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WHITE PAPER

Good News for Biosimilar Adoption Rates as Pharmacies Find Workable Strategies

Generic and biosimilar drugs both face challenges in terms of FDA approval, third-party payer pricing and physician/patient adoption. Yet biosimilars have unique complications as well. After a slow start — frequently the case with the introduction of new types of drugs — biosimilar adoption rates are trending upward in the United States.

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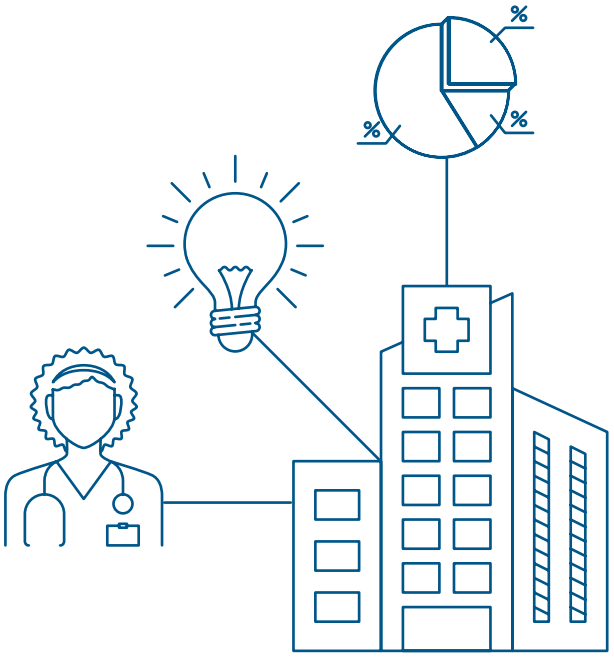
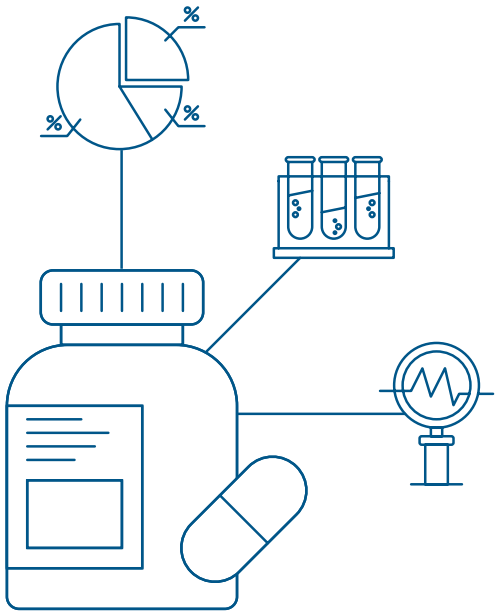




Biosimilars vs. generics

Both biosimilars and generic drugs are alternatives to brand name drugs and may be more affordable. But important differences set them apart from each other.

A generic drug contains the same active ingredients as the brand name and is a proven equivalent — an identical copy of the original drug.

Biosimilars must be highly similar to the reference product (the single biological product approved by the FDA) with no clinically meaningful differences. However, they are not completely identical to the original medicine. The biosimilar must be proven in clinical studies to be as safe, pure and effective as the reference product.[4, 5]

Healthcare system pharmacies are often driven by drug costs, choosing formulary drugs that support maximum reimbursement and lower patient copays. Innovative, relatively new treatments such as biosimilars may receive little consideration as alternatives since hospital pharmacies rarely have the time or resources to explore these options.

Navigating the use of biosimilars with the 340B Pricing Program

The 340B drug pricing program, a section of the Public Health Act, was passed by Congress in 1992 to provide discounted outpatient drugs to eligible healthcare providers. Over the years, however, the program has proven more and more difficult to navigate as treatments evolve and specialty drug costs keep rising. Biosimilars further complicate these critical discounts since they don't fit neatly into the same boxes as traditional generics.

Defying categories

Perhaps the only place where generic and biosimilar drugs overlap is in their ability to help lower costs. Prescription formularies divide drugs into categories such as treatment for asthma or arthritis, listing covered medications in each category. Programs like McKesson's 340B Impact[1] optimize generic purchasing by providing insight into historical prices and comparing them with similar drugs. Biosimilar drugs are, by nature, not interchangeable,[2] and are therefore not part of an existing class of drugs to treat a condition. The single exception, which received FDA approval in the summer of 2021 as the first interchangeable biosimilar product approved in the United States, is Semglee insulin.[3] While pharmacists are accustomed to considering drugs as part of a class, biosimilars must be considered individually.

