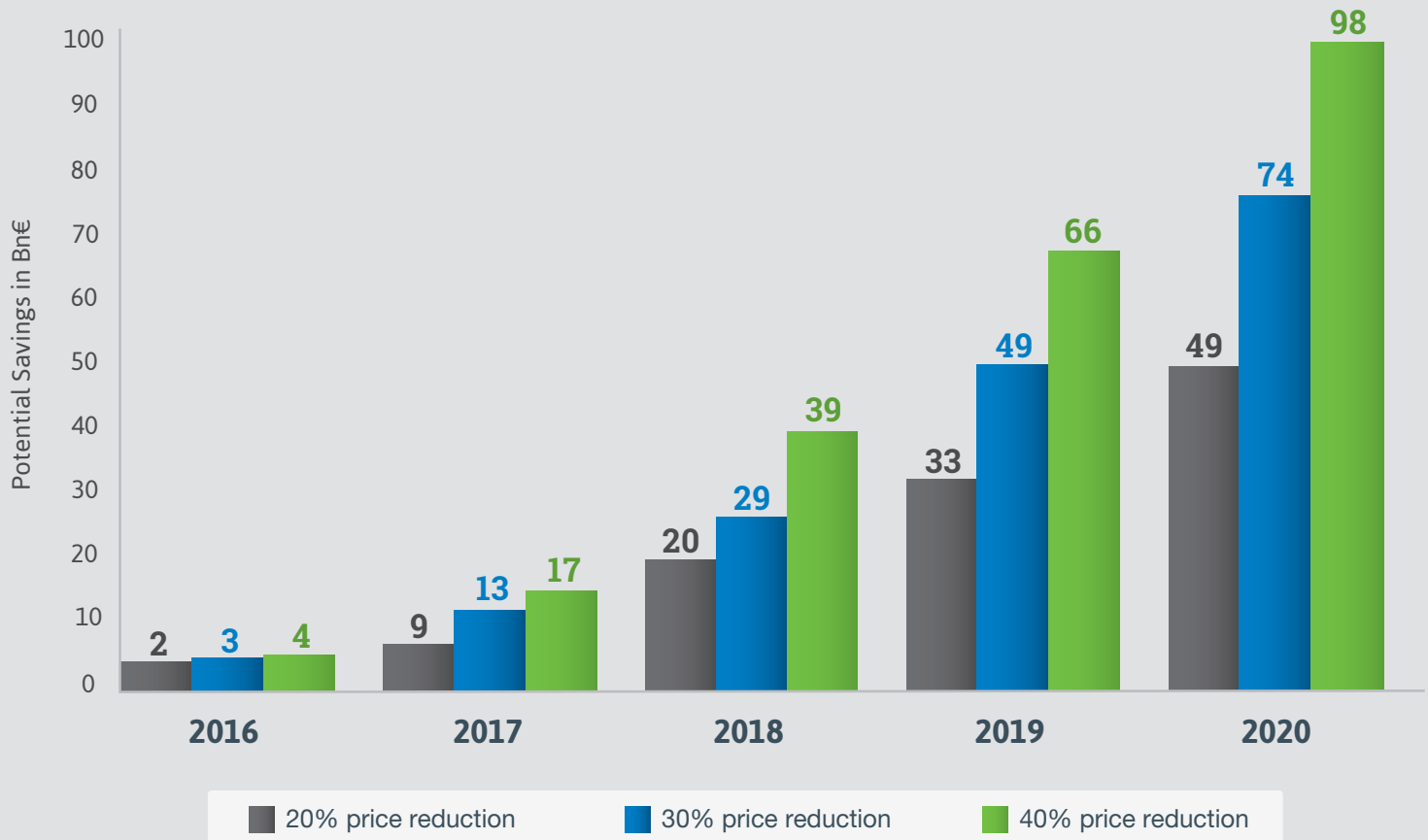
local regulations, and publication of success of adoption. In the United Kingdom, Granulocyte-colony stimulating factors (G-CSF) are prescribed in the hospital. After a single preferred agent is selected, hospital protocols are changed to reflect the preferred agent. This has led to approximately 90% uptake of the market of the biosimilar G-CSF.ⁱⁱⁱ

