Boston Medical Center
HEALTH SYSTEM

Biosimilar Adoption & Barriers to Success: Current and Future Considerations

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Objectives

A Review current and future **economics** of biologics

B Discuss **challenges** with biosimilar adoption within health systems

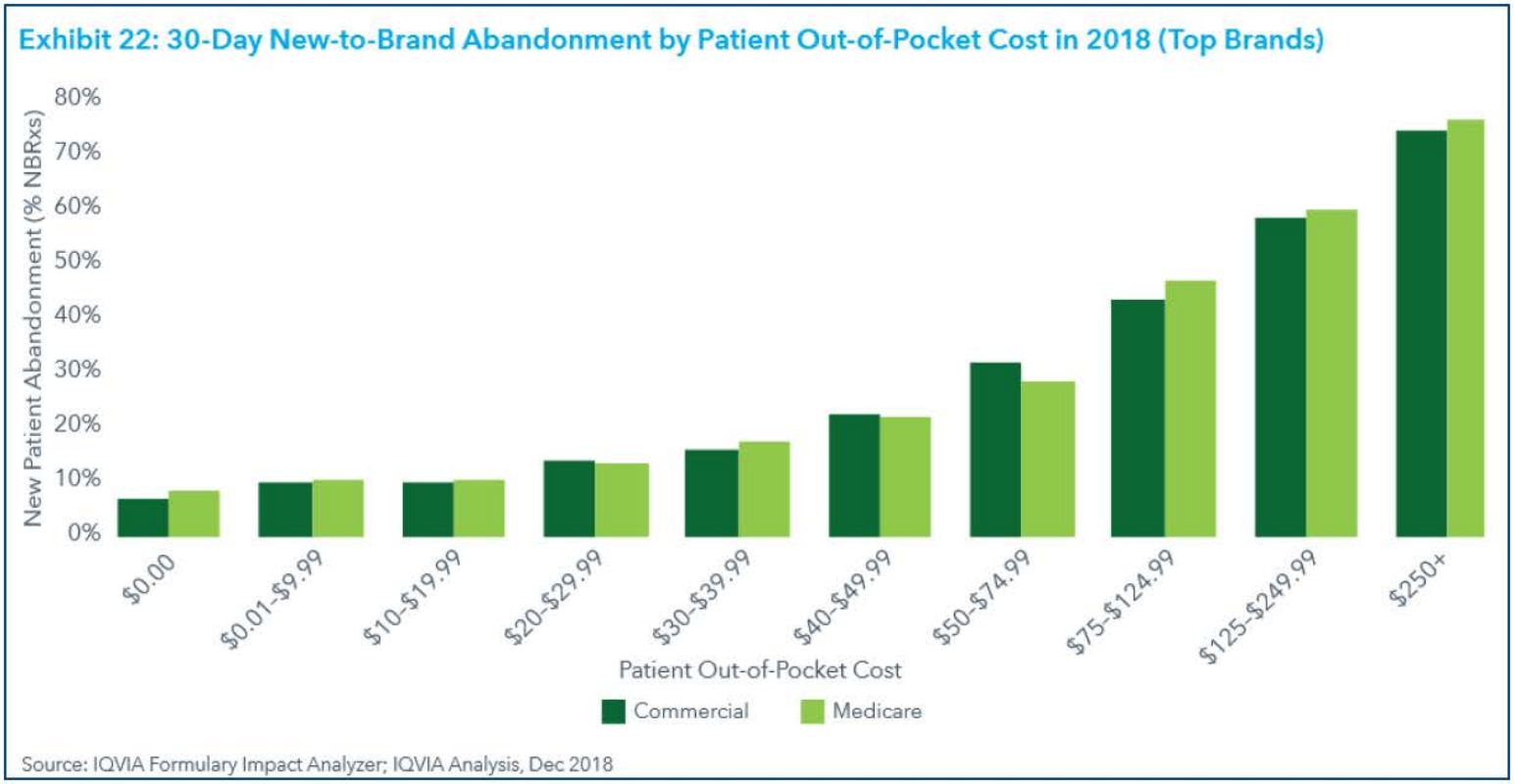
C Describe ways to **improve** biosimilar adoption

