

[EDU-R4] New mAbs on the Block: A Rocking Research Update on Biosimilar Uptake and Benefit Design Strategies in the United States

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Learning Objectives

1. Describe the therapeutic areas, pipeline, and regulatory environment affecting the biosimilar landscape in the United States.
2. Report results of current research on barriers to biosimilar adoption and impact of benefit design and formulary policies on utilization.
3. Discuss prospective payer management strategies in anticipation of market entry of pharmacy benefit biosimilars.

Financial Relationship Disclosures

Disclosure Information	Advisory Board	Consultant	Grants / Research	Salary / Contractual	Supported Promotional Education	Stock / Shareholder	Other Financial Support
Jennifer Evans, PharmD, BCACP <i>Planner</i>	MD Tobacco Control Resource Center	None	None	AMCP	None	None	None
Karen Goolsby, PharmD, MPA <i>Peer Reviewer</i>	None	None	None	CVS Health	None	None	None
Tasmina Hyder, PharmD, MBA, BCGP <i>Speaker</i>	None	None	None	Xcenda	None	None	None
Cate Lockhart, MS, PharmD, PhD <i>Speaker</i>	None	None	None	BBCIC	None	None	None
Jennifer Snow, MBA <i>Speaker</i>	None	None	None	Xcenda	None	None	None

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Questions

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Faculty



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Biosimilar Landscape

US Biosimilar Market Landscape

As of September 17, 2021

Class	Supportive care	Oncology
Molecule	Filgrastim	
Reference product	NEUPOGEN Amgen	
Launched Manufacturer launch date	ZARXIO Sandoz Sep 2015	
Approved Manufacturer FDA approval date		

Adapted from US Biosimilar Report by AmerisourceBergen as of September 17, 2021.

US Biosimilar Market Landscape

As of September 17, 2021

Class	Supportive care			Oncology		
Molecule	Filgrastim	Epoetin	Pegfilgrastim	Rituximab	Bevacizumab	Trastuzumab
Reference product	NEUPOGEN Amgen	EPOGEN / PROCRIT Amgen / JnJ	NEULASTA Amgen	RITUXAN Genentech	AVASTIN Genentech	HERCEPTIN Genentech
Launched Manufacturer launch date	ZARXIO Sandoz Sep 2015 NIVESTYM Pfizer Oct 2018	RETACRIT Pfizer/Vifor Nov 2018	FULPHILA Mylan July 2018 UDENYCA Coherus Jan 2019 ZIEXTENZO Sandoz Nov 2019 NYVEPRIA Pfizer Dec 2020	TRUXIMA Teva Nov 2019 RUXIENCE Pfizer Jan 2020 RIABNI Amgen Jan 2021	MVASI Amgen July 2019 ZIRABEV Pfizer Jan 2020	KANJINTI Amgen July 2019 OGIVRI Mylan Nov 2019 TRAZIMERA Pfizer Feb 2020 HERZUMA Teva March 2020 ONTRUZANT Organon Apr 2020
Approved Manufacturer FDA approval date						

Key: JnJ – Johnson & Johnson.

Adapted from US Biosimilar Report by AmerisourceBergen as of September 17, 2021.

US Biosimilar Market Landscape

As of September 17, 2021

Class	Tumor necrosis factor blockers		
Molecule	Infliximab	Etanercept	Adalimumab
Reference product	REMICADE JnJ	ENBREL Amgen	HUMIRA AbbVie
Launched Manufacturer launch date	INFLECTRA Pfizer Nov 2016 RENFLEXIS Organon July 2018 AVSOLA Amgen July 2020 IXIFI ^a Pfizer Dec 2014 <small>^aNot launching in the US.</small>	Ongoing litigation ERELZI Sandoz Aug 2016 ETICOVO Samsung Apr 2019	Biosimilars referencing Humira will launch in 2023 AMJEVITA Amgen Sep 2016 CYLTEZO Boehringer Ingelheim Aug 2017 HYRIMOZ Sandoz Oct 2018 HADLIMA Organon July 2019 ABRILADA Pfizer Nov 2019 HULIO Mylan Jul 2020
Approved Manufacturer FDA approval date			

Adapted from US Biosimilar Report by AmerisourceBergen as of September 17, 2021.

US Biosimilar Market Landscape

As of September 17, 2021

Class	Tumor necrosis factor blockers			Insulin
Molecule	Infliximab	Etanercept	Adalimumab	Insulin glargine
Reference product	REMICADE JnJ	ENBREL Amgen	HUMIRA AbbVie	LANTUS Sanofi
Launched Manufacturer launch date	INFLECTRA Pfizer Nov 2016 RENFLEXIS Organon July 2018 AVSOLA Amgen July 2020 IXIFI ^a Pfizer Dec 2014 <small>^aNot launching in the US.</small>	Ongoing litigation ERELZI Sandoz Aug 2016 ETICOVO Samsung Apr 2019	Biosimilars referencing Humira will launch in 2023 AMJEVITA Amgen Sep 2016 CYLTEZO Boehringer Ingelheim Aug 2017 HYRIMOZ Sandoz Oct 2018 HADLIMA Organon July 2019 ABRILADA Pfizer Nov 2019 HULIO Mylan Jul 2020	SEMGLEE ^b Viatris/Mylan July 2021 <small>^bInterchangeability approval by FDA.</small>
Approved Manufacturer FDA approval date				

Adapted from US Biosimilar Report by AmerisourceBergen as of September 17, 2021.

US Biosimilar Market Landscape

As of September 17, 2021

Class	Tumor necrosis factor blockers			Insulin	Ophthalmology
Molecule	Infliximab	Etanercept	Adalimumab	Insulin glargine	Ranibizumab
Reference product	REMICADE JnJ	ENBREL Amgen	HUMIRA AbbVie	LANTUS Sanofi	LUCENTIS Genentech
Launched Manufacturer launch date	INFLECTRA Pfizer Nov 2016 RENFLEXIS Organon July 2018 AVSOLA Amgen July 2020 IXIFI^a Pfizer Dec 2014 <small>^aNot launching in the US.</small>	Ongoing litigation ERELZI Sandoz Aug 2016 ETICOVO Samsung Apr 2019	Biosimilars referencing Humira will launch in 2023 AMJEVITA Amgen Sep 2016 CYLTEZO Boehringer Ingelheim Aug 2017 HYRIMOZ Sandoz Oct 2018 HADLIMA Organon July 2019 ABRILADA Pfizer Nov 2019 HULIO Mylan Jul 2020	SEMGLEE^b Viatris/Mylan July 2021 <small>^bInterchangeability approval by FDA.</small>	BYOOVIZ Biogen Sept 2021
Approved Manufacturer FDA approval date					

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US Biosimilar Market Landscape

As of September 17, 2021

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Approved Manufacturer FDA approval date					

Adapted from US Biosimilar Report by AmerisourceBergen as of September 17, 2021.

