Uptake or Heartbreak with Biosimilars?

Progress and Perspectives

February 24, 2021

AMCP

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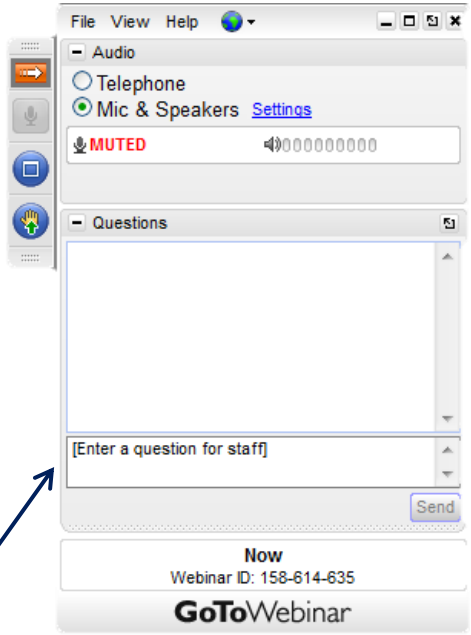
How to Ask a Question



Type your question in the ‘Questions’ area

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Panelists

April M. Kunze
Sr. Director
Clinical Formulary Development &
Trend Management Strategy
Prime Therapeutics

Laurie Fazio
Head of Market Access
FormularyDecisions

Amanda O'Hora
Senior Director
Reimbursement Policy Insights
Xcenda

Moderator

Jocelyn Ulrich, MPH
Deputy Vice President,
Policy, Research and Membership
PhRMA

Webinar Overview

In this session, you will learn:

- Current biosimilars reimbursement trends
- Payer perception and treatment of biosimilars in formulary decision making
- Key considerations for manufacturers to support effective reimbursement and formulary placement
- What’s on the horizon in the biosimilars space

Polling Question

What's your opinion on biosimilars uptake in the US compared to initial expectations?

1 - Much more successful than expected

2 - Slightly more successful than expected

3 - At par with expectations

4 - Less successful than expected

5 - Much less successful than expected

What is a “biologic?”

The Public Health Service Act (PHSA) defines a “biological product” as follows:

- The term “biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

FDA has interpreted the definition of a “protein” as follows:

- Any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size.

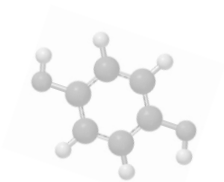
Although FDA previously regulated insulin and some other hormones, as well as certain other products, under New Drug Applications, as of March 23, 2020, such products are “deemed” to be licensed under a Biologics License Application (BLA).

Biologic medicines differ from small molecule medicines

Biologics differ from small molecule medicines in terms of their size and how they are developed.

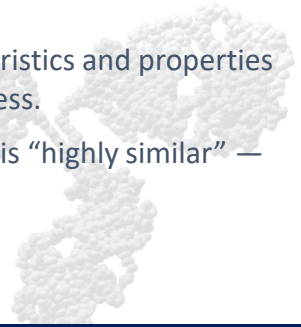
Small Molecule Medicines

- Chemically synthesized.
- Typically a tablet or capsule taken orally (but can be injectables).
- Can be copied as generics where they share the identical active ingredient as a brand medicine.



Biologic Medicines

- Structurally complex and larger than small molecules.
- Typically injected or infused in a doctor's office or hospital setting.
- Made by or from living cells with characteristics and properties heavily influenced by manufacturing process.
- Biosimilars approved on a showing that it is "highly similar" — will never be an exact copy like a generic.



Sources: FDA[1]

Passed in 2010, the Biologics Price Competition and Innovation Act (BPCIA) created a legal framework for biosimilars

ABBREVIATED PATHWAY FOR BIOSIMILARS: Requires biosimilar applicant to demonstrate that their product is highly similar to the reference biologic and that there are no clinically meaningful differences in safety, purity and potency.

IF SEEKING INTERCHANGEABILITY: Requires showing the biosimilar will produce the same clinical result as the reference biologic in any given patient and no additional risk in safety or diminished efficacy with switching back and forth between the products. If interchangeability is demonstrated, biosimilar can be substituted for the reference biologic.

LEGAL FRAMEWORK FOR BIOSIMILARS

PATENT RESOLUTION FRAMEWORK: Creates a process for identification of patents for litigation and a process for resolving patent disputes through litigation.

INCENTIVES FOR INNOVATION: Promotes continued innovation of new life-saving medicines by providing originators 12 years of reference product exclusivity from date of first licensure for new biologics until a biosimilar can be approved.

Sources: FDA [4]

Status of implementation of the biosimilar pathway

Biosimilars are approved under section 351(k) biologics license applications (BLAs)

- Within the last two years, the number of approved biosimilars in the U.S. has more than doubled.
- As of January 2021, 29 biosimilars have been approved by FDA.
  - Referencing 9 originator products
  - 20 have launched
- Numerous final and draft guidances have been released by FDA.
- As of FY2020, there were 104 programs enrolled in the Biosimilar Product Development (BPD) Program.