Biologics are facing price inflation without clinical justification

Rank	Drug	Q42016 to Q42018 Percentage Change		Increase in Drug Spending Due to Net Price Change ($M)
		WAC	Net Price	
1	Humira (Adalimumab)	19.1%	15.9%	$1,857
2	Rituxan (Rituximab)	17.0%	23.6%	$806
3	Lyrica (Pregabalin)	28.3%	22.2%	$688
4	Genvoya (EVG/COBI/FTC/TAF)	14.3%	21.7%	$651
5	Truvada (TDF/FTC)	14.3%	23.1%	$550
6	Neulasta (Pegfilgrastim)	14.6%	13.4%	$489
7	Cialis (Tadalafil)	26.2%	32.5%	$403
8	Tecfidera (Dimethyl Fumarate)	16.7%	9.8%	$313
--	Revlimid (Lenalidomide)	25.8%	--	--

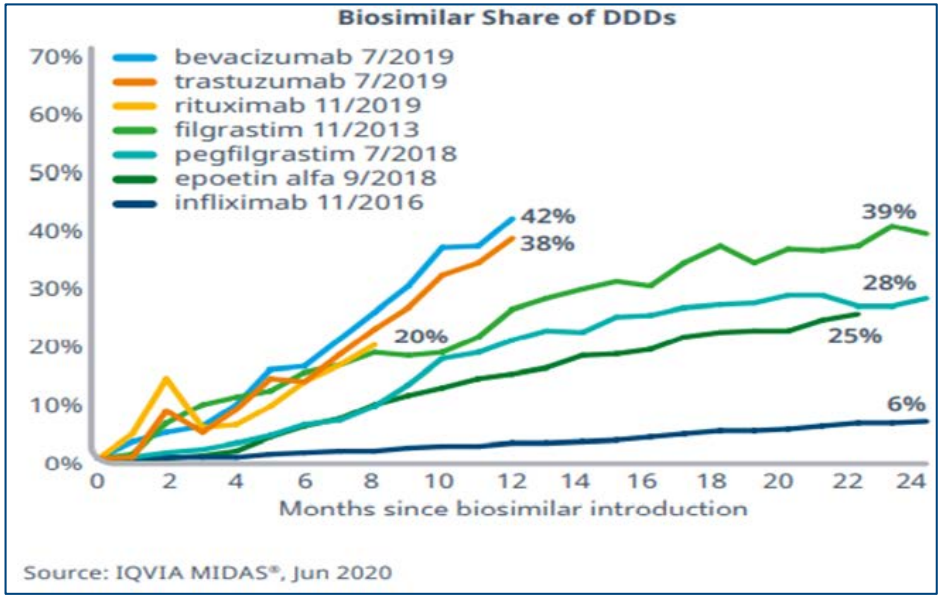
Source: ICER Unsupported Price Increase Report, 2019 Assessment

The rate of prescription abandonment increases as cost exposure to biologics rises