US Insulin Biosimilar Market Landscape

As of September 17, 2021

	Insulin (long-acting)		
Molecule	Insulin glargine		Insulin detemir
Reference product	LANTUS (Sanofi)	TOUJEO (Sanofi)	LEVEMIR (Novo Nordisk)
Authorized generic			
Follow-on biologic	BASAGLAR (Eli Lilly) SEMGLEE (Viatris/Mylan)		
Approved but not yet launched biosimilars Manufacturer FDA approval date	SEMGLEE (Viatris/Mylan) July 2021		


SEMGLEE (insulin glargine injection) (follow-on biologic)

- June 2020 – FDA-approved as brand (follow-on biologic) via the 351(a) pathway
- Currently available

SEMGLEE (insulin glargine-yfgn) (biosimilar)

- July 2021 – FDA approved as an interchangeable biosimilar via the 351(k) pathway
 - NOT currently available
- Viatris/Mylan forecasting the launch of biosimilar SEMGLEE near the end of 2021


Adapted from US Biosimilar Report by AmerisourceBergen as of September 17, 2021.



Biosimilar State Substitution Laws

State

All



State	Citation Bill Number Lead Sponsor	First Summary Description (The brief summaries reproduced below are not intended to describe all statutory provisions – see full text for further information)	FDA Must Certify Interchangeability	Prescriber / Doctor "Notification" or "Communication" Required?	Timeframe for "Notification" or "Communication"	Patient Notification Required?	Prescriber's "Brand Necessary" or "Dispense Written" Blocks Sub
Alabama	SB245 Signed 2019 Sponsor: Butler		Yes	Yes	24 hours	Yes	Yes
Alaska	SB 32 Signed 7/13/2018 Sponsor: Sen. Hughes (R-F)	Relates to biological products and the practice of pharmacy. Substitution of an interchangeable biologic is permitted only if the prescriber does not personally indicate that a substitution is not to be made. Requires a pharmacist to make an electronically accessible entry in a patient record system, requiring the Board of Pharmacy to post a link to the U.S. FDA's list of all currently approved interchangeable biological product.	Yes	Yes	3 days	Yes	Yes
Arizona	H 2310 Signed 5/17/2016 as Act No. 293	Allows a pharmacist to substitute a biological product for a prescribed biological if certain conditions are met, including a requirement that the pharmacy inform the patient of the substitution and a requirement that the pharmacy retain a record, requires notification of any	Yes	Yes	5 days	Yes	Yes

Current as of August 30, 2021

Source: Biosimilars Resource Hub. FormularyDecisions. Updated August 30, 2021. Accessed September 3, 2021.



Biosimilar State Substitution Laws

State

All



State-specific insights provided by the tool:

- Does the FDA need to certify interchangeability first?
- Does the prescriber need to be notified?
 - What is the time frame for notification?
- Do patients need to be notified?
- Does a prescriber notation of "brand medically necessary" or "dispense as written" block substitution?
- Do pharmacy records need to be retained?

State

All

Alabama							
Alaska							
Arizona	H 2310 Signed 5/17/2016 as Act No. 293	Allows a pharmacist to substitute a biological product for a prescribed biological if certain conditions are met, including a requirement that the pharmacy inform the patient of the substitution and a requirement that the pharmacy retain a record, requires notification of any	Yes	Yes	5 days	Yes	Yes

Current as of August 30, 2021

Source: Biosimilars Resource Hub. FormularyDecisions. Updated August 30, 2021. Accessed September 3, 2021.

Reactions to an Interchangeable Biosimilar

“Biosimilar and interchangeable biosimilar products have the potential to greatly reduce healthcare costs.”

– Janet Woodcock, MD, Acting FDA Commissioner

“Approval of the first interchangeable biosimilar product furthers FDA’s longstanding commitment to supporting a competitive marketplace for biological products.”

– Janet Woodcock, MD, Acting FDA Commissioner

“Access to affordable insulin is critical and long-acting insulin products, like insulin glargine, play an important role.”

– Peter Stein, MD, Director of the Office of New Drugs, FDA Center for Drug Evaluation and Research

“New FDA-approved biosimilar interchange at the pharmacy can lead to cost savings.”

– LinkedIn user

“The first interchangeable biosimilar is now on the market, with more on the horizon. Let’s see if this helps translate into uptake!”

– LinkedIn user

“Now that the first biosimilar **#insulin** product (SEMGLEE) has received the **#FDA** interchangeability designation, US pharmacists need to be informed about their state’s requirements for **#interchangeability** and pharmacy-level **#substitution** of biologics.”

– LinkedIn user

“I am curious what everyone is doing with **#lantus** to **#semglee** **#biosimilarinterchange**. I would appreciate if you could share comments/insights on the following (independent of payer requirements):

1. Are you changing for all patients or just new patients?
2. Are you telling the doctor before changing (assuming no DAW)?
3. Are you asking the patient if they are okay with the change, if they are a new patient?
4. What are the biggest barriers for interchange?”

– LinkedIn user

Key: DAW – dispense as written.

Sources: FDA approves first interchangeable biosimilar insulin product for treatment of diabetes. News release. FDA. July 28, 2021. LinkedIn posts featuring “biosimilar interchange.” Accessed September 3, 2021.

Audience Participation

- What marketplace dynamics will be the key influences in adoption of interchangeable biosimilars? (Please select all that apply.)

- A. Formulation
- B. Regulatory
- C. Patient affordability
- D. Payer coverage

US Biosimilar Market Landscape

As of September 17, 2021

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Approved Manufacturer FDA approval date			

Adapted from US Biosimilar Report by AmerisourceBergen as of September 17, 2021.

A Closer Look at the Targeted Immunomodulator Landscape

ENBREL

- Due to ongoing litigation, biosimilars are not expected to launch until 2028/2029

STELARA

- Patent expiration in Sept 2023
- Manufacturers in various stages of clinical trials for biosimilars

Indication											
	Rheumatoid arthritis	Psoriatic arthritis	Juvenile idiopathic arthritis	Ankylosing spondylitis	Crohn's disease	Plaque psoriasis	Ulcerative colitis	Hidradenitis suppurativa	Uveitis		
Product	Manufacturer	Market size (\$B)									
▶ Humira CF	AbbVie	25.9		X	X	X	X	X	X	X	
▶ Humira non-CF	AbbVie	10.1		X	X	X	X	X	X	X	X
▶ Enbrel	Amgen	7.8		X	X	X	X	X			
▶ Stelara	JnJ	13.4			X		X	X	X		
▶ Remicade	JnJ	8.3		X	X		X	X	X	X	
▶ Inflectra	Pfizer	1.5		X	X		X	X	X	X	
▶ Renflexis	Organon	0.6		X	X		X	X	X	X	
▶ Avsola	Amgen	0.0		X	X		X	X	X	X	

Key

- ▶ Products with biosimilars, either launched, approved, or in the pipeline
- ▶ Launched biosimilars

Content on this slide, to include brand drug names and manufacturers, is for educational purposes only.

Key: WAC – wholesale acquisition cost.

Market size based on WAC sales (Source: IQVIA).

Adapted from AmerisourceBergen, data on file.

