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Practical Recommendations in Immuno & Molecular Oncology

# Will Biosimilars Reduce Financial Toxicity of Cancer Therapy?

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# Learning Objectives

1) Identify biosimilar cost trends

2) Discuss emerging biosimilar challenges and opportunities

3) Describe how a biosimilar dashboard can drive value for your practice

# Background

- Cancer drug cost increasing at twice the rate of general healthcare cost
- Median monthly cost of new U.S. cancer drugs surpassed the median monthly household income in year 2000 and more than doubled by 2014
- Biologics, 2% of prescriptions, driving ~50% of the spend.
- Oncology pipeline includes >700 drugs in clinical trials
- Rising and unsustainable healthcare cost calls for cost containment strategies


1. *Unlocking the Potential of Biosimilars*. Cigna's Newsroom. Accessed October 5, 2021
2. Medicine Use and Spending in the U.S. A Review of 2018 and Outlook to 2023. May 2019. IQVIA Institute for Human Data Science. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us---a-review-of-2018-outlook-to-2023.pdf?_=1602972025818. Accessed October 17, 2020.
3. Goll, G., Kvien, T. *An Opportunity Missed: Biosimilars in the United States*. American College of Theumatology. Vol 72, No. 7, July 2020, 1046-1048
4. Biosimilars in the United States 2020-2024. September 2020. https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024.Accessed October 6, 2021
5. Aggarwal, G., Nagpal, M., Sharma, A., Puri, V., Dhingra, G. *Upcoming Drifts in Biosimilars*. Current Reviews of Clinical and Experimental Pharmacology. (2021) 16, 39-51

# Scientific Demonstration

# Science for Biosimilarity Demonstration in Evolution

Biosimilar approvals

- 2007 in Europe
- 2015 in U.S.

Relevance of biosimilar animal studies under question

- Several not evaluated by FDA
- FDA & EMA have approved > 100 products, none of which have failed animal toxicity testing


1. Niazi, S. Biosimilars: *A Futuristic Fast-to-Market Advice to Developers*. Expert Opinion on Biologic Therapy. Vol. 22, No. 2, 149-155. Dec 27, 2021
2. Nahleh, Z., Lyman, G., Schilsky, R., Peterson, D., Tagawa, S., Chavez-MacGregor, M., Rumble, B., Gupta, S. *Use of Biosimilar Medications in Oncology.* Journal of Clinical Oncology. Vol 18, Issue 3, 177-186. 2022



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# Science for Biosimilarity Demonstration

Bioequivalence technology advances

- Protein mass spectrometry (10 million-fold more sensitive than a decade ago)
- In-process analytic controls producing higher batch-to-batch consistency

FDA - "biosimilars may be approved based on PK and PD biomarker data without comparative clinical study with efficacy endpoint(s)."

- shorter, less costly clinical studies
- potential more sensitive testing vs clinical efficacy endpoints
- None of 100+ FDA/EMA approved biosimilars failed clinical efficacy testing if they met the analytics similarity and clinical pharmacology testing

- EMA has started to pilot clinical trial programs to advise how clinical testing can be reduced or avoided for biosimilars


1. Niazi, S. Biosimilars: *A Futuristic Fast-to-Market Advice to Developers*. Expert Opinion on Biologic Therapy. Vol. 22, No. 2, 149-155. Dec 27, 2021
2. De Mora, F. *Biosimilars: A Value Proposition*. BioDrugs 33:353-356. 2019

# Approach to Switching

- Interchangeability determined at federal level (FDA)
- Substitution regulated at state level
  - At least 45 states & Puerto Rico permit or require pharmacists to interchange allow
    - If biosimilar is considered interchangeable &
    - Covered under payer's pharmacy benefit
- Pharmacy & Therapeutics (P&T) Committee substation approval
- Health plans nonetheless treat biosimilars as "interchangeable"
- Interchangeability pursue expected to align with pharmacy benefit
- "more political than scientific;" years of mistrust.


1. Afzali, A., Furtner, D., Melsheimer, R. *The Automatic Substitution of Biosimilars: Definitions of Interchangeability are not Interchangeable.* Adv Ther (2021) 38:2077-2093
2. Declerck, P., Bakalos, G., Zintzaras, E., Barton, B., Schreitmuller, T. *Monoclonal Antibody Biosimilars in Oncology: Critical Appraisal of Available Data on Switching*. Clinical Therapetuics. Vol. 40; Nov 5, 2018.
3. Nabhan, C., Valley, A., Feinberg, B. *Barriers to Oncology Biosimilars Uptake in the United States*. The Oncologist. 2018;23:1261-1265
4. Lyman, G., Balaban, E., Diaz, M., Ferris, A., Tsao, A., Voest, E., Zon, R., Francisco, M., Green, S., Sherwood, S., Harvey, D., Schilsky, R. American Society of Clinical Oncology Statement: Biosimilars in Oncology. Journal of Clinical Oncology. Vol. 36 No. 12 April 2018.
5. Barbier, L., Mbuaki, A., Simoens, S., Declerck, P., Vulto, A., Huys, I. *Regulatory Information and Guidance on Biosimilars and Their Use Across Europe: A Call for Strengthened Once Voice Messaging*. Frontiers in medicine. Vol. 9 Article 820755. March 2022
6. Niazi, S. *No Two Classes of Biosimilars: Urgent Advice to the US Congress and the FDA. Journal of Clinical Pharmacy and Therapeutics*. June 29, 2022.