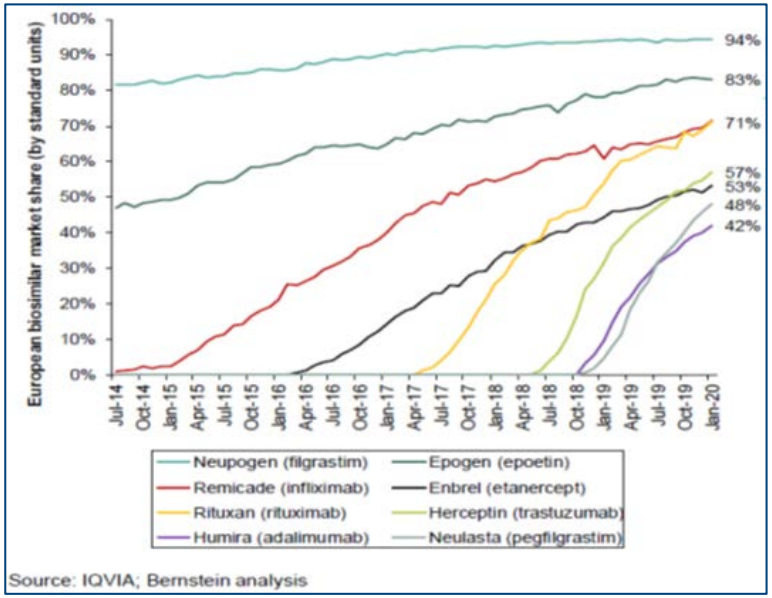


The current U.S. biosimilar market share is well below Europe's

US biosimilars
As volume share of reference molecule market



European biosimilars
Market share by standard units

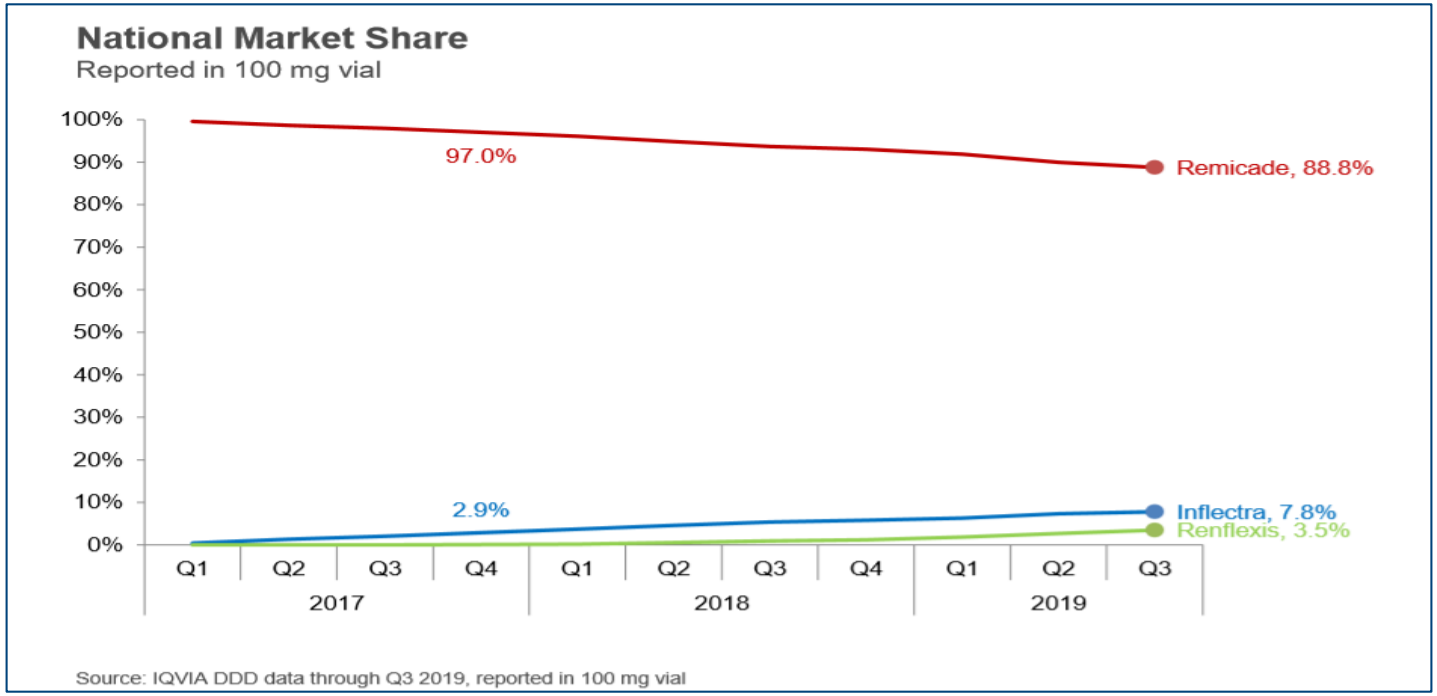


There are many challenges with biosimilar adoption within health systems

Deep dive to follow

- Payor coverage
- Preference of reference biologic due to reimbursement
- Provider buy-in
- Patient buy-in
- Multiple biosimilars
- Off-label uses
- Skinny label
- Lack of interchangeability data
- Operational infrastructure
- Chronic vs. short-term use