A Closer Look at the Targeted Immunomodulator Landscape

Key

- ▶ Products with biosimilars, either launched, approved, or in the pipeline
- ▶ Launched biosimilars
- ▶ Pipeline biosimilars that have been submitted for interchangeability status

HUMIRA non-citrate free (CF)

- Multiple FDA-approved biosimilars will begin launching in Q1 2023

HUMIRA CF

- Alvotech/Teva biosimilar pending FDA approval

Content on this slide, to include brand drug names and manufacturers, is for educational purposes only.

Key: BI – Boehringer Ingelheim; CF – citrate free; WAC – wholesale acquisition cost.

Market size based on WAC sales (Source: IQVIA). Adapted from AmersourceBergen, data on file.

Product	Manufacturer	Market size (\$B)	Indication									
			Rheumatoid arthritis	Psoriatic arthritis	Juvenile idiopathic arthritis	Ankylosing spondylitis	Crohn's disease	Plaque psoriasis	Ulcerative colitis	Hidradenitis suppurativa	Uveitis	
▶ Humira CF	AbbVie	25.9	X	X	X	X	X	X	X	X	X	
▶ Humira non-CF	AbbVie	10.1	X	X	X	X	X	X	X	X	X	
▶ Enbrel	Amgen	7.8	X	X	X	X		X				
▶ Stelara	JnJ	13.4		X			X	X	X			
▶ Remicade	JnJ	8.3	X	X		X	X	X	X			
▶ Inflectra	Pfizer	1.5	X	X		X	X	X	X			
▶ Renflexis	Organon	0.6	X	X		X	X	X	X			
▶ Avsola	Amgen	0.0	X	X		X	X	X	X			
Pipeline biosimilars												
Amjevita	Amgen	Expected launch: 1/21/2023	X	X	X	X	X	X	X			
Hadlima	Organon	Expected launch: 6/30/2023	X	X	X	X	X	X	X			
▶ Cyltezo	BI	Expected launch: 7/1/2023	X	X	X	X	X	X	X			
Hulio	Mylan	Expected launch: 7/31/2023	X	X	X	X	X	X	X			
Hyrmoz	Sandoz	Expected launch: 9/30/2023	X	X	X	X	X	X	X			
▶ Abrilada	Pfizer	Expected launch: 11/20/2023	X	X	X	X	X	X	X			
CHS-0214	Coherus	Pending FDA approval										
▶ AVT02	Alvotech/Teva	Pending FDA approval										



Patent Thickets

- A July 13 hearing in the Senate Judiciary Competition/Antitrust Subcommittee included new ideas to address patents on biologic drugs¹
- Congress could prevent future “patent thickets” by²:
 - Limiting the number of continuation/divisional patents from a single patent filing
 - Specifically capping the number of patents that could be asserted against a biosimilar product

Sources: 1. Senate Subcommittee on Competition Policy, Antitrust, and Consumer Rights. A prescription for change: cracking down on anticompetitive conduct in prescription drug markets. Meeting held on July 13, 2021. 2. Werble C. Patent thickets and legislative logjams. Pink Sheet: Informa Pharma Intelligence. August 23, 2021. Accessed September 7, 2021. <https://pink.pharmaintelligence.informa.com/PS144834/Patent-Thickets-And-Legislative-Logjams>

US Biosimilar Regulatory Landscape

- HR 2148 – Prescription Drug Price Relief Act of 2021
 - At least annually, the Department of Health and Human Services (HHS) reviews all brand name drugs for excessive pricing^a; HHS must also review prices upon petition
 - If any such drugs are found to be excessively priced, HHS must (1) void any government-granted exclusivity; (2) issue open, nonexclusive licenses for the drugs; and (3) expedite the review of corresponding applications for generic drugs and biosimilar biological products. HHS must also create a public database with its determinations for each drug
 - Drug manufacturers report specified financial information for brand name drugs, including research and advertising expenditures

^a A price is considered excessive if the domestic average manufacturing price exceeds the median price for the drug in Canada, the United Kingdom, Germany, France, and Japan. If a price does not meet this criteria, or if pricing information is unavailable in at least 3 of the aforementioned countries, the price is still considered excessive if it is higher than reasonable in light of specified factors, including development cost, revenue, and the size of the affected patient population.
Source: Prescription Drug Price Relief Act of 2021, HR 2148, 117th Cong (2021). Accessed September 7, 2021. <https://www.congress.gov/bills/117/h-congress/house-bill/2148?sa=1&r=4>

US Biosimilar Regulatory Landscape (cont.)



- S 1427/HR 2869 – Cosponsor Biosimilars Shared Savings Demo
 - Directs CMS to establish a voluntary, national demonstration project under Medicare Part B to evaluate the benefit of providing a shared savings payment for biosimilars
 - Participating providers would receive a portion of the savings for prescribing a biosimilar with a lower average sales price (ASP) than the reference biologic
 - This program would create a financial incentive to administer biosimilars, guaranteeing savings for Medicare and taxpayers



- HR 2846 – Cosponsor the Ensuring Access to Lower-Cost Access for Seniors Act
 - Ensures seniors are able to access and fully benefit from low-cost generics and biosimilars through the Medicare Part D program
 - HR 2846 would ensure new generics and biosimilars are covered upon launch, provide that generics are placed only on generic tiers with lower cost-sharing and not higher brand cost-sharing tiers, and establish a new specialty tier for biosimilars and specialty generics



- HR 2815 – Cosponsor the BIOSIM Act
 - Currently, providers in Medicare Part B are reimbursed for administering biosimilars at ASP+6% of the brand name biologic
 - The BIOSIM Act would increase reimbursement for biosimilars by 2% to ASP+8% and would apply only when the biosimilar's ASP is lower than the brand name biologic's ASP
 - Currently, biosimilars have, on average, a 30% lower ASP than their respective reference biologic

Key: ASP – average sales price; CMS – Centers for Medicare & Medicaid Services.

Source: Biosimilars Council - A Division of AAM. Increase patient access to lower-cost biosimilar medicines. March 12, 2020. Accessed September 3, 2021. <https://biosimilarscouncil.org/resource/increase-patient-access-to-lower-cost-biosimilar-medicines/>

US Biosimilar Pipeline Landscape

- Targeted immunomodulators
 - Infliximab, etanercept, adalimumab, ustekinumab, tocilizumab
- Insulins
- Supportive care
 - Filgrastim, epoetin, pegfilgrastim
- Oncology
 - Rituximab, bevacizumab, trastuzumab
- Ophthalmology
 - Ranibizumab, aflibercept
- Immunosuppressants
 - Eculizumab, omalizumab, natalizumab
- Bone health
 - Denosumab
- Growth hormone
 - Somatropin, somapacitan
- Infertility
 - Corifollitropin alfa, follitropin alfa, follitropin delta

Adapted from US Biosimilar Report by AmerisourceBergen as of September 17, 2021.

Existing Research on Biosimilar Coverage, Adoption, and Utilization

Audience Participation

Which Wahlberg was in New Kids on the Block?



Please note the word cloud will form as the attendees respond.