Biosimilars are achieving significant market uptake and are increasingly leading to cost savings

The introduction of biosimilars is increasingly leading to cost savings in the U.S. market with many originator medicines now competing with multiple biosimilar versions

- Biosimilars are achieving significant market uptake, with three of the biosimilars launched in 2019 achieving between 20% and 42% of market share within their first year.[1]
- Annualized savings from biosimilars reached $6.5 billion in the second quarter of 2020,[2] and savings are modeled to exceed $100 billion in aggregate over the next five years.[3]
- Market trends suggest that uptake by doctors and patients of the coming wave of biosimilars will occur much more quickly than occurred for biosimilars launched earlier, in part due to increased education, awareness and experience among health care providers and patients.[4]

1. IQVIA Institute Report (2020). Biosimilars in the United States 2020 – 2024.
2. San-Juan-Rodriguez A, Gellad WF, Good CB, Hernandez I. (2019) Trends in List Prices, Net Prices, and Discounts for Originator Biologics Facing Biosimilar Competition. JAMA Netw Open. 2(12)
3. IQVIA Institute Report (2020). Biosimilars in the United States 2020 – 2024.
4. Fein, Adam. (2019). We Shouldn't Give Up on Biosimilars – And Here Are the Data to Prove It. Drug Channels. Retrieved from https://www.drugchannels.net/2019/09/we-shouldnt-give-up-on-biosimilarsand.html.

Biosimilars: Payer Perspective

April Kunze, PharmD

Sr. Director, Clinical Formulary Development and Trend Management Strategy

Prime Therapeutics

Landscape of biosimilar management in the U.S.

- **U.S. Biosimilar uptake has been slow relative to the European market**
  - Patents and litigation in the U.S. delay approval and launch of biosimilars
  - A single-payer system in Europe allows for quick adoption
  - Pharma manufacturers deliver mixed messages regarding the similarity/interchangeability of biosimilars
  - Lack of consensus in payer, prescriber and patient communities in the utilization of biosimilars (e.g., indications, place in therapy, etc.)
  - Real-world evidence is not centralized
- **Biosimilars are largely adjudicated in the medical benefit (vs. pharmacy benefit)**
  - Preferred product management on the medical benefit is not as widely adopted as it is on the pharmacy benefit
  - Moving market share can be challenging and takes time
  - Pricing of biosimilars on the medical benefit has been tricky

How is Prime supporting biosimilar adoption?

Prime created a clinical position on biosimilars:

> "Based upon the FDA's requirements for biosimilar approval, including evidence that there are no clinically meaningful differences between a biosimilar and its reference drug, Prime believes that biosimilars can be utilized in place of the reference drugs in most clinical circumstances. This includes indication extrapolation of the respective biosimilar to that of its reference product. Prime holds this position with endorsement from clinicians/specialists from the Prime Therapeutics National P&T committee."

What is happening in the payer market?

National payers are generally in support of and often prefer biosimilars

Kaiser Permanente	United Healthcare	Cigna	Aetna Humana Anthem
• Integrated model • Reporting 80-95% adoption of biosimilars[1] • Uptake attributed to physician buy-in due to clinical review, specialties represented in their P&T	"UnitedHealthcare strives to provide coverage for biosimilars whenever possible to ensure a robust pipeline of future products. Each innovator (original biologic) and its biosimilar are evaluated one by one and when financially supportable, we prefer the biosimilar."[2]	"...Prefer biosimilar(s) over reference product – this is our predominant strategy as we prefer biosimilars over four reference products"[3]	Various communications on biosimilars or specific preferred product placements

1. https://biosimilarsrr.com/2019/11/07/how-did-kaiser-permanente-reach-95-utilization-of-biosimilar-herceptin-and-avastin-so-quickly/. Nov 7, 2019
2. https://www.uhc.com/broker-consultant/news-strategies/resources/specialty-medical-injectable-drug-program-update-moving-to-biosimilars-for-rituxan#:~:text=UnitedHealthcare%20strives%20to%20provide%20coverage,supportable%2C%20we%20prefer%20the%20biosimilar. August 29, 2020
3. https://thedose.cignabigpicture.com/archive/february-2021/how-we-address-biosimilar-products-today/ Accessed 2/11/2021

A Look Forward

- Uptake continues to grow in the U.S. Drug spend in biologic drugs continues to be a driver of trend. Strategies will continue to manage this trend with payers including preferred product selection within the biosimilar space.
- Organizations work to align on position statements and educational materials for providers, patients and others (e.g., AMA, AMCP, etc.)
- Payment structures will quickly adapt to support biosimilar use.
- Biosimilars will launch in drugs adjudicated in the pharmacy benefit and payers will likely use traditional management strategies (e.g., UM, exclusion) to move market share to low net cost drugs.

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An Overview of Biosimilar Activity 2019–2020

Provided by FormularyDecisions℠

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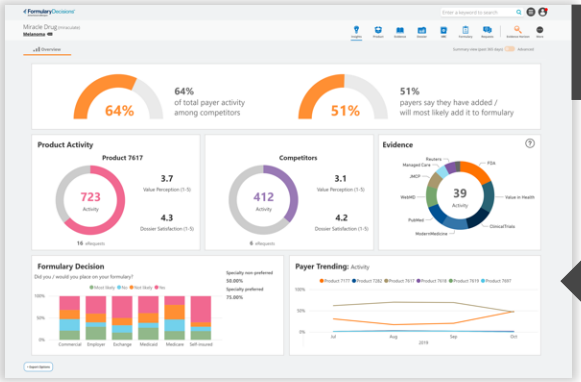
Information Exchange with Largest Active US Payer Community

Manufacturers

Includes pharmaceutical, biotech and medical devices.