In Germany where G-CSF appears in the retail setting, quotas are used to increase uptake. Clinician education and publication of real world utilization emphasizing safety plays a large part in Germany’s effort to promote

biosimilars; G-CSF biosimilar uptake has been roughly 60% over the reference product market.ⁱⁱⁱ In Austria, where price setting is employed, biosimilars have not seen an impressive uptake. It has been suggested that price setting of not only the biosimilar, but the reference product, delays competition and provides no incentive to use biosimilars over reference agents.

At the end of 2015, there were 41 biosimilar medications in the pipeline for four original biologic drugs, including Remicade, Enbrel, Mabthera, and Humira.^{iv}

Savings Potentials Across the European Union 5



Source: IMS Health, MIDAS, IMS Health Market Prognosis; IMS Institute for Healthcare Informatics, Dec 2015

The chart above shows savings potentials across the European Union 5 (France, Germany, Italy, Spain and the U.K.) and the U.S. In the European Union 5 alone, the combined value of the eight top-selling biologic medicines losing exclusivity protection between 2015 and 2020 was approximately \$47.5 billion. With similar but lagging biosimilar approval trends in the U.S., payers have a great interest in adopting utilization and reimbursement models to realize potential savings from biosimilar drugs.ⁱⁱⁱ



Biosimilar Strategy at MedImpact

To take full advantage of the potential savings afforded by biosimilars, and to help ensure appropriate use, MedImpact has enhanced clinical and technical product evaluations. We have one reviewer trained in biosimilar issues who researches all biosimilars. MedImpact also has people monitoring the regulatory websites to stay abreast of biosimilars in development.

The Clinical Pipeline

MedImpact is proactively tracking biosimilar-related regulations as they relate to pharmaceutical manufacturers. We also monitor and report on products in the biosimilar FDA approval pathway. For example, clients can get regular updates on biosimilars in our Quarterly Clinical Pipeline® report that tracks biosimilar product approval progress, noting innovator product and interchangeability.

Approximately 50 distinct biosimilars are in development, most likely resulting in a highly competitive marketplace over the next five years.ⁱⁱⁱ Although these patent expiration dates may be closing in, biosimilars are faced with legal and regulatory challenges that may potentially delay their introduction to the market.

Market Trends: Move to Manage Costs via Evidence-Based Utilization Management

In prior years, open access was the norm with a focus on generic utilization, brand and rebate optimization and network discounts. The dramatic increase in costs, due to truly innovative high-cost specialty drug launches, has plan sponsors implementing more heavily managed utilization and greater cost-sharing to steer beneficiaries toward therapeutically equivalent, low-net-cost options as a means to manage the budget impact of these drugs.

Formulary trends also are being shaped by the implementation of healthcare reform. Developing strategies to ensure the acceptance of biosimilars will be critical to the success of payer cost-containment efforts

in both the private and public sectors as government entities define access and nondiscriminatory benefit rules.

There is an increase in the use of restrictions based on scientific, evidence-based clinical rules to ensure clinically appropriate access for members who meet the criteria. MedImpact researches industry standard guidelines and consults with subject matter experts to understand best practices in the clinical setting and apply those best practices to our clinical edits. We develop and implement prior authorization criteria designed to provide the drug to the members who will derive maximum benefit.

Clinical Formulary Strategy

MedImpact conducts a thorough clinical review of biosimilar products, including clinical outcomes, pharmacokinetics, immunogenicity, and manufacturing consistency by a dedicated reviewer. Our Pharmacy & Therapeutic experts review and approve all utilization management strategies to ensure the most appropriate drug is given to the right person at the right time.