Biosimilar Coverage Policies

Based on database of 535 coverage decisions, regarding 9 available biosimilars, at 17 of the largest commercial health plans in the US

Coverage decisions where biosimilars were:



Adapted from Chambers J, et al. JAMA. 2020;323(19):1972-1973.

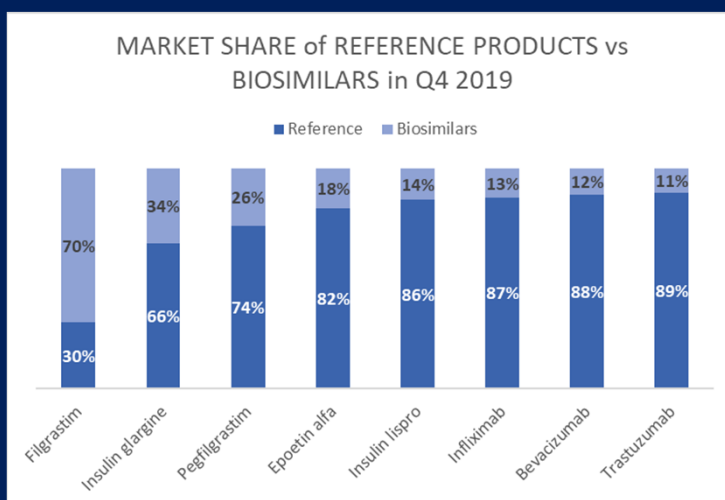
Biosimilar Coverage Policies (cont.)

Biosimilar product	Preferred	On par	NON-preferred
Bevacizumab-awwb	0%	98%	2%
Epoetin alfa-epbx	21%	71%	7%
Filgrastim-aafi	39%	57%	4%
Filgrastim-sndz	51%	49%	0%
Infliximab-abda	0%	35%	65%
Infliximab-dyyb	5%	36%	59%
Pegfilgrastim-cbqv	13%	80%	7%
Pegfilgrastim-jmdb	14%	64%	21%
Trastuzumab-anns	0%	100%	0%

Adapted from Chambers J, et al. *JAMA*. 2020;323(19):1972-1973.

Biosimilar Coverage Policies (cont.)

- Select biosimilars launched through 2019
- Regression models estimated that the market share of reference products would decline by ~0.38% to 0.46% for each month a biosimilar was available

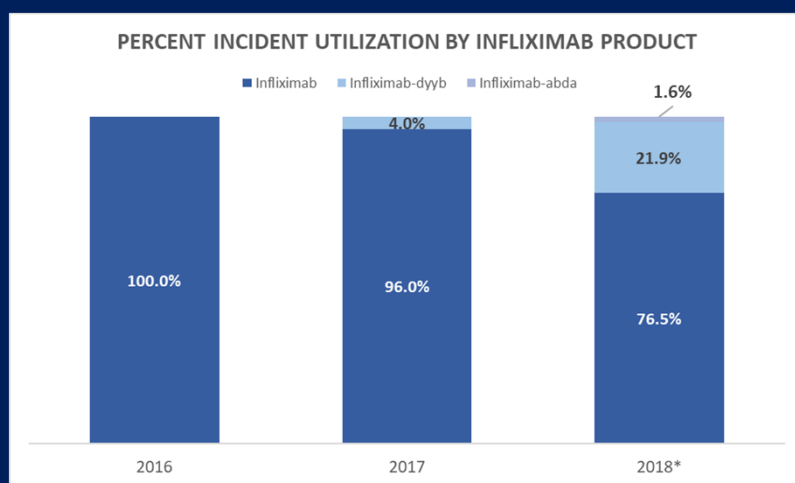


Adapted from Stern A, et al. *Health Affairs*. 2021;40(6):989-999.

Biosimilars: Real-World Utilization

- Biologics and Biosimilars Collective Intelligence Consortium (BBCIC)
- Longitudinal utilization and patient characteristics
- Products with marketed biosimilars:
 - Infliximab
 - Filgrastim
 - Insulins
 - Trastuzumab

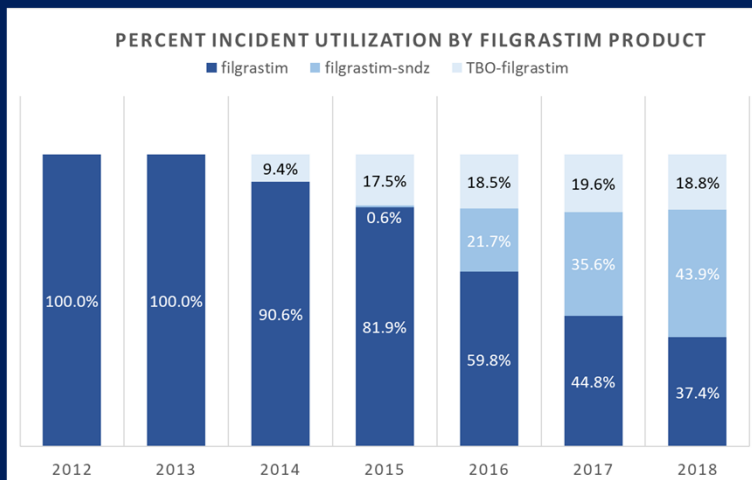
Biosimilar Utilization - Infliximab



*NOTE: 2018 data were incomplete for some partners.

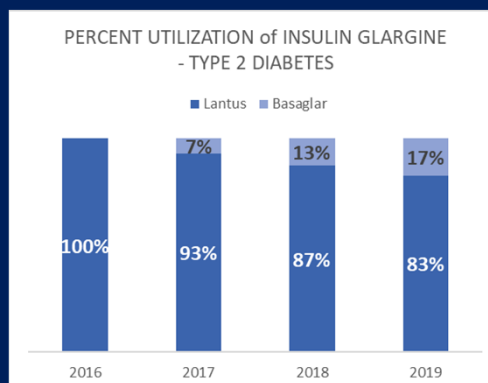
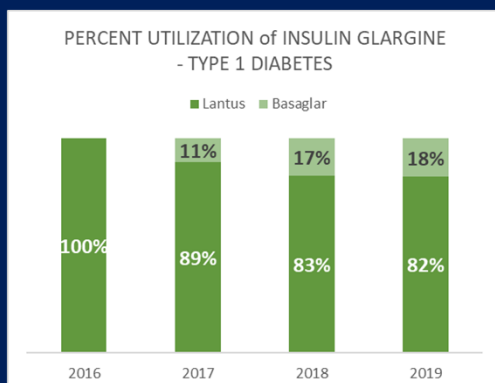
Adapted from Mendelsohn A, et al. *Pharmacol Res Perspect.* 2021;9(1):e00708.