# Barriers to Market Entry

# Biosimilar Marketplace Uncertainty

- No patent exclusivity
- Limited FDA-designated interchangeability
- Incomplete label indication (where applicable)
- Order of market entry uncertainty
- No guaranteed payer coverage
- No guaranteed market share
- No guaranteed sales

# Patent Litigation "Patent Dance"

Biologics exclusivity by the Biologics Price Competition and Innovation Act

Several product patents

- Primary patent on molecule and manufacturing
- Formulations
- Delivery systems
- Absorption
- Others
- May extend exclusivity for years

Infringement litigation

Affecting most biosimilars; months to years of delays


1. Schwieterman, P. *A Strategic Review of Biosimilars in Oncology Practice*. Hematology/Oncology Pharmacy Association (HOPA) News. Volume 15, Issue 1 (2018)
2. *What if Biosimilars Never Arrive? Five Key Barriers Create Uncertainty for Biosimilars.* Optum.
3. Wechsler, J. *FDA Struggles to Advance Biosimilars*. PharmExec.com Commercial Insights for the C-Suite. Volume 38, Issue 9. Sept,01,2018

# Barriers to Entry – Patent Litigation

Adalimumab Case; U.S. Experience

Risankizumab-rzaa

- Improved effectiveness in severe plaque psoriasis
- More favorable dosing schedule
- Expanding indications (e.g. Psoriatic Arthritis 1/21/22)

Upadacitinib

- Evidence of improved efficacy in RA
- 82 active clinical trials listed in ClinicalTrials.gov*

1. Upadacitinib Current Studies Listed in ClinicalTrials.Gov https://clinicaltrials.gov/ct2/results?cond=upadacitinib&term=&cntry=&state=&city=&dist= Accessed Sept. 15, 2024

# Adalimumab

U.S. Market Prepares to Receive Adalimumab Biosimilar

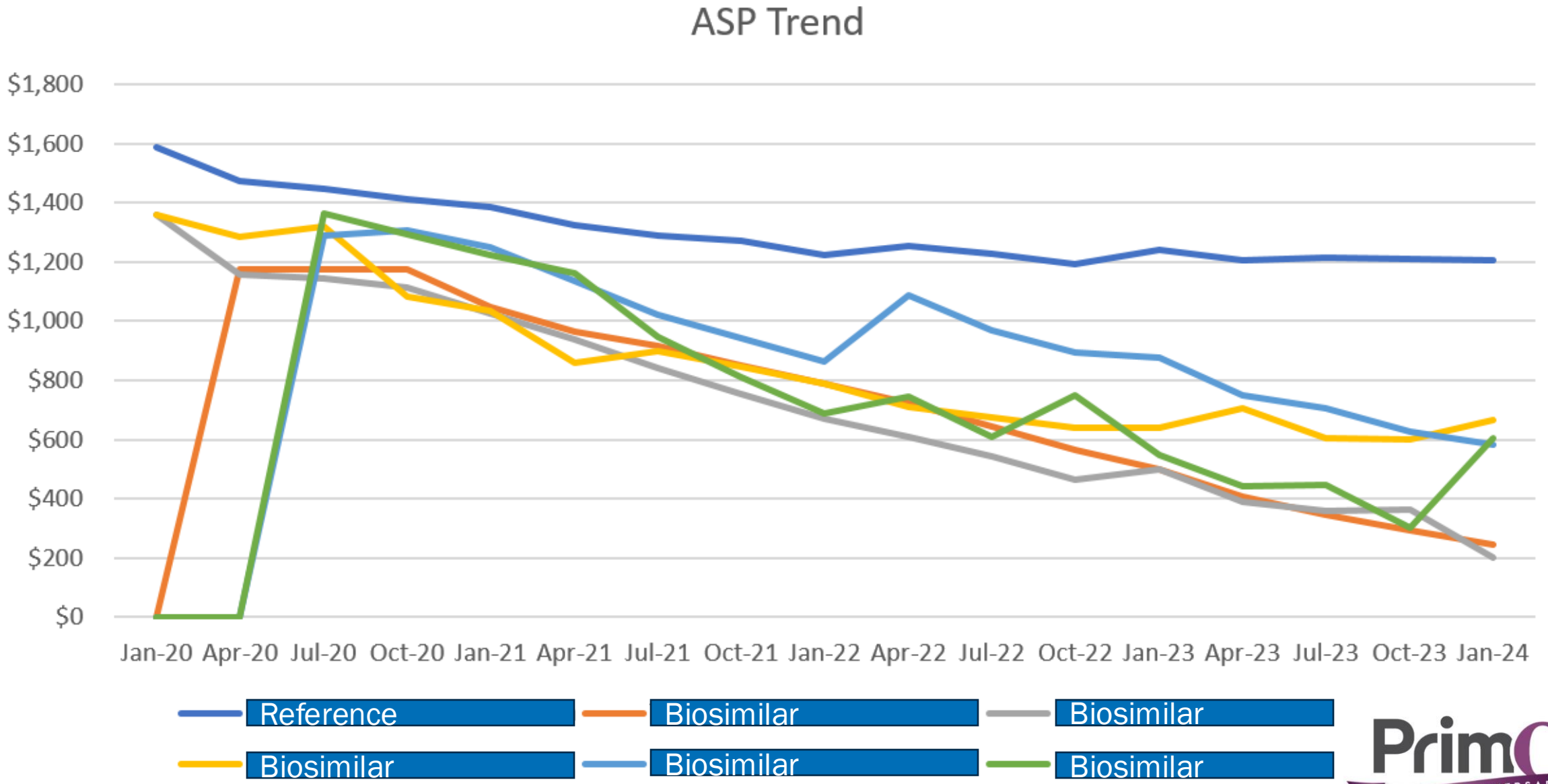
- (adalimumab-atto)
  - Debuted in U.S. Jan 2023
- (adalimumab-aaty)
- (adalimumab-aqvh)
  - Partnered w/ Mark Cuban's online pharmacy
- (adalimumab-adaz)
- (adalimumab-adbm)
- (adalimumab-bwwd)
- (adalimumab-fkjp)
- l(adalimumab-aacf)
- (adalimumab-afzb)
- (adalimumab-ryvk)
  - High concentration

