Lahey Health | Lahey Clinical Performance Network

Pharmacy Program *Update*

Fact Sheet: Biosimilars

Background

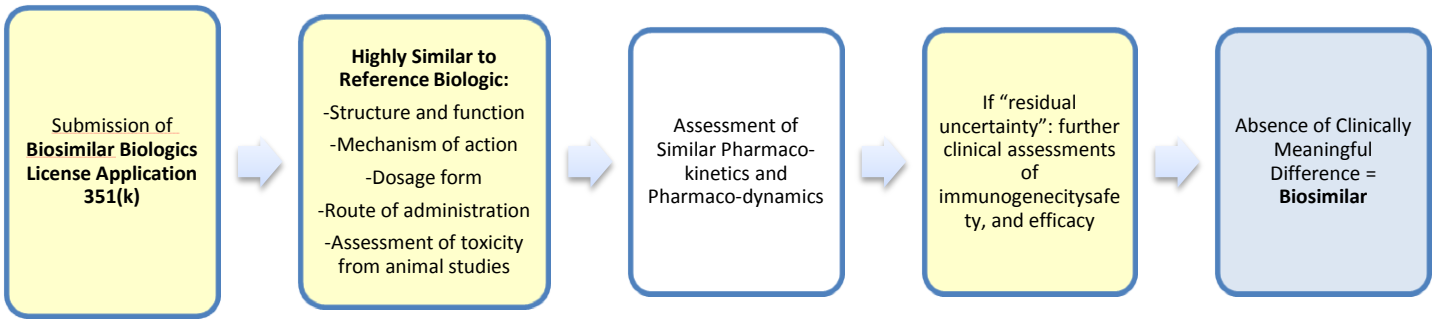
- National data from 2014 showed that specialty drugs - which include biologics - accounted for only 1% of prescriptions but 32% of total spending.
- Inflammatory conditions account for the highest drug spend (26.4% trend, commercial plans); Humira® and Enbrel® account for 70% of market share in this class. Unit costs for these agents increased by 11-18% in 2016.
- As more expensive biologics lose their patent, **biosimilars** will enter the marketplace to provide lower-cost alternatives and introduce market competition

Key Points

- A biosimilar is a drug product designed to be **highly similar to an existing marketed biologic (reference biologic)**, and have **no clinically meaningful differences in safety and efficacy**.
- **Biosimilars are NOT considered generics** to reference products; they can never be chemically identical as all biologics are large drug molecules that have natural variability from batch to batch.
- Biosimilars have been used in the European Union, Australia, and Japan since 2006. In the EU, there are over 20 biosimilars.
- Current FDA-approved Biosimilars in the US are listed in the table.

Product Name	Proprietary Name	Reference Product	Approval Date	Launch Date
Filgrastim-sndz	Zarxio	Neupogen	3/2015	9/2015
Infliximab-dyyb	Inflectra	Remicade	4/2016	11/2016
Infliximab-abda	Renflexis	Remicade	4/2017	Fall 2017
Etanercept-szzs	Erelzi	Enbrel	8/2016	Unknown
Adalimumab-atto	Amjevita	Humira	9/2016	Unknown

- Generic drugs are approved if the drug is chemically identical to the brand product, and is shown to have same rate and extent of absorption. However, since biosimilars cannot be structurally identical, they must follow a more rigorous approval process. Therefore, the **Biologics Price Competition and Innovation Act of 2009 (BPCIA)** created an **abbreviated licensure pathway** for biologics shown to be biosimilar to or interchangeable with an FDA-licensed reference product:



- BPCIA includes a provision to allow for **"interchangeable" biological products**, which **may be substituted** for the reference product by a pharmacist.
  - Manufacturers must conduct additional studies which include switching between reference biologic and biosimilar
  - Currently there are **NO biosimilars available in the US that are designated as interchangeable**

Reference Biologic	Claim $** / 30-day supply	Total spend 2016**	PMPM	Biosimilar (~10% lower cost)
Neupogen (filgrastim)	$3400	$20,000	$0.03	Zarxio (filgrastim-sndz)
Remicade (infliximab)	$5000 / 500mg*	$760,000	$1.12	Inflectra (infliximab-dyyb) Renflexis (infliximab-abda)
Enbrel (etanercept)	$4000	$3.6 million	$5.24	Erelzi (etanercept-szzs)***
Humira (adalimumab)	$4900	$5.2 million	$7.61	Amjevita (adalimumab-atto)***

**Average claim amt. for average dose per infusion* ***BCBS, HPHC, Tufts patient Rx claim data* ****Not yet available*

Biosimilar FAQs

Should I consider biosimilars the "same" as a brand product that is already on the market (ie. reference biologic)?
Biosimilars undergo a rigorous approval process in which manufacturers must show they are "highly similar" to the reference biologic as far as structure, mechanism of action, dose, and dosage form. They must also show that the manufacturing process is up to standards, report toxicity results, and conduct clinical studies that demonstrate pharmacokinetics, pharmacodynamics, and immunogenicity. Although all biologics have some natural structural variability, biosimilars should be considered to have no clinically meaningful differences from the reference product in terms of safety and efficacy. Providers should feel just as confident prescribing a biosimilar for an approved condition as they would for the reference biologic.