Biosimilar Utilization - Filgrastim

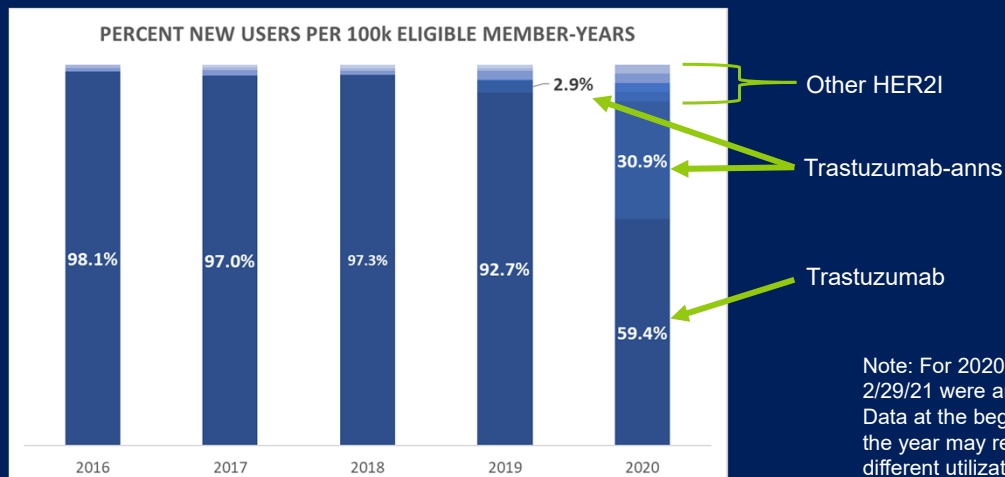


Adapted from Mendelsohn A, et al. *Drugs Real World Outcomes*. 2021;8(2):125-130.

Biosimilar Utilization - Insulin



Biosimilar Adoption and Utilization



Note: For 2020, data up to 2/29/21 were analyzed. Data at the beginning of the year may reflect different utilization compared to the rest of the year due to coverage changes.

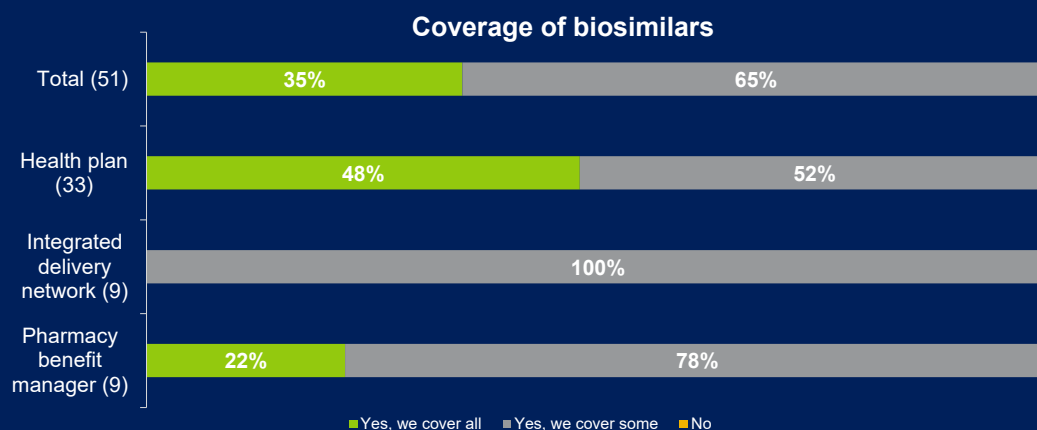
Adapted from Nam YH, et al. Poster presented at: AMCP Nexus 2021; October 19-21, 2021; Denver, CO.

Biosimilars Research From the Payer Perspective

Audience Participation

- What is the best New Kids on the Block (NKOTB) song?
 - A. Step by Step
 - B. You Got It (The Right Stuff)
 - C. Hangin' Tough
 - D. Other
 - E. None. Just None.

Payers Are not Covering all Biosimilars



N=51
Q1. Does your organization cover biosimilars?

Payers Agree That Biosimilars Provide Meaningful Cost-Savings

Level of agreement with the following statement:
Biosimilars have provided my organization with meaningful cost-savings

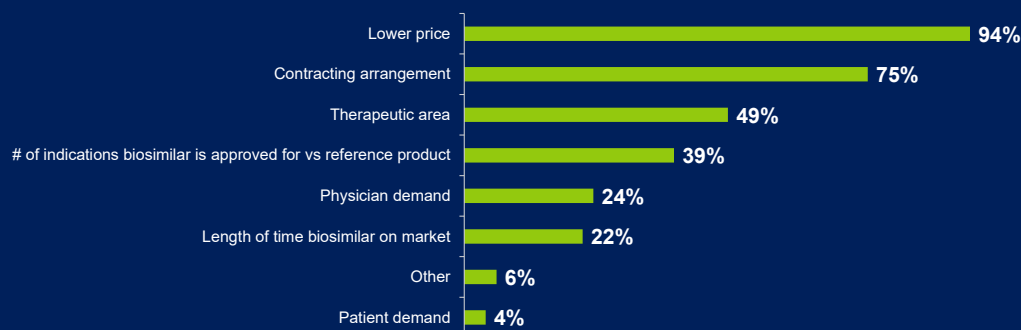


N=51

Q9. Please rate your level of agreement with the following statement: biosimilars have provided my organization with meaningful cost-savings.

Pricing Drives Preferred Product Decisions

Factors influencing preferred product designations when 1 or more biosimilars are available



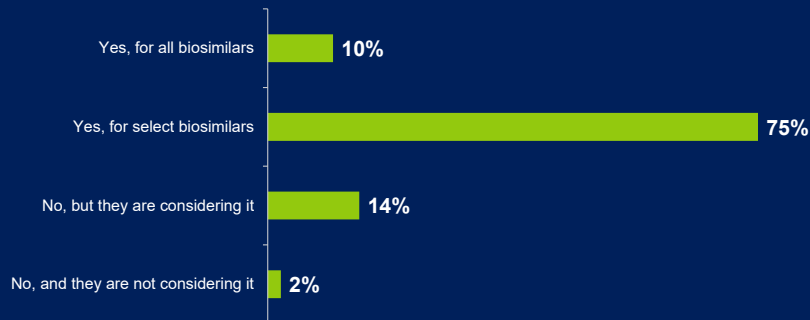
N=51

Q6. Which of the following factors (if any) influence your decision to designate a preferred product (reference product or biosimilar) when 1 or more biosimilars are available? Please select all that apply.

Organizations Are Contracting With Biosimilar Manufacturers



Contracting with biosimilar manufacturers

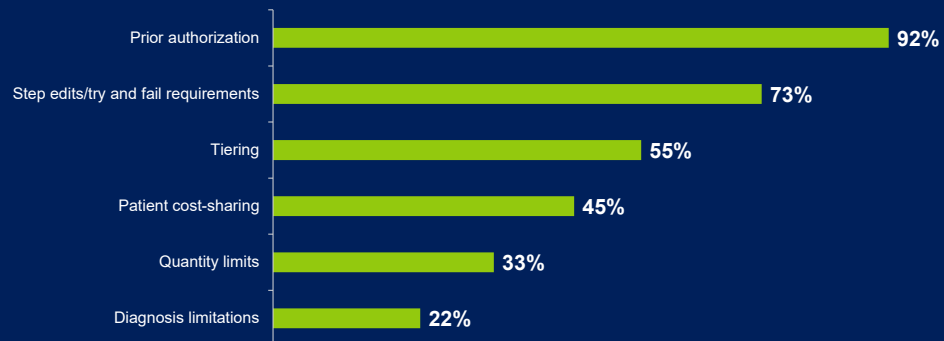


N=51
Q5. Does your organization contract with biosimilar manufacturers?