# Economic Considerations

# Implementation of a Biosimilar Dashboard

- Pricing
- Manufacturing contract discounts
- GPO discounts
- Product charge
- J-codes
- Drug billing units
- Drug CMS status indicator
- ASP
- Medicare payment
- Commercial actual rate of payment

# Biosimilar Dashboard

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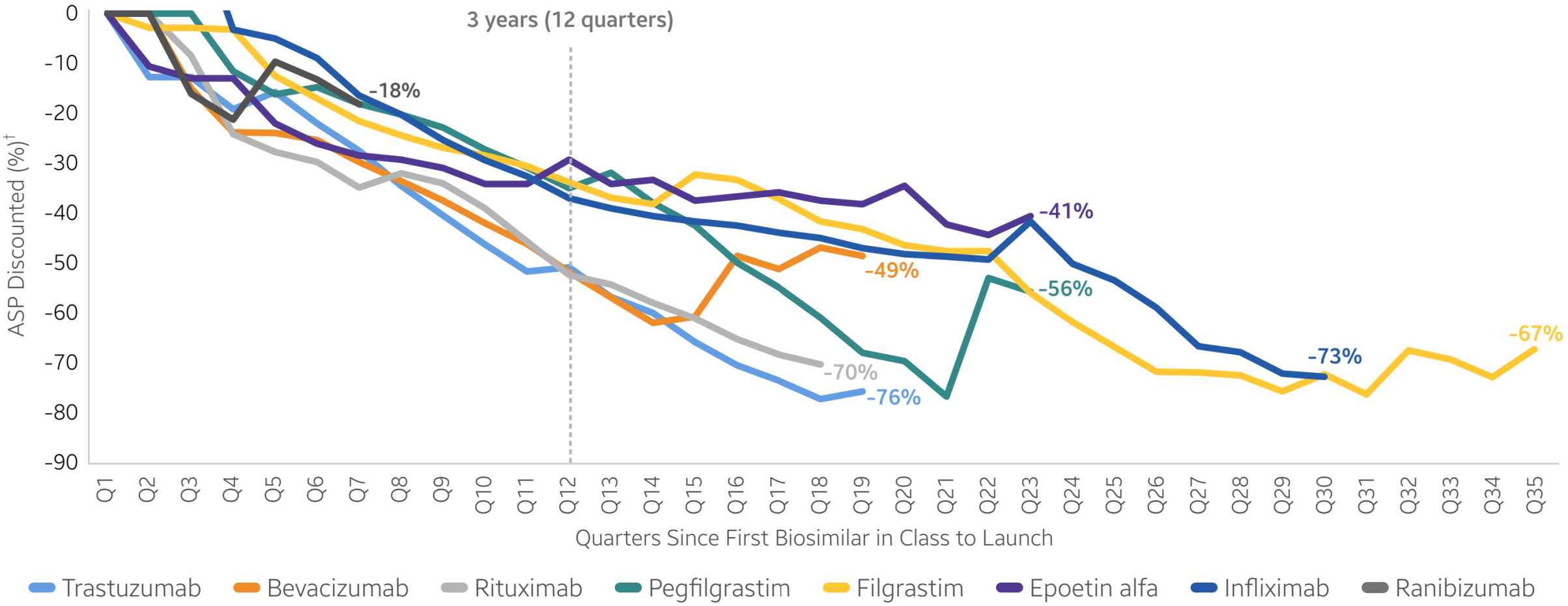
# ASP Trend by Molecule