Financial Formulary Strategy

We conduct a regular review of the FDA website and other sources to track the progress of companies developing new biosimilar agents. We work closely with pharmaceutical manufacturers to help secure the best discounts and rebates for both reference medications and their biosimilar counterparts. Our formulary placement and utilization management strategies help ensure our clients are receiving

the best combination of clinically effective and safe products at the best price for **Lower Cost** and **Better Care**.

Additional considerations include interchangeability, the potential for successful conversion of members from the brand to the biosimilar, and other pertinent dynamics that drive a successful biosimilar strategy.

Biosimilar Considerations for Government Programs

Price Advantage for Medicaid Plans

In the Managed Medicaid space, manufacturers often can't offer rebates on their branded products due to best-price rules. This makes biosimilars a potential low-net-cost product versus the branded agent, as they are generally priced lower than the brand and can offer rebates.

No Price Advantage for Medicare Part D Plans

In the Medicare space, the Centers for Medicare & Medicaid Services (CMS) discourages the use of biosimilars, as it considers these products "generics" in the reimbursement process. When patients are in the coverage gap, also known as the "donut hole," or are in catastrophic coverage, the branded manufacturer is required to reimburse up to 50% of the cost of the drug through the Discount Program. Manufacturers of drugs deemed to be generics, such as

biosimilars, do not pay a portion of the drug cost in the gap or catastrophic coverage. Because the plan pays the entire cost of the drug minus the member copay, biosimilars are not the lowest-cost agent for plans offering Medicare Part D coverage.^v

MedImpact has created a Medicare Part D Biosimilar and Interchangeable Biologic Product Program to ensure CMS compliance for adjudication and reporting.

Network Strategy

Since we do not own fulfillment, we are able to engage with our unique pharmacy network to provide plan sponsors with competitive options. We direct fulfillment to the most cost-effective, clinically appropriate pharmacy. As the payer advocate, we enforce preferential dispensing of formulary preferred products to support the formulary strategy and optimize utilization of medically appropriate preferred products for lowest-net cost. Through close collaboration with our pharmacy partners, we receive up-to-date reporting of any adverse events or other issues associated with biosimilar products to promote the best possible patient outcomes.

Ongoing Surveillance

We monitor client utilization and compare it to previous MedImpact and national benchmarks by line of business. In addition, we continually report on efficacy or adverse events with strategies for solving any issues. We also provide overall class spend and trend analyses.



MedImpact System Enhancements

MedImpact has incorporated FirstData Bank biosimilar drug attributes into the drug file and adjudication processes, and added biosimilar drugs to the Medicare Part D pre-processing drug lists. We proactively implement other enhancements as necessary for adjudication, reporting and monitoring biosimilars and their utilization.

MedImpact Communications

As always, we will keep clients informed about biosimilars coming to market and their potential financial impact. We constantly are assessing the best communication tools to address plan sponsor, prescriber and patient needs.

Implementing Strategies

MedImpact offers flexibility in utilization management for its clients to balance member satisfaction and trend management through customized utilization management programs depending on the goals of the client. MedImpact uses scientific, evidence-based criteria to help ensure the right person gets the right drug at the right time.

Contact Us for More Information

Please contact your account representative for more information on how we can assist you in lowering costs through effective biosimilar management. If you don't have an account, email us at info@medimpact.com.

Source Notes

ⁱ Information on Biosimilars. (2016, May 10). Retrieved June 13, 2016, from <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm>

ⁱⁱ Avey, S. (2016) Optimize the Use of the New Biosimilars [Powerpoint] Retrieved from <https://Conference.MedImpact.com>

ⁱⁱⁱ MedImpact Book of Business 2015

^{iv} Aitken, M. (2016). Delivering on the Potential of Biosimilar Medicines: The Role of Functioning Competitive Markets (p. 1, 7, 10, Publication). Parsippany, NJ: IMS Institute for Healthcare Informatics

^v Costs in the Coverage Gap. (n.d.). Retrieved June 14, 2016, from <https://www.medicare.gov/part-d/costs/coveage-gap/part-d-coverage-gap.html>



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