Formulary Management Occurs Most Often Through Prior Authorization



Formulary management techniques to encourage preferred products

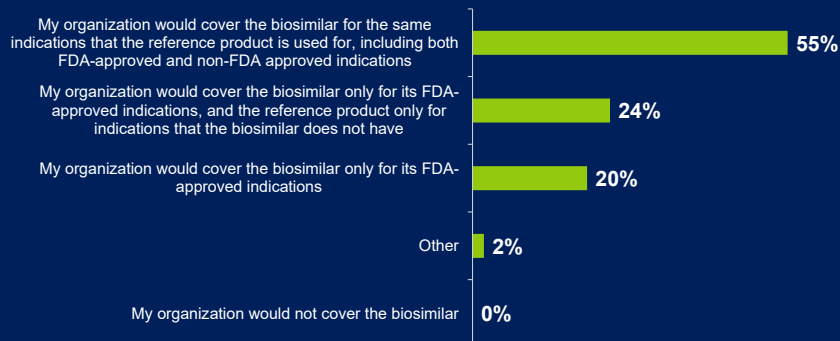


N=51
Q4a. What formulary management techniques does your organization utilize to encourage use of the preferred products (reference product or biosimilar)? Please select all that apply.

FDA-Approved Indications Are not the Deciding Coverage Factor



Coverage of biosimilars by indications



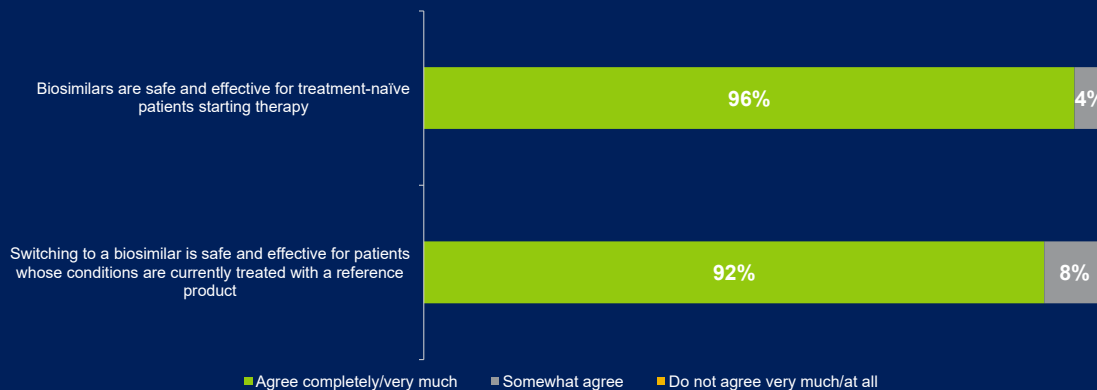
N=51

Q8. If the reference product has FDA-approved indications that the biosimilar does not, how (if at all) does that affect your organization's decision to cover the biosimilar?

Switching Is Seen as Safe and Effective



Level of agreement with statements about biosimilar safety and effectiveness



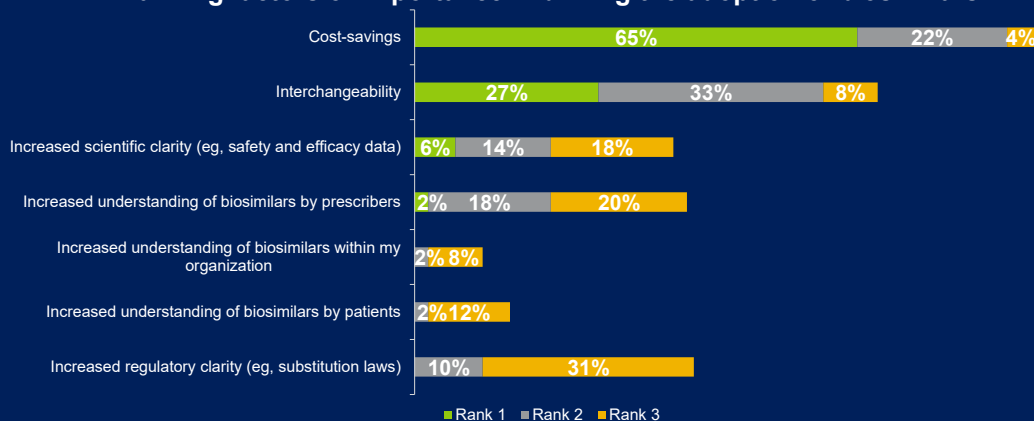
N=51

Q7. Please rate your level of agreement with the following statements: switching to a biosimilar is safe and effective for patients whose conditions are currently treated with a reference product; biosimilars are safe and effective for treatment-naïve patients starting therapy.

Cost-Savings and Interchangeability Could Drive Further Adoption of Biosimilars



Ranking factors of importance in driving the adoption of biosimilars



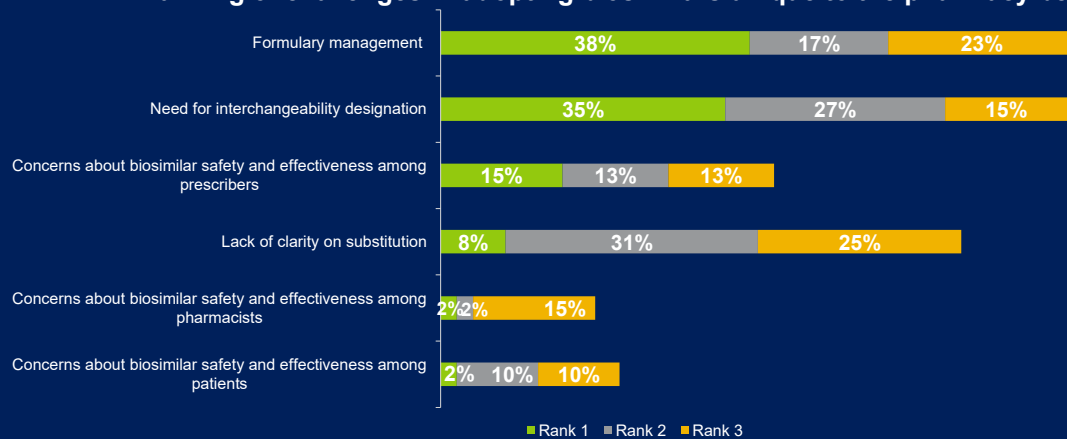
N=51

Q10. Please rank, in order of importance, the following factors that would help drive adoption of biosimilars within your organization.