TA: Therapeutic area; ASP: Average sales price
*: Trastuzumab, bevacizumab, and rituximab are included
†: ASP discounted % vs. reference product ASP when first biosimilar in class launch

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# Biosimilar Dashboard

| Drug | Vial Size | Billing Units per Vial | HCPCS | NDC (-) | SI | ASP | ASP + 4.3% | ASP + 8% | Estimated Medicare Reimbursement |
|---|---|---|---|---|---|---|---|---|---|
| Trastuzumab | 150 MG | 15 | J9355 | 50242-0132-01 | K | $1,270.91 | $1,325.56 | $1,347.17 | $984.96 |
| Trastuzumab-qyyp | 150 MG | 15 | Q5116 | 00069-0308-01 | G | $848.08 | $884.55 | $898.97 | $884.55 |
| Trastuzumab-anns | 150 MG | 15 | Q5117 | 55513-0141-01 | G | $752.59 | $784.95 | $797.75 | $784.95 |
| Trastuzumab-dkst | 150 MG | 15 | Q5114 | 67457-0991-15 | G | $847.73 | $884.18 | $898.59 | $884.18 |
| Trastuzumab-dttb | 150 MG | 15 | Q5112 | 00006-5033-02 | G | $941.75 | $982.24 | $998.25 | $982.24 |
| Trastuzumab-pkrb | 150 MG | 15 | Q5113 | 63459-0303-43 | G | $810.89 | $845.76 | $859.55 | $845.76 |

For illustrative purposes only. Numbers do not reflect real-world experience. Not intended as product preference recommendation.

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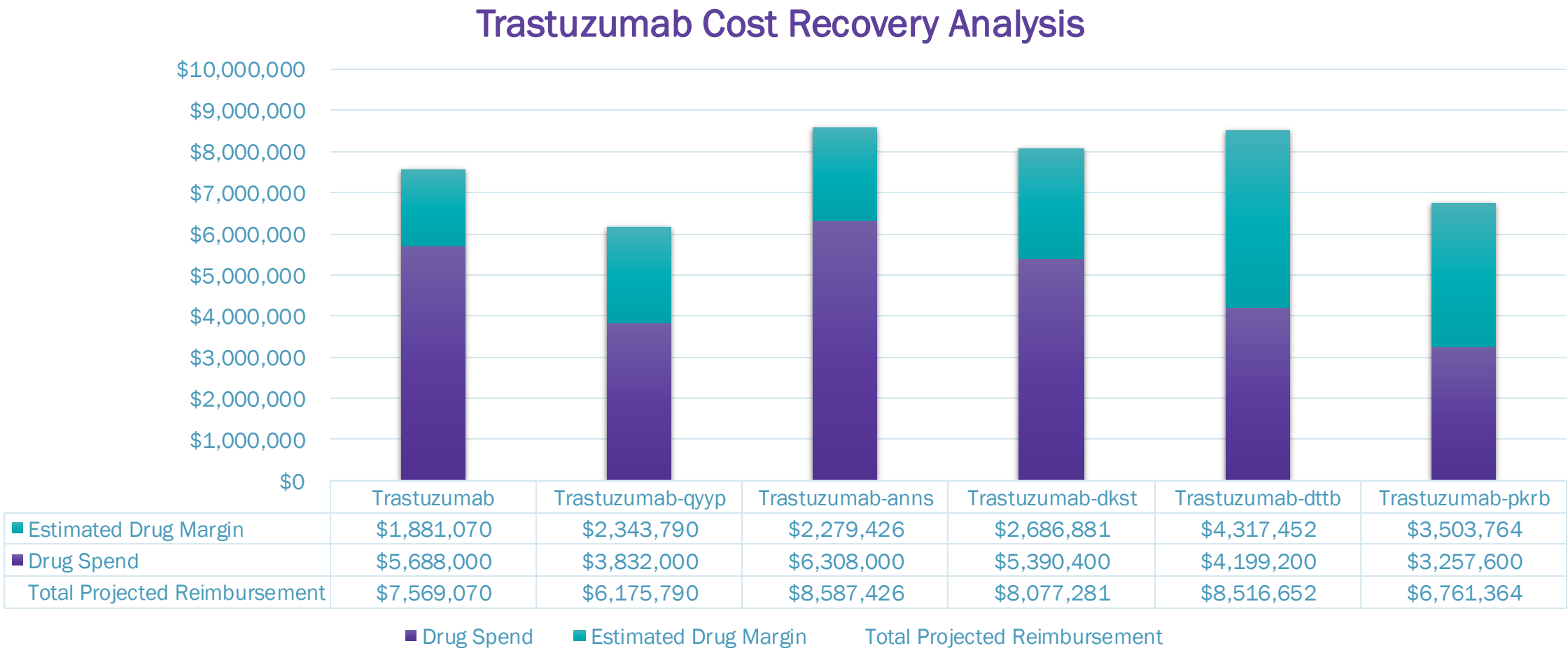
# Biosimilar Dashboard