Rising adoption rates

Biosimilar approval and adoption are on the rise in the U.S. among 340B-eligible entities as well as non-covered entities, despite naysayers' reports to the contrary.[6] As of November 2021, 31 biosimilars were approved for use in the United States, compared to 65 in the European Union and 27 in Canada, both of which have a different payer mix that can play a key role in adoption.

Approved U.S. Biosimilars

Approved: 31 **Launched: 21**

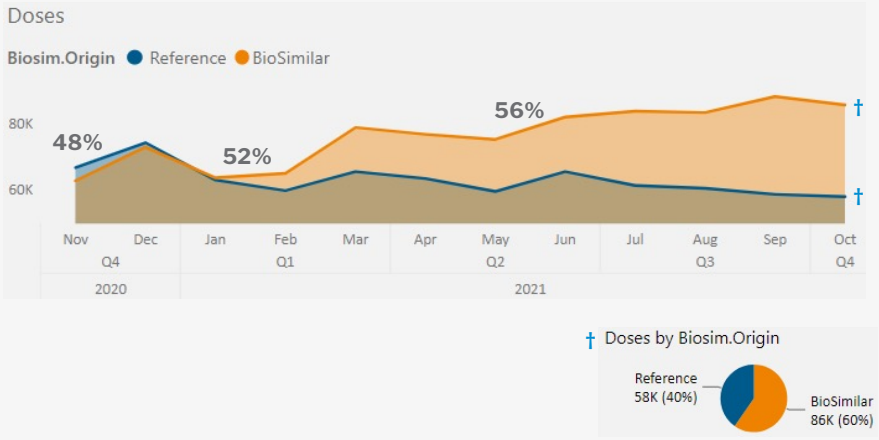
Drug Name	Therapeutic Area	Approved Biosimilars	Launches	Originator/Manufacturer
Adalimumab	RA, plaque psoriasis, ankylosing spondylitis, Crohn's disease, UC	6	0	Humira/AbbVie
Bevacizumab	Colorectal cancer, NSC lung cancer, glioblastoma, kidney, cervical, renal cell carcinoma	2	2	Avastin/Genentech
Epoetin alfa	Anemia	1	1	Procrit,Epogen/Amgen
Etanercept	RA, plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, polyarticular juvenile idiopathic arthritis	2	0	Enbrel/Amgen
Filgrastim	Neutropenia	2	2	Neupogen/Amgen
Infliximab	Crohn's disease, UC, RA, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis	4	3	Remicade/Janssen Biotech
Insulin Glargine	Diabetes mellitus	1	1	Lantus/Sanofi
Pegfilgrastim	Febrile neutropenia, acute myelosuppressive radiation exposure	4	4	Neulasta/Amgen
Ranibizumab	Neovascular age-related macular degeneration, macular edema, mopic choroidal neovascularization	1	0	Lucentis/Novartis
Rituximab	NH lymphoma, chronic lymphocytic leukemia, RA, granulomatosis with polyangiitis	3	3	Rituxan/Biogen-Genentech
Trastuzumab	Breast and gastric cancer	5	5	Herceptin/Genentech

Since biosimilars tend to be cheaper than reference products, using dollars to analyze biosimilar adoption is difficult. Yet we can see an upward trend using a metric of Equivalent Doses Sold of reference products and biosimilars gleaned from McKesson analytics over time. For each group of biosimilar and reference product, we assumed an equivalent dose and used this normalizing metric to measure adoption rate. We excluded Semglee® from this analysis but anticipate that it will become part of our biosimilar basket in the future.

Adoption of Biosimilars All Health Systems, October 2021

For all health systems, adoption of biosimilars* is moving in a positive direction over time. Of note, 340B covered entities have a lower biosimilar adoption rate in comparison to non-covered entities and it has taken longer. This lag for covered entity hospitals may be due to difficulty navigating the various pricing files and reimbursement differences which make the determination of economic value more complex for these health systems.

*Biosimilars include bevacizumab, epoetin, filgrastim, infliximab, pegfilgrastim, rituximab, trastuzumab

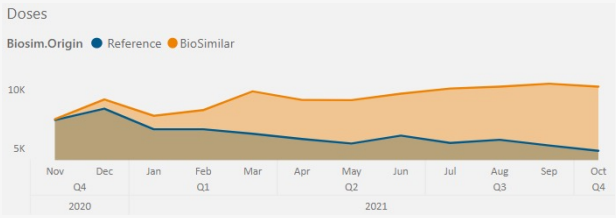


Working with winners

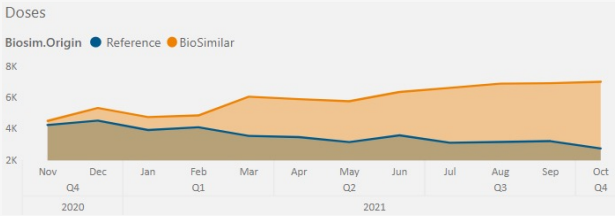
Looking at specific drugs reveals that some products have been readily adopted, while others have not broken through. The differences can be explained by considering, among other things, whether the products are for chronic or acute care, along with factors such as reference product use of innovative delivery devices as with Neulasta® Onpro®.