Lack of payor coverage is a significant barrier for biosimilar adoption in the US



- Nationally, Inflectra® only reached 7.8% of market share in 3rd quarter of 2019
- Remicade's market share is likely driven by expanded payor coverage vs. Inflectra

Barriers to provider buy-in for biosimilar adoption are largely centered around lack of broader organizational support and education

Provider buy-in is difficult to achieve due to:

1. Education surrounding bio-similarity pathway (Extrapolation of indications)
2. Understanding interchangeability vs non-medical switch
3. Statistical design implications for biosimilar clinical trials
4. Support from other KOL provider champion for biosimilar use
5. National guideline support for biosimilars
6. Payor coverage preference of reference product over biosimilar
7. Multi-specialty utilization of biosimilars across health system
8. Pharmacy and nursing support for biosimilar conversion
9. What are the financial implications to patients and system

Barriers to patient buy-in for biosimilars are mainly driven by unfamiliarity, clinical concerns, and the financial benefit not accruing to patients

Patient buy-in is difficult to achieve given:

1. Insurance covers both reference product and biosimilar at parity
2. No difference in cost
3. Long-term response to reference product
4. Provider support
5. Lack of education / comprehension of biosimilar vs. reference product
6. Lack of patient advocacy group / disease foundation support

B We should look to better understand the implications of using biosimilars for off-label use…

Rituximab®

- Autoimmune thrombocytopenic purpura (ITP)
- Dermatomyositis
- Acute renal rejection
- Systemic lupus erythematosus (SLE)
- Autoimmune encephalitis
- Multiple sclerosis

Remicade®

- Refractory Sarcoidosis
- Sjogren's syndrome
- GVHD
- Vasculitis
- Uveitis

…and in what cases manufacturers may “skinny label”

Definition	Biosimilar manufacturers seek approval for only **some** of the approved indications of a branded drug
Examples	▪ **Truxima**® (Rituximab-abbs) only approved for NHL and CLL ▪ **Udenyca**® (pegfilgrastim-cbqv) not approved for patients exposed to myelosuppressive doses of radiation
Implications on practice	▪ Is the product truly not a biosimilar or has a different mechanism of action for those indications so the FDA has not approved it for all indications
Rationale	▪ Patent infringement or orphan indication, faster path to distribution

Regulatory requirements around interchangeability need to be better understood

Overview	▪ Interchangeable product must show that the proposed interchangeable product “can be expected to produce the same clinical result as the reference product in any given patient” ▪ Based on state regulations, only interchangeable biosimilars can be substituted for reference biologics without provider intervention
Considerations	▪ Does non-medical switch = interchangeability ? ▪ How does state regulations for interchangeability apply to hospital pharmacy?
Interpretation	▪ Interchangeability is not a higher designation, it is a regulatory term not a clinical term ▪ Does not apply to institutional protocols

There is a significant operational lift to ensure smooth biosimilar adoption

- IT (order sets, billing, coding, modifier)
- Payor coverage assessment
- Patient/Provider/Nursing/Finance education/buy-in/satisfaction
- P&T presentation
- System-wide adoption & consensus
- Contract negotiations
- Inventory management

Pharmacists can help drive adoption of biosimilars

Using a high-touch model for patients, pharmacists can help improve adoption of biosimilars:

- Develop patient education material (customized to level of patient health literacy)
- Patient receives educational material prior to any changes
- Patient discusses one-on-one with pharmacist
- Provider may have a touch point before to prime patient of system wide adoption of biosimilar and their support of it
- Financial implications to health care system and patient (per member per month)
- Disease organization/patient advocacy support and education
- Peer-to-Peer patient champion
- European/U.S. data (clinical trials, real world evidence, etc.)