| | Trastuzumab | Trastuzumab-qyyp | Trastuzumab-anns | Trastuzumab-dkst | Trastuzumab-dttb | Trastuzumab-pkrb |
|---|---|---|---|---|---|---|
| Estimated Drug Margin | $1,881,070 | $2,343,790 | $2,279,426 | $2,686,881 | $4,317,452 | $3,503,764 |
| Drug Spend | $5,688,000 | $3,832,000 | $6,308,000 | $5,390,400 | $4,199,200 | $3,257,600 |
| Total Projected Reimbursement | $7,569,070 | $6,175,790 | $8,587,426 | $8,077,281 | $8,516,652 | $6,761,364 |

For illustrative purposes only. Numbers do not reflect real-world experience. Not intended as product preference recommendation.

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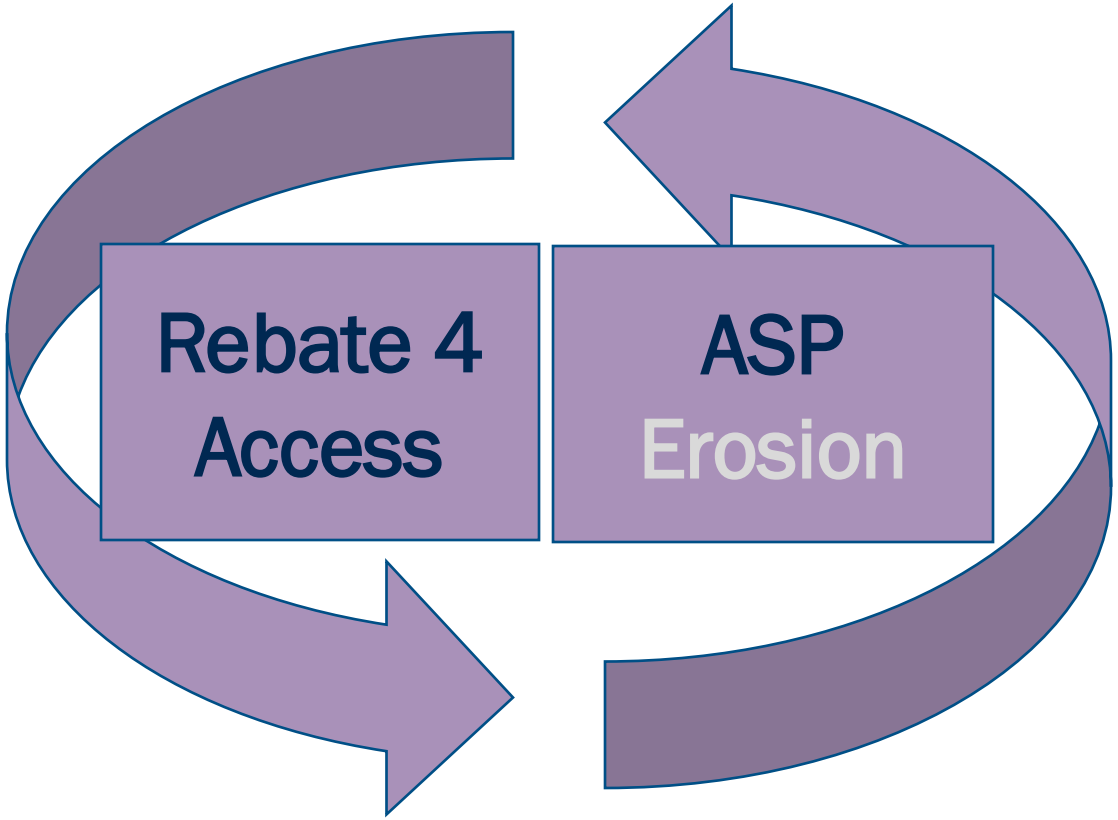
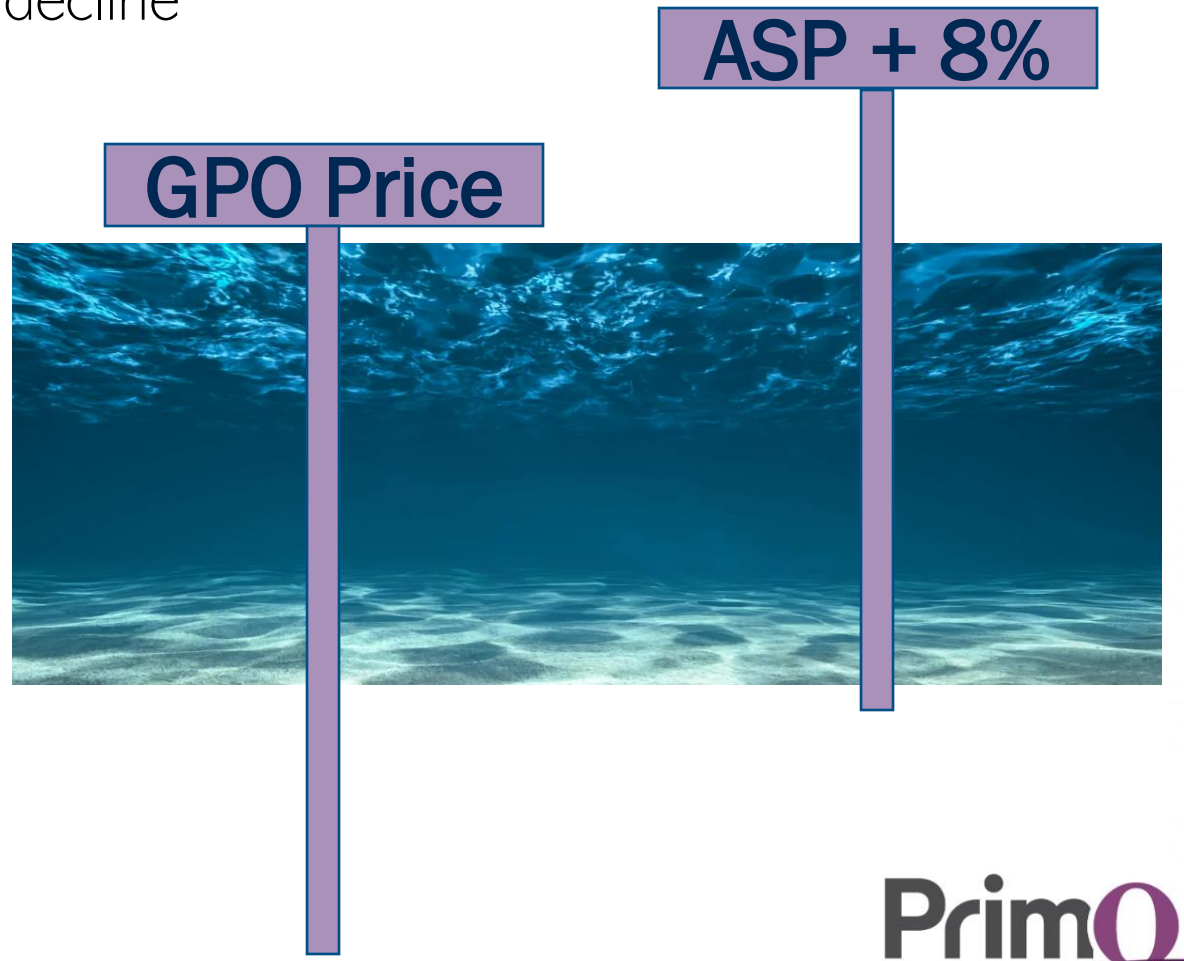
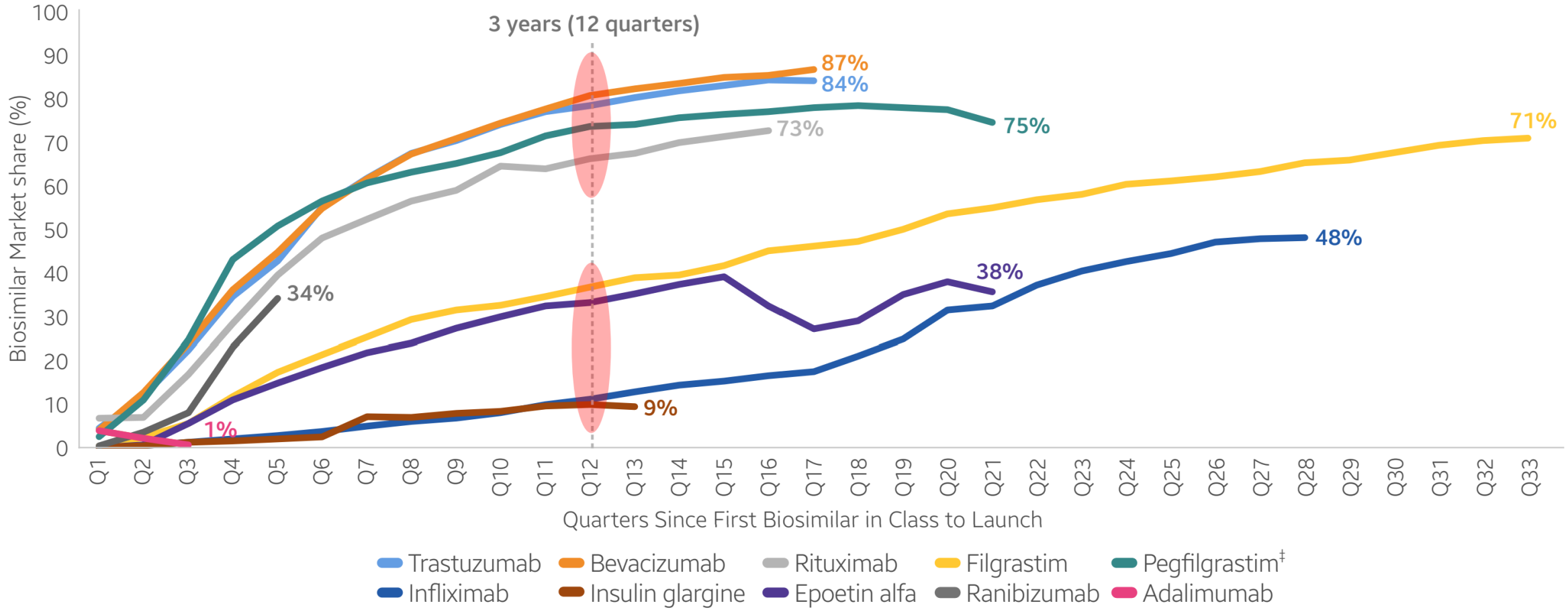
# Economic Considerations