Adoption Winners, October 2021

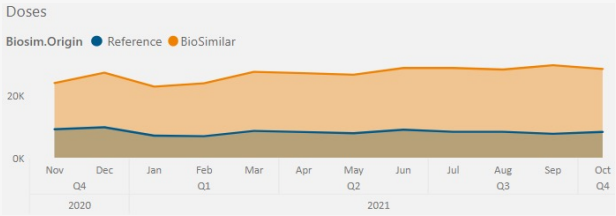
Trastuzumab



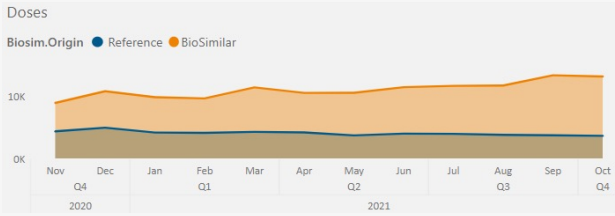
Bevacizumab



Filgrastim



Epoetin



Rituximab

Adoption Losers, October 2021

Trastuzumab

Bevacizumab

Most of the “winners” are acute care or episodic drugs such as epoetin for anemia or trastuzumab for breast and gastric cancers, respectively. Yet chronic care drugs such as infliximab for Crohn’s disease have not been as widely adopted in favor of reference products. The reason may be as simple as staying with what works. If a patient has Crohn’s disease and is stable on the reference product for Infliximab, changing to the biosimilar may not be a pragmatic choice in the minds of physicians and their patients. Rituximab is seeing a favorable biosimilar adoption; however, it has lagged behind others. For episodic diseases like breast cancer, patients have never been on the reference product, so initiating therapy with a biosimilar is an easier decision. Biosimilars for disease states that rely on subjective evidence of improvement, unlike others that have measurable objective evidence (radiologic scans, laboratory tests), may also have lower adoption rates.

What is clear is that varying adoption rates are seen for biosimilars according to disease state, patient and physician preference, and economics. Aggregating all biosimilars into one “class” of drugs as is typical of articles on the subject does not give a clear picture. The trend for biosimilar adoption is moving directionally toward increased adoption albeit at different rates and with different barriers to address.

Educating patients and physicians

The innovative nature of biosimilars may cause both physicians and patients to be skeptical. Plus biosimilars go through the same rigorous testing and clinical trials required for other drugs. Patients who rely on their physician's guidance for treatment may be uncomfortable with this uncertainty. Education about biosimilars[7] can provide clarity in adoption decisions. While much remains to be studied, clinical questions can be addressed with confidence.

Considering the costs and reimbursement

Financial concerns also play a big role in biosimilar adoption. Cost to buy the biosimilar product is less for health systems; however, rebates and reimbursement concerns can lead to confusing economics. For third-party payers, hospital-based clinics — specifically those that are 340B eligible — and patients, the cost of biosimilars is often a deciding factor. Medicare has changed its reimbursement formula, giving most biosimilars pass-through status — reimbursement at average sales price (ASP) plus 20% of the reference product price. The reference products are reimbursed at ASP minus 6% for 340B hospitals. Biosimilars now have an advantage that will drive adoption.[8] Pass-through status can expire in time and biosimilars within a group lose pass through status at different times; furthering the difficult math gymnastics for covered entities to calculate. Commercial payers have thus far not followed Medicare's lead. Health system pharmacies must maintain access to multiple products to meet different payer requirements.

Adapting to the unknown

Biosimilar adoption and reimbursement models will continue to change. Health systems, which are already strained for resources, must make a concerted effort to stay informed and, in turn, help providers keep up with evidence that supports brand, generic and biosimilar decision making. This may involve designating a group to study reimbursement practices, market influences, third-party payers and alternative payment models such as Medicare's. In the long run, strategies to take advantage of increased competition in the growing biosimilar market will create better access for patients and financial benefits for hospital pharmacies.

This white paper was authorized by McKesson Corporation.

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