Payer Engagement and Integrated Value Communication

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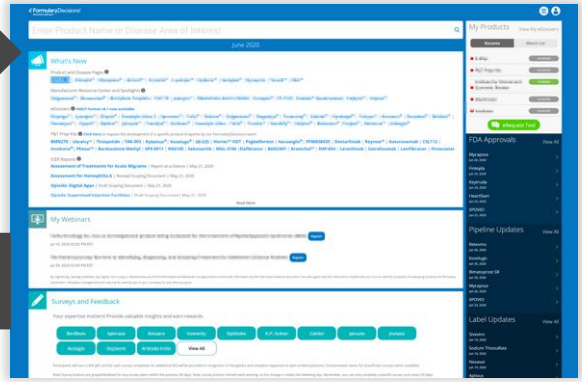
Syndicated Payer Feedback, Insights, and Market Intelligence

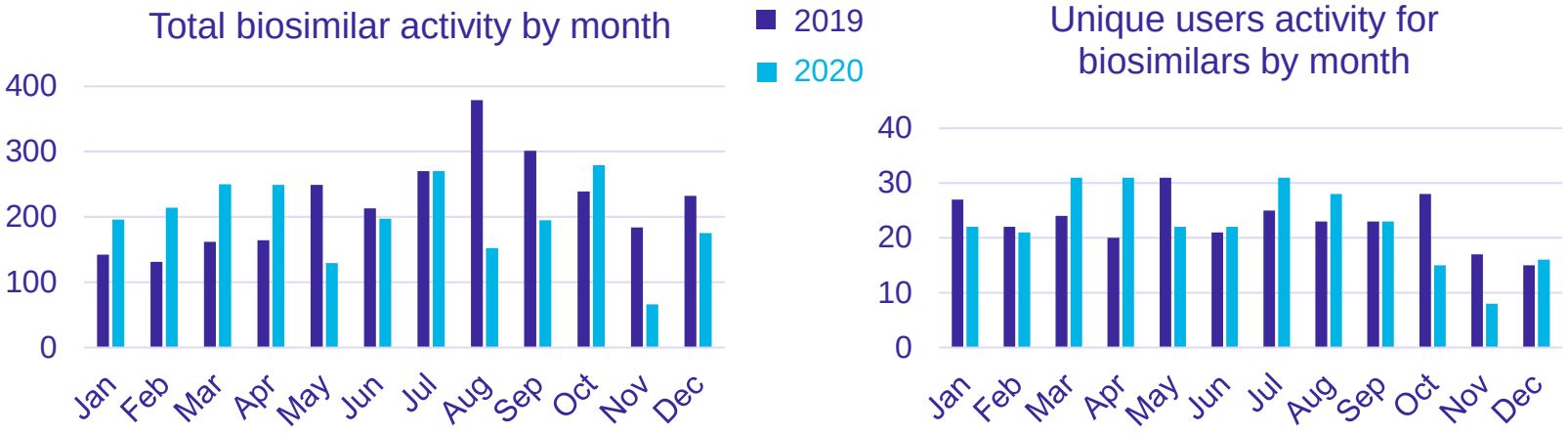
Payer and HCDM Community

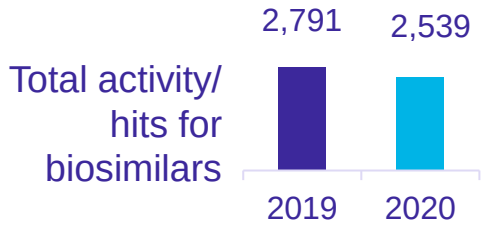
Closed platform of verified HCDMs

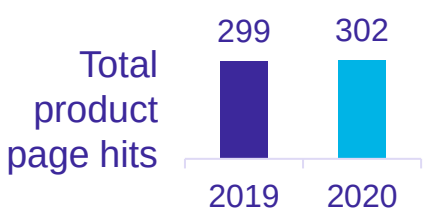


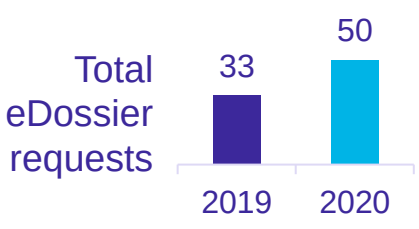
FormularyDecisions enables a bi-directional information exchange between life science organizations and healthcare decision makers

Payers frequently engage with biosimilars on FormularyDecisions℠ to assist with formulary decision making