- Across all biosimilars, ASP has declined by 50% within the first 13 quarters.
- Some products have experienced a 90% decline



# Biosimilar Market Share Post-Launch




TA: Therapeutic area
*Trastuzumab, bevacizumab, and rituximab are included
†Adalimumab and infliximab are included
‡Onpro is not included

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# Payment Model Evolution


- Increasing number of providers working in Accountable Care Organizations (ACOs) and "narrow networks"
- University of Pittsburgh Medical Center (UPMC) / Highmark - Allegheny Health System
- Kaiser achieved 97% bevacizumab biosimilar 1 month after launch
- Self-insured Employee Health Plans

1. Kvien, T., Patel, K., Strand, V. *The Cost Savings of Biosimilars Can Help Increase Patient Access and Lift the Financial Burden of Health Care Systems.* Seminars in Arthritis and Rheumatism 52 (2002) 151939

# Role of Employers in Value-Based Care

- Employers are the number one purchaser of health insurance
- Employers have a limited understanding of opportunities and risks
- Employers are in a position to influence benefit designs (e.g. biosimilar coverage) but need to understand obstacles
- Employers can align incentives at point of purchase
  - Getting system-owned specialty pharmacy in network
  - At-parity biosimilar coverage
- Payer rebate transparency

# Inflation Reduction Act (IRA); Drug Price Negotiations

- Government-imposed price controls on selected drugs
- Two-year notice; allowance for 7 years post approval, at 9 years, negotiated price kicks in.
- Aims to save CMS $102 billion over a decade
- Impact on biosimilars?
  - (ustekinumab)
  - Selected for inaugural round
  - Poised to have multiple biosimilars in 2025
  - Biosimilars launch at 30-40%
  - Impact on biosimilar development
  - Potential to exacerbate ASP erosion
  - Impact on pricing of new drugs

*Proposed two-year waiver from price controls for biologic drugs with a "high likelihood" to have biosimilar competitors. **2022-2023 estimated drug price inflation rate 3.80%; 4.18% within the specialty category. *** Biologics get an extra four years over small molecule before negotiated price is enforced.