There are also actions health systems can take to enable faster adoption of biosimilars

- Expand biosimilar adoption experience (# of biosimilars adopted)
- Build biosimilar pipeline intelligence
- Engage in early contract negotiations
- Optimize payor communication
- Develop P&T approved protocol for newly approved biosimilars – may consider abbreviated pathway
- Create European provider peer–to-peer connections

Real-world evidence can be referenced to build the case for biosimilar adoption: Presented at the American Society of Hematology

A Retrospective Review of Engraftment Data for Tbo-Filgrastim vs. Filgrastim in Patients Undergoing High Dose Chemotherapy and Autologous Stem Cell Transplantation

Taylor Teschner, Stephen Lo, Dina Brauneis, Anthony Shelton, Bhavesh Shah, J. Mark Sloan, Cindy Varga, Karen Quillen, Vaishali Sanchorawala

In this retrospective chart review, we did not find any significant difference in time to neutrophil engraftment after HDC/SCT when comparing patients who received Filgrastim and then switched to Tbo-Filgrastim after SCT. Even though Tbo-filgrastim is not approved as a biosimilar and lacks interchangeability designation we feel that based on our experience the safety, efficacy and immunogenicity is comparable to filgrastim and there are no clinical meaningful differences between the two products.

Source: Shah, et al. A Retrospective Review of Engraftment Data for Tbo-filgrastim vs Filgrastim in Patients Undergoing High Dose Chemotherapy and Autologous Stem Cell Transplantation. Presented at American Society of Hematology. Orlando, FL December 2015

Review real-world evidence: Boston Medical Center, JMCP

Process and Clinical Outcomes of a Biosimilar Adoption Program with Infliximab-Dyyb

Shubha Bhat, PharmD, MS[1], Sarah Altajar, MD[2], Divya Shankar, MD[2], Toni Zahorian, PharmD[1], Regine Robert, CPhT[1], Taha Qazi, MD[3], Bhavesh Shah, RPh[1], Francis A. Farraye, MD, MSc[4]

RESULTS: Of 151 eligible patients, 146 (97%) successfully transitioned to IFX-dyyb. Based on our conversion rate to IFX-dyyb, our health system is forecasted to save approximately $500,000 annually. From March to June 2018, 63 of 75 (84%) eligible IBD patients transitioned from IFX to IFXdyyb. In this cohort, of the 40 patients with HBI or SCCAI scores before and after transition, 36 (90%) maintained remission. For 32 patients, the mean CRP (SD) before transition was 11.2 (22) and 4.1 (4.8) after transition (P=0.09). Since the IFX-dyyb transition, 9 patients had a colonoscopy, of which 5 (56%) were in endoscopic remission. As of October 2018, 56 (89%) patients continued with IFX-dyyb after transition. Of the 46 patients who had 12-15 months posttransition data, 38 (83%) remained on IFX-dyyb.

CONCLUSIONS: Implementation of a biosimilar adoption program can be successful and result in significant cost savings without compromising clinical outcomes. A model that uses actionable strategies and embraces collaboration among stakeholders is described here, with outcomes demonstrating successful IFX-dyyb uptake and no changes in clinical outcomes of transitioned adult patients with IBD.

Source: Bhat, et al. J Manag Care Spec Pharm. 2020;26(4):410-16

Key takeaways

- There are **83 biosimilars** in development and registered with the FDA for **38 different biologics**
- In the US, there is still some **hesitancy** to fully embrace biosimilars, but implementing early and aggressive adoptions strategies for the use of biosimilars can lead to **major cost savings** for the health care system
- More **educational activities** need to be fostered that help patient and provider buy into the global financial and clinical benefit from biosimilars
- Having more **real-world evidence** in the US from biosimilar adoption experience will also help facilitate faster adoption of biosimilars

Questions?

Thank You

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