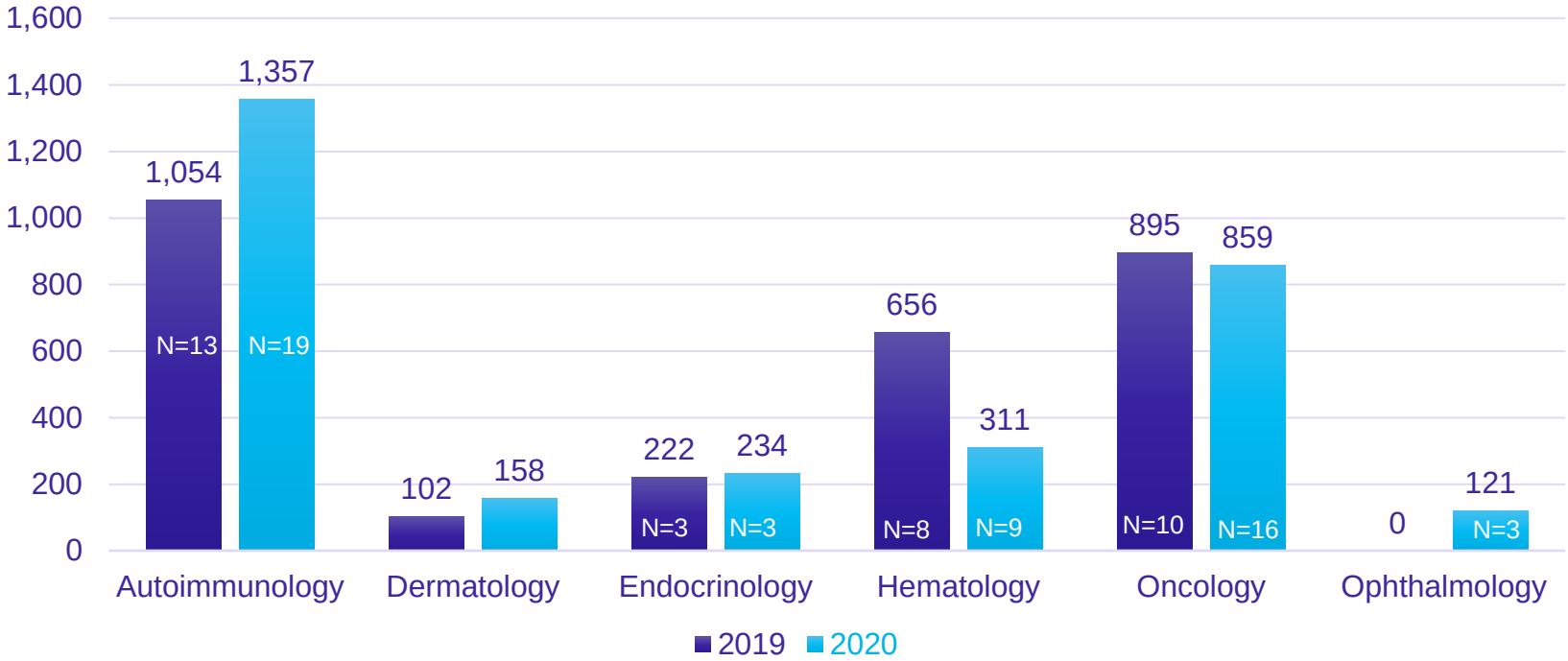




FormularyDecisions℠ data 2019/2020.
46 biosimilar products as of 2020.

Total biosimilar activity increased on average 29%

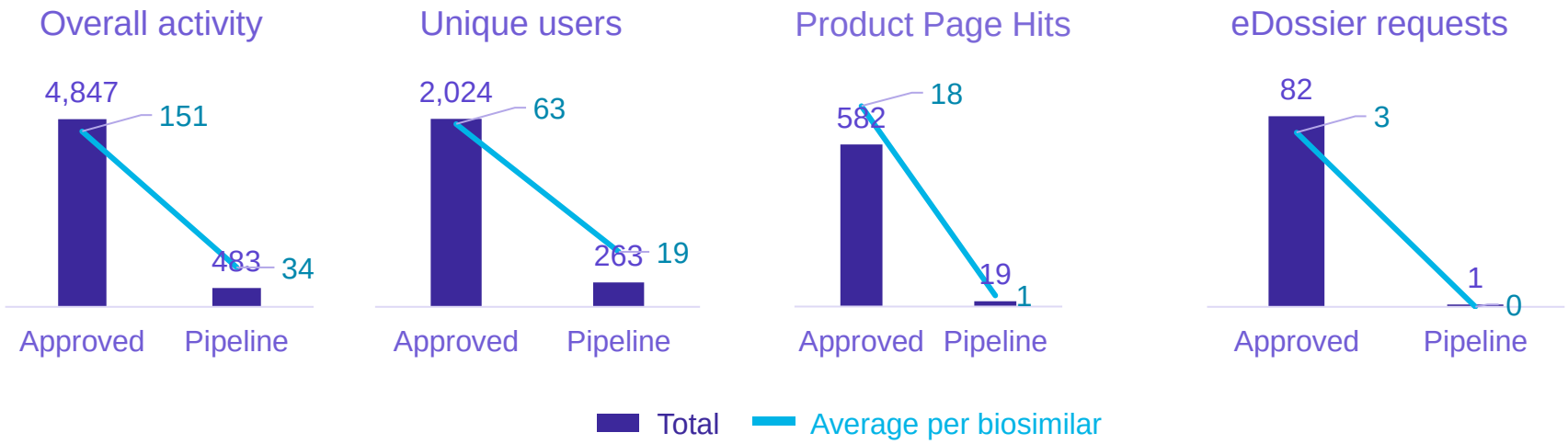
Total activity per therapeutic area



FormularyDecisions℠ data 2019/2020.

46 biosimilar products as of 2020. Some biosimilars have more than one therapeutic area.

Payer engagement is higher with approved (n=32) versus pipeline biosimilars (n=14)



FormularyDecisions℠ data 2019/2020.

Unique users to each biosimilar product pages.