1. The IRA Is Sabotaging Biosimilars Competition. Dan Leonard RealClearHealth February 13, 2024.

# Connection With Purpose

# Biosimilars Success Impact Beyond the Walls of the U.S.

The WHO estimates worldwide cancer cases to increase by 60%

- 18.1 million in 2018
- 29.5 million by 2040

Spending on all medicines used to treat cancer patients

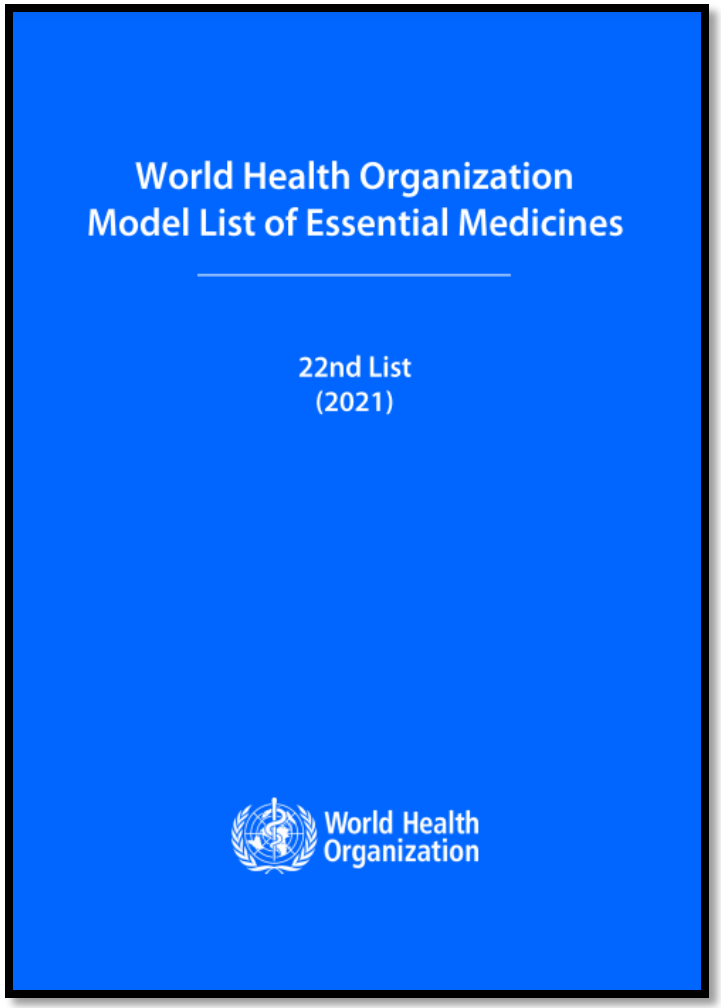
- $150 billion in 2018
- $240 billion by 2023

Cost and accessibility barriers

- Global uptake of biologics greatly limited by cost constrains
- Disparities in patient care and outcomes


1. Peeters, M., Planchard, D., Pegram, M., Goncalves, J., Bocquet, F. *Biosimilars in an Era of Rising Oncology Treatment Options. Future Oncology* (2021) 17(29), 3881-3892
2. Tariman, J. *Biosimilars; Exploring the history, science, and progress.* Clinical Journal of Oncology Nursing. Vol. 22 No. 5. October 2018

# Biosimilars Success Impact Beyond the Walls of the U.S.




## WHO Model List of Essential Medicines – 23rd List (2023)

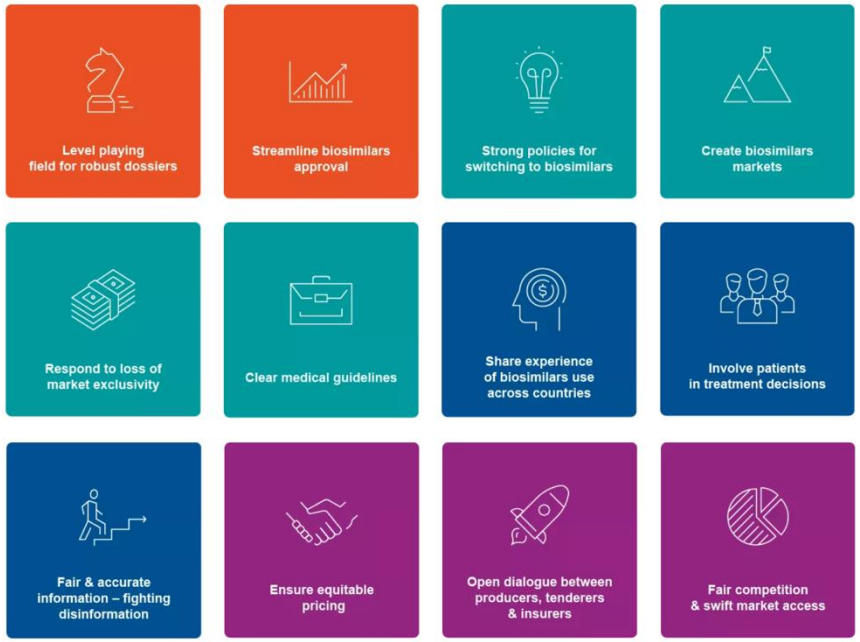
| ***8.2.2 Targeted therapies*** | |
|---|---|
| ***Complementary List*** | |
| *rituximab** <br> **including quality-assured biosimilars* | ***Injection (intravenous):*** *100 mg/10 mL in 10 mL vial; 500 mg/50 mL in 50 mL vial.* <br> – *Burkitt lymphoma* <