Potential for Formulary Management and Interchangeability to Drive Utilization



Ranking of challenges in adopting biosimilars unique to the pharmacy benefit



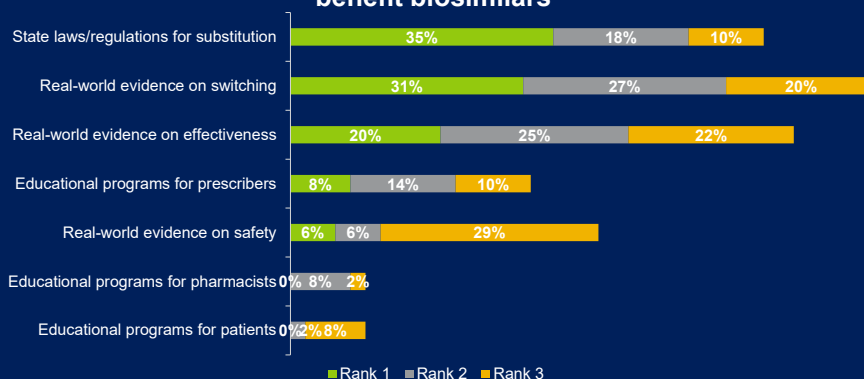
N=51

Q17. Please rank, in order of importance, the challenges to adoption of biosimilars you anticipate that are unique to pharmacy benefit vs those covered by the medical benefit?

Payers Highlight Need for Substitution Laws and Real-World Evidence on Switching



Ranking of solutions to overcome barriers to the adoption of pharmacy benefit biosimilars



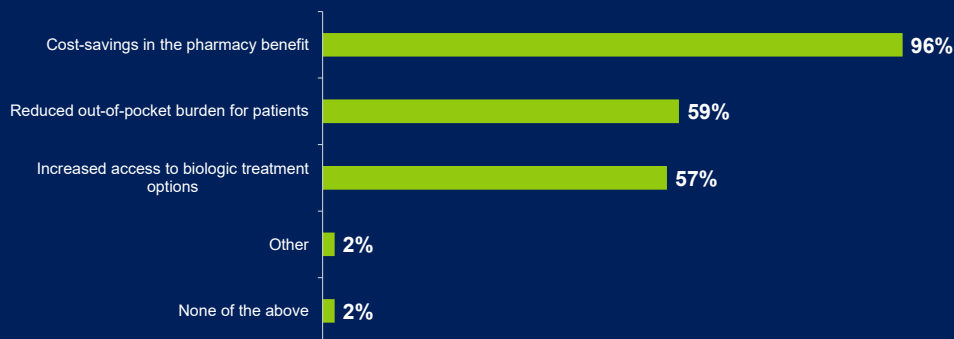
N=51

Q18. Please rank, in order of importance, solutions that would be most likely to help overcome those barriers to adoption of pharmacy benefit biosimilars.

Cost-Savings Anticipated to Be Primary Effect of Pharmacy Benefit Biosimilars



Impact of pharmacy benefit biosimilars



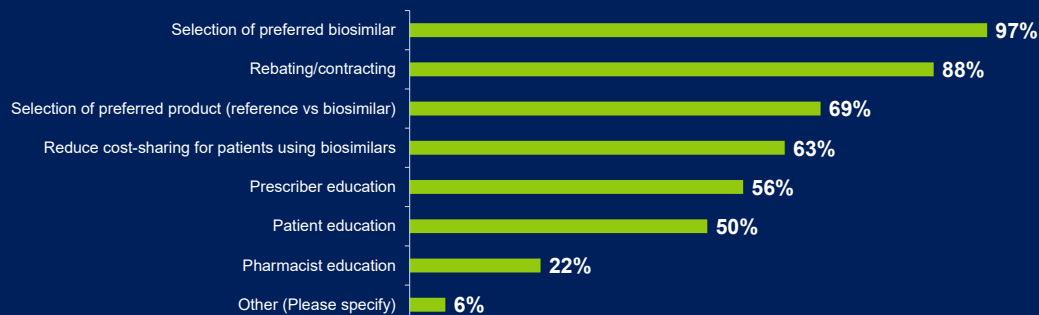
N=51

Q19. How do you anticipate availability of pharmacy benefit biosimilars will impact your organization? Please select all that apply.

Among Payers Planning for Pharmacy Benefit Biosimilars, Most Anticipate a Preferred Product



Planned policies or strategies



N=51

Q20. Is your organization discussing policies or formulary strategies in anticipation of pharmacy benefit biosimilar entry (ie, Humira® patent expiry in 2023)?

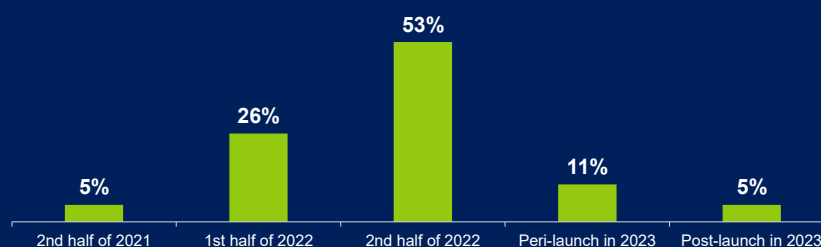
N=32

Q21. What policies or formulary strategies is your organization planning in anticipation of pharmacy benefit biosimilars? Please select all that apply.

88% Are Monitoring the Pipeline, With Policy Development Next Year



Policy development timeline for pharmacy benefit biosimilars



N=19

Q24. When will your organization develop policies or formulary strategies for pharmacy benefit biosimilars (assuming the first pharmacy benefit biosimilars are launched in 2023)?

Framework for Success

Audience Participation

I just spent the last 15 minutes looking up what 'New Kids on the Block' is.



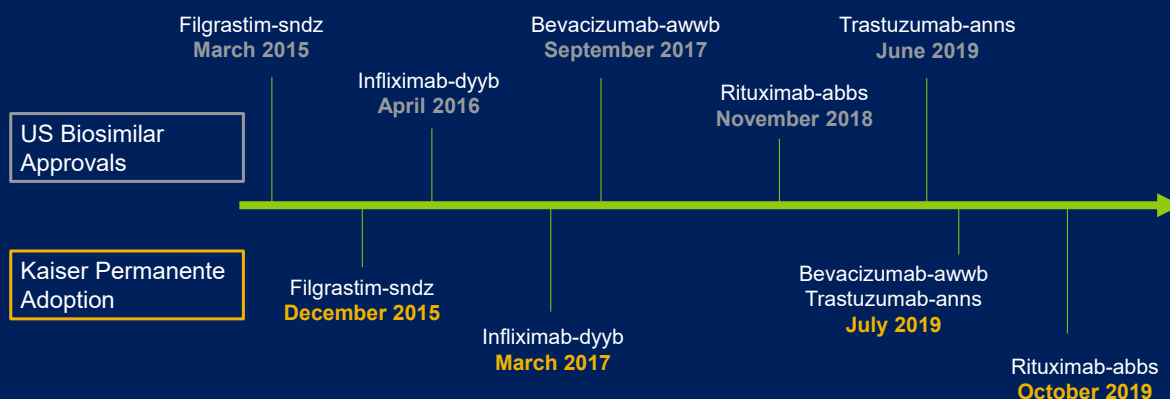
Utilization Management Success

- Providence St. Joseph Health (PSJH) – Nonprofit system with 51 hospitals and >800 clinics, mainly on the West Coast of the US
- Built tools in its EHR system guiding prescribers to preferred biosimilars
- Streamlined prescriber/pharmacist workflow, simplified ordering processes, and improved efficiency
- Medication utilization management saved PSJH almost \$10 million on biologic drugs in 2019 by using biosimilars