How much less costly are biosimilars compare with their reference biologic?
Thus far, we have seen biosimilars priced about 15-30% less than their reference biologic products. Although this is not the same significant savings seen with generic products, biosimilars are expected to drive market competition, thus leading to manufacturers lowering prices of the reference product.

Do biosimilars have the same generic (or "nonproprietary") name as their corresponding reference biologic?
No. For approved biosimilars, the FDA assigned a random four-letter suffix to the nonproprietary (generic) name of the product to differentiate it from the reference biologic. For example, Inflectra®, the biosimilar for Remicade® (infliximab), was given the generic name infliximab-dyyb. The four-letter suffix is random and has no clinical meaning. The FDA has recently issued guidance that will require all biologics (both reference biologics and biosimilars) to include a random four-letter suffix. The differentiation in generic name allows the FDA to track reported adverse events and associate them with either the reference biologic or the biosimilar. .

Are many health plans only covering biosimilars in efforts to cut costs?
Health plans make drug coverage decisions based upon safety, efficacy and cost. In addition to considering average wholesale price (AWP), they must include manufacturer contracting and incentives. Some plans may prefer the biosimilar, some may prefer the reference biologic, and others may cover both at the same cost to the patient. The patient's health plan formulary or hospital formulary (if administered in hospital or as outpatient infusion) should always be reviewed prior to prescribing.

Will a pharmacist automatically switch my patient to a biosimilar if it is available?
As of now, there are no biosimilars on the US market that are "interchangeable", meaning none of them may be substituted for a reference biologic. Therefore a pharmacist must dispense the brand product written on the prescription. If the provider wants to prescribe a biosimilar, the specific product name must be on the prescription. Should an interchangeable biosimilar become available, a pharmacist may substitute for a reference biologic unless provider specifies "no substitution", however they must notify the provider and patient of the substitution as well as document in patient record.

My patient is stable on their current drug. Are there concerns switching them to a biosimilar?
Available data from Europe, particularly in switching from Remicade® to a biosimilar, show no decrease in efficacy, increase in adverse effects, or increase in immunogenicity. However long-term data is lacking on switching multiple times between reference biologics and biosimilars, or between biosimilars if more than one product exists. If a patient is switched to a biosimilar when they are already stable on their current drug, the patient should be monitored for change in clinical status and adverse reactions.

Are there patient financial assistance programs available for biosimilars?
Yes, programs are available for the two commercially available biosimilars (follow links for info and patient eligibility): Zarxio® (filgrastim-sndz) and Inflectra® (infliximab-dyyb). However, it is important to note that although patient assistance programs may save out-of-pocket costs for patients, the institution and/or insurer still absorb the same cost. Lower-cost agents should be considered prior to initiating more expensive biologic

References and Additional Resources

Express Scripts 2016 Drug Trend Report. http://lab.express-scripts.com/lab/drug-trend-report
Biosimilars Resource Center. https://www.biosimilarsresourcecenter.org/. Accessed 12/15/16
Panesar K. Biosimilars: Current Approvals and Pipeline Agents. US Pharm. 2016;41(10):26-29
Megerlin F, Lopert R, Taymor K, Trouvin JH. Biosimilars And The European Experience: Implications For The United States. Health Affairs. 2013;32(10):1803-1810
Li E, Ramanan S, Green L. Pharmacist Subsitution of Biological Products: Issues and Considerations. J Manag Care Spec Pharm. 2015;21(7):532-39
Blackstone EA, Fuhr JP. The Economics of Biosimilars. Am Health Drug Benefits. 2013;6(8):469-478
Manolis CH, Rajasenan K, Harwin W, McClelland S, Lopes M, Farnum C. Biosimilars: Opportunities to Promote Optimization Through Payer and Provider Collaboration. J Manag Care Spec Pharm. 2016;22(9-a):S3-S9
US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Guidance for Industry. April 2015

Want to learn more?

Contact your Accountable Care Unit Pharmacist →

Author
Kenneth Noyes, PharmD, BCPS
Kenneth.Noyes@lahey.org

Lahey
Andrew Levitsky, PharmD, MEd, BCPS
Andrew.M.Levitsky@lahey.org

Kenneth Noyes, PharmD, BCPS
Kenneth.Noyes@lahey.org

Northeast
Carol Freedman, RPh, MAS, BCGP
cfreed@nhs-healthlink.org

LCPN
Pam Sherry, PharmD, BCACP
Director, Network Pharmacy Management
Pamela.S.Sherry@lahey.org

Winchester (ACO Patients Only)
Elizabeth Toabe, PharmD
etoabe@winhosp.org