Subscribers receive insights directly from payers

Clinical Efficacy

Biosimilars have a similar efficacy to each other and the originator brand

Economic Value

Biosimilars have a lower cost, which increases value

Needs

- Switch studies
- Superiority trials

"Additional trials using Biosimilar 1 rather than just using the data from Innovator and proving they are not different—this would give patients more peace of mind in using product." **– Pharmacist: 0–100,000 Covered Lives**

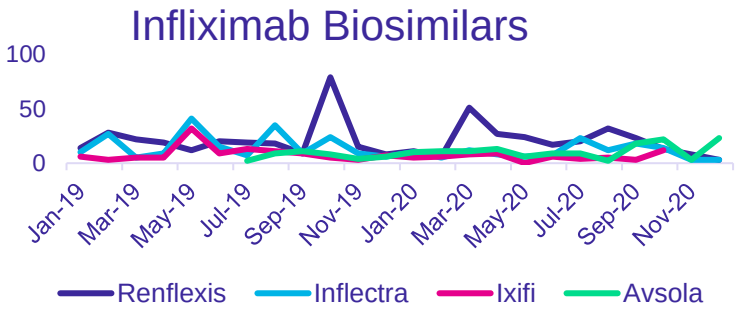
"Comparative data between Biosimilar 1 and Biosimilar 2 would shed light on the values of these two biosimilar products."
– Pharmacist: 100,000–300,000 Covered Lives

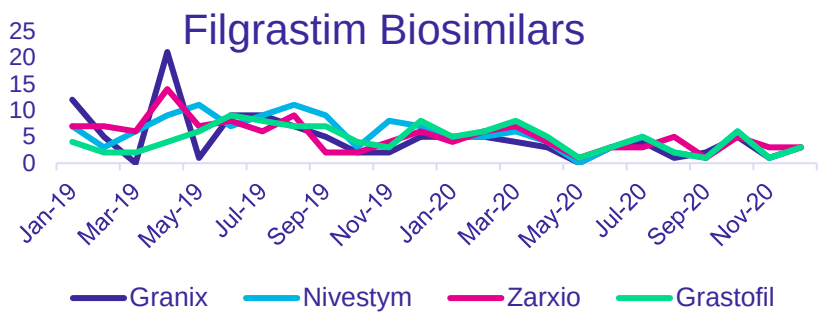
"We view as an organization that biosimilar products have essentially the same efficacy as the reference."
– Pharmacist: 500,000–1,000,000 Covered Lives

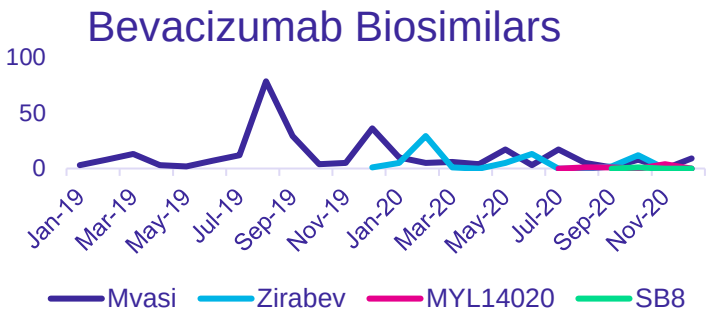
"Biosimilar 1 and Biosimilar 2 are much less expensive than Innovator with similar outcomes. Clinical efficacy would be improved with more clinical trial data in disease states that have not yet been studied. Switch studies would also improve the ability to mandate patients switch from Brand Innovator to Biosimilar 1." **– Pharmacist: 500,000–1,000,000 Covered Lives**

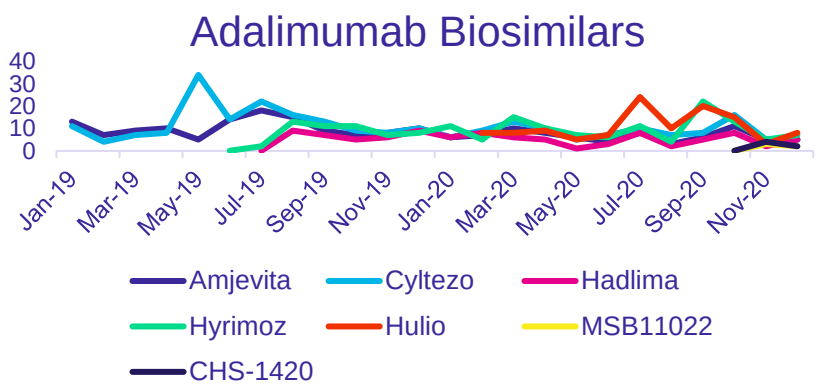
FormularyDecisions℠ data 2019/2020.

Competitive biosimilar products have similar activity trends





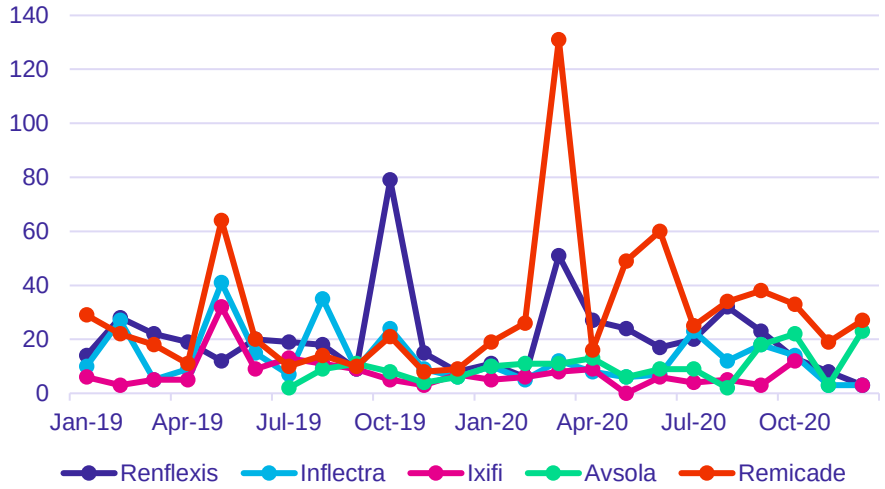




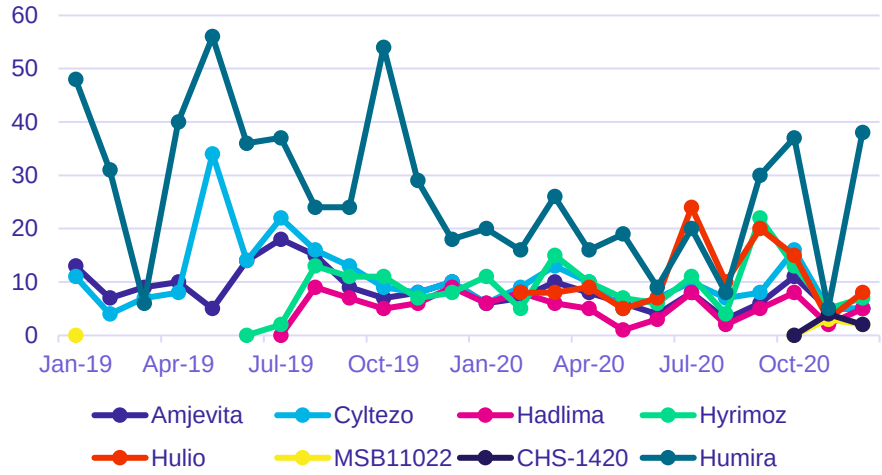
FormularyDecisions℠ data 2019 to 2020.

Some brand originators maintain a higher level of activity

Infliximab biosimilars



Adalimumab biosimilars



FormularyDecisions℠ data 2019 to 2020.

Executive Summary

- Payer engagement with biosimilars is steady
- Dossier requests are increasing
- Payer engagement is higher with approved vs pipeline biosimilars
- Many groups of competitive biosimilar products have similar activity trends
- Payer interest in originator may be sustained

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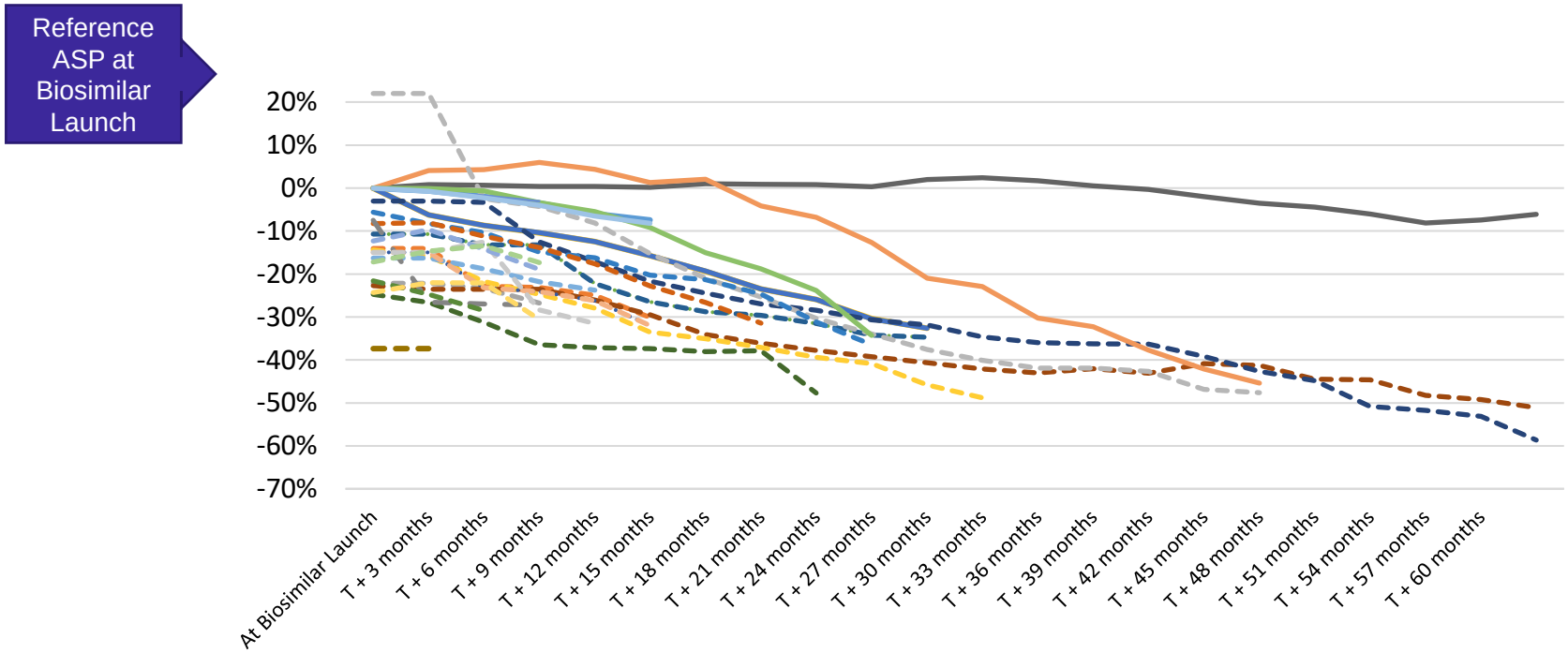
Trends in Biosimilars

Biosimilars have resulted in lower ASPs of originator and biosimilars in every class



Key: Solid lines = originator product; dotted lines = biosimilar; ASP = average sales price

Source: Xcenda Analysis of CMS January 2021 ASP file. Represents 9 originators and 18 biosimilars.

Payer formularies vary with regards to biosimilars coverage

Payer	Neupogen	Granix	Zarxio	Nivestym	Neulasta	Fulphila	Nyvepria	Udenyca	Ziextenzo
United Healthcare	Non-Preferred	Non-Preferred	Preferred	Non-Preferred	Preferred	Non-Preferred	Non-Preferred	Non-Preferred	Preferred
Aetna Premier Plans	PA, ST	PA, ST	PA	PA	PA, QL	PA, ST, QL	Not Listed	PA, QL	PA, ST, QL
Humana 4-Tier Traditional	SM	SM	SM	SM	SM	SM	SM	SM	SM
Harvard Pilgrim Value 5-Tier	Tier 4, PA	Tier 4, PA	Tier 4, PA	Tier 4, PA	Tier 5, PA	Tier 5, PA	Non-Formulary	Tier 5, PA	Tier 5, PA
Kaiser Permanente POS Plan With Specialty Drug Tier	Tier 4, PA	Tier 4, PA	Tier 4, PA	Tier 4, PA	Tier 4, PA	Tier 4, PA	Tier 4, PA	Tier 4, PA	Tier 4, PA
Pharmacy Benefit Manager									
CVS Caremark Performance Drug List	Non-Preferred	Non-Preferred	Non-Preferred	Preferred	Non-Preferred	Non-Preferred	Not Listed	Non-Preferred	Preferred
Express Scripts	Excluded	Excluded	Preferred	Preferred	Excluded	Preferred	Not Listed	Excluded	Preferred

Key: PA – prior authorization; POS – Point-of-Service; ST – step therapy; SM – Specialty Medicine .

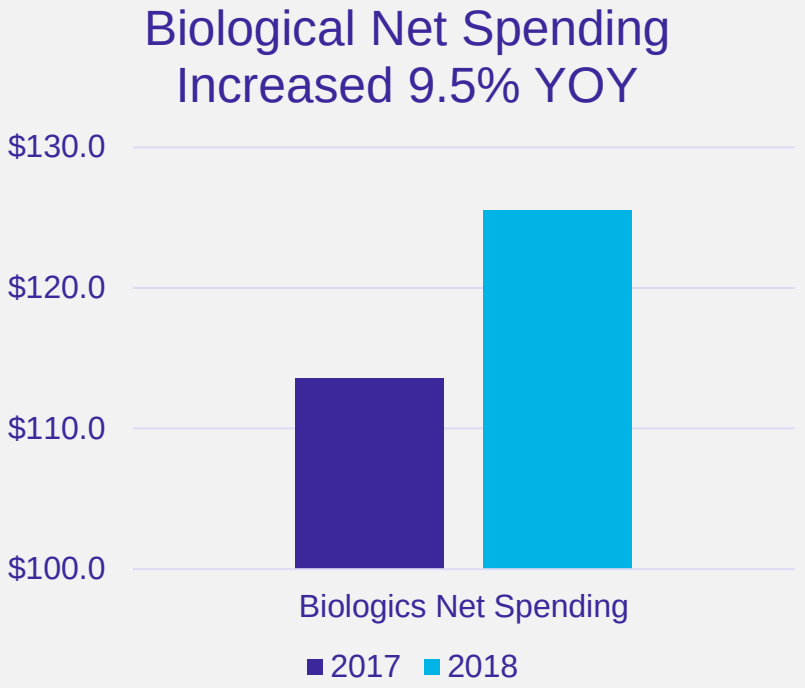
Source: Xcenda Analysis of individual plan formularies websites, February 2021.

Biosimilar market share is small, but is expected to continue increasing

Biosimilar spending has doubled since 2017 but still represents under 2% of the total US biologics market.

The Biosimilar share of the accessible market has generally been rising, and now averages 31%.

The impact of brands losing exclusivity over the next five years, is expected to generate savings of $78 billion for that same period. Part of those savings could be reached through increased biosimilar adoption.



Sources: IQVIA Medicine Use and Spending in the U.S., May 2019; The Center for Biosimilars May, 2019

Cautiously optimistic future for biosimilars

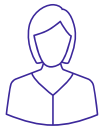
Market share potential of biosimilars continues to grow

- New biosimilar products in new classes; additional biosimilars in existing classes
- Payer formulary and coverage decisions drive utilization and prescribing behaviors

Regulatory and policy changes could affect reimbursement and access

- Changes in drug pricing calculations and payment methodologies
- Patient out-of-pocket costs
- Severability of the Affordable Care Act

What manufacturers are doing with biosimilars



Patients

- Product education
- Patient support programs
  - Copay support
  - Free goods

Providers

- Product education
- Hub services
- Reimbursement tools
- Field reimbursement

Payers

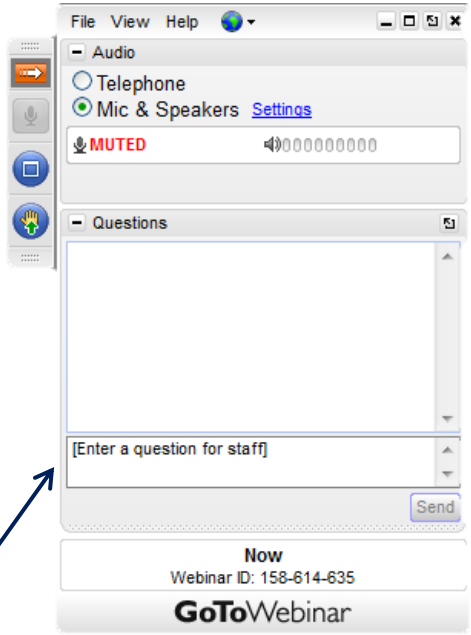
- Product education
- Contracting and rebating
- Pharmacoeconomic analysis

Other Stakeholder-Specific Needs

- Counter-detailing from originator manufacturers
- Marshal support from opinion leaders
- Monitor payer formularies and regulatory/ legislative changes

Questions?

How to Ask a Question



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Questions?

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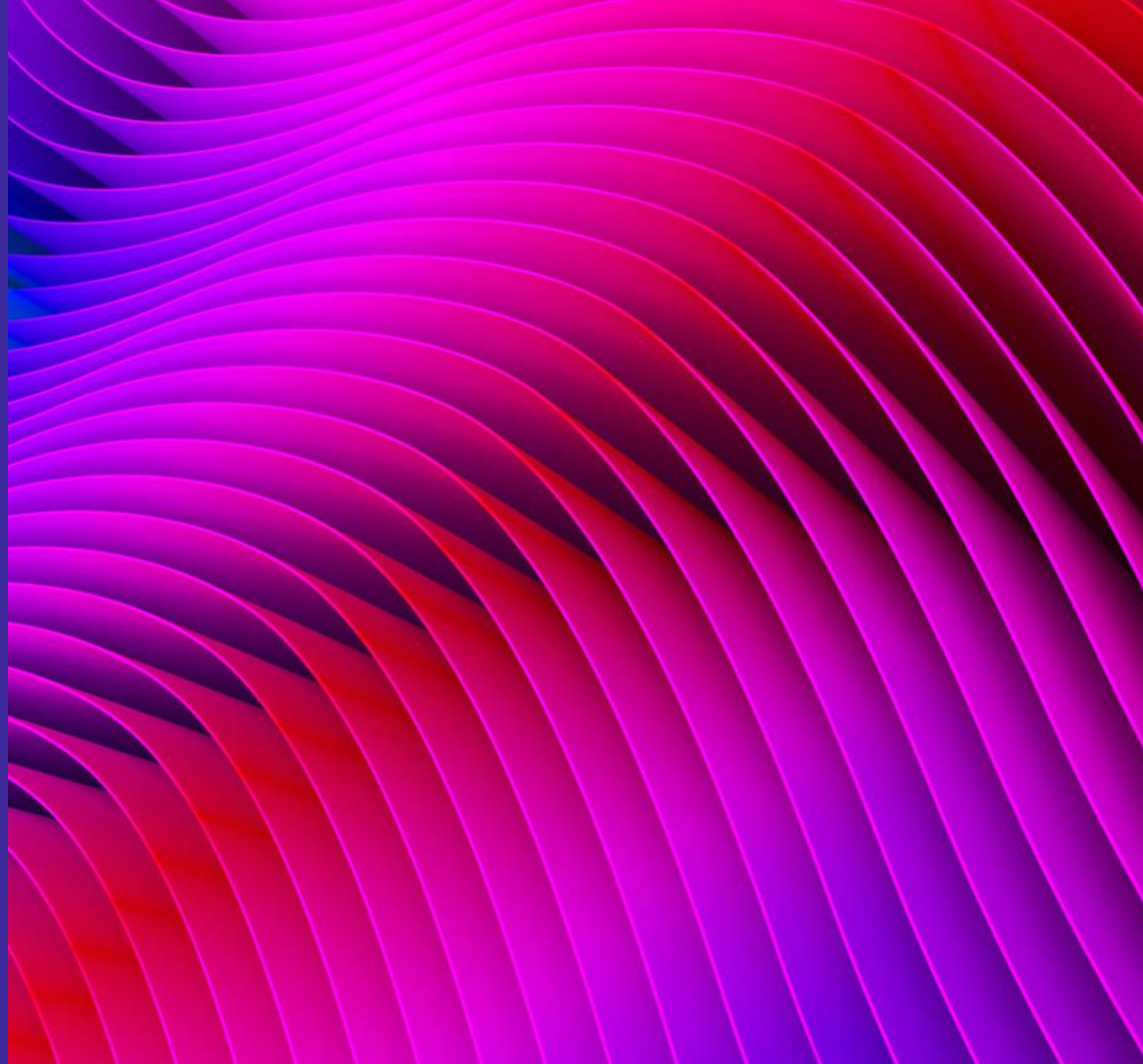
- Email Xcenda at insights@xcenda.com
- Contact us at http://www.xcenda.com



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