Source: Humphreys S. Hospital system boosts biosimilar use with EHR system. April 4, 2020. Accessed September 2, 2021. <https://www.centerforbiosimilars.com/view/hospital-system-boosts-biosimilar-use-with-ehr-system>

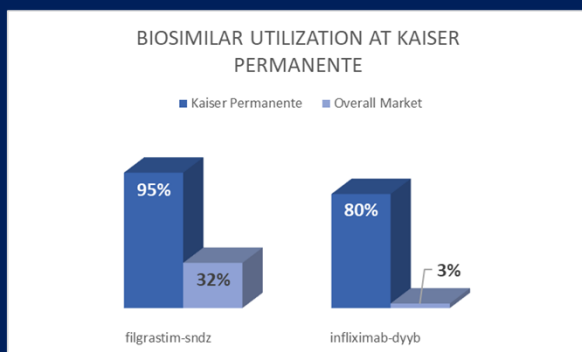
Utilization Management Success (cont.)

- Kaiser Permanente formulary management



Source: Kaiser Permanente Institute for Health Policy. Biosimilars at Kaiser Permanente. December 2020. https://www.kpihp.org/wp-content/uploads/2020/12/Biosimilars_at_KP_121420_FINAL.pdf

Utilization Management Success (cont.)



- Integrated delivery network
- Prescriber confidence in the formulary
- Unified effort across the organization

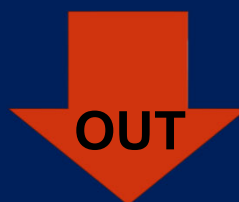
Source: Kaiser Permanente Institute for Health Policy. Biosimilars at Kaiser Permanente. December 2020. https://www.kpihp.org/wp-content/uploads/2020/12/Biosimilars_at_KP_121420_FINAL.pdf

Pharmacy Benefit Manager (PBM) Response to Biosimilars

CVS Caremark has reordered its list of preferred therapeutics, adjusting the emphasis on biosimilars, and demonstrating that preferential status can change at any time



Insulin glargine (BASAGLAR)
 Insulin detemir (LEVEMIR)
 Bevacizumab-bvzr (ZIRABEV)
 Trastuzumab-anns (KANJINTI)
 Trastuzumab-qyyp (TRAZIMERA)
 Rituximab-pvvr (RUXIENCE)
 Pegfilgrastim-bmez (ZIENTENZO)



Insulin glargine (LANTUS)
 Bevacizumab (AVASTIN)
 Trastuzumab (HERCEPTIN)
 Rituximab (RITUXAN)
 Rituximab-arrr (RIABNI)
 Rituximab-abbs (TRUXIMA)
 Pegfilgrastim (all other options)

Source: Hagen T. CVS juggles biosimilar options on its formulary. AMJC – The Center for Biosimilars. Posted August 26, 2021. Accessed September 9, 2021. <https://www.centerforbiosimilars.com/view/cvs-juggles-biosimilar-options-on-its-formulary>

Framework for Success

- Biosimilar adoption in the US had a slow start
- Starting to see increased utilization with less lag-time from launch
- Legal and regulatory hurdles still exist
- Different state laws can lead to confusion
- Many managed care settings are having success implementing strategies to encourage biosimilar use
- Managed care organizations are anticipating pharmacy-benefit biosimilars and identifying formulary strategies
- We now have examples of successful utilization strategies

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FACULTY BIOGRAPHY

Tasmina Hyder, PharmD, MBA, BCGP
Assistant Director of Integrated
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AmerisourceBergen/Xcenda

Tasmina Hyder PharmD, MBA, BCGP, is an Assistant Director of Integrated Technology Solutions at AmerisourceBergen/Xcenda. She leads payer engagement and experience for FormularyDecisions®, a secure online platform facilitating the bi-directional exchange of information between life sciences companies and healthcare decision makers for medical policy and formulary development. Prior to joining AmerisourceBergen/Xcenda, Dr. Hyder served as a consultant for payers for nearly 7 years, with roles including pipeline drug monitoring, budget impact forecasting, proposing innovative strategies for value-based pricing and arrangements, and supporting formulary management services.

She has expertise in gathering payer insights, evidence generation strategies, value framework engagements, outcomes analyzers, quality improvement programs, and publications. Her areas of therapeutic interest include immunology, dermatology, rheumatology, hepatology, and rare diseases. She has authored a variety of scientific publications appearing in the Journal of Managed Care and Specialty Pharmacy, Annals of Pharmacotherapy, Drug Target Insights, Pharmacotherapy, Drug and Alcohol Dependence, and others.

Dr. Hyder received her Doctor of Pharmacy from Albany College of Pharmacy and Health Sciences and Master of Business Administration from Boston College Carroll School of Management. She is an Adjunct Professor at MCPHS University - Boston and University of Massachusetts Medical School.

FACULTY BIOGRAPHY

Cate Lockhart, MS, PharmD, PhD
Executive Director
Biologics and Biosimilars Collective
Intelligence Consortium

Timshel Tarbet, MBA started at SCAN Health Plan in December 2020 as the VP of Business Excellence and Diversity Strategy. Timshel is focused leading initiatives expanding inclusivity both as an from a human resources standpoint but also as a means for SCAN to differentiate ourselves by serving new and existing populations in ways that are linguistically and culturally competent.

Prior to SCAN Timshel spent 16 years at Portland based Cambia Health Solutions, which is part of the BCBS association of plans. During her tenure at Cambia Timshel led the Ethics department where she succeeded in transforming the program into a nationally recognized, award winning program which enhanced engagement across a 5,500 FTE organization. She also spent time at Cambia leading the Enterprise Risk Management and Corporate Accountability area's and in Human Resources as a Human Resources Business Partner, Manager Compensation, Diversity, Equity and Inclusion, and HRIS.

Prior to Cambia Timshel worked in human resources at Multnomah County, the State of Oregon Department of Fish and Wildlife and was a Staff Sergeant in the United States Air Force. Timshel is the proud mother of Mekel (24), Keenan (16), Lily (12), and Dahlia (10).

FACULTY BIOGRAPHY

Jennifer Snow, MPH
Vice President, Reimbursement and
Policy Insights
AmerisourceBergen/Xcenda

Jennifer Snow, MPH, is the Vice President of Reimbursement and Policy Insights and keeps clients and stakeholders informed on the latest legislative and regulatory updates and their commercial impact. Her team analyzes the healthcare environment and provides strategic guidance on how to best navigate challenges to patient coverage and access. Ms. Snow is a subject matter expert on the Affordable Care Act, biosimilars, quality measures, medication adherence and federal health programs, particularly the Medicare Prescription Drug Benefit (Part D). Ms. Snow holds an M.P.H. from the University of North Carolina-Chapel Hill and a B.S. in Russian from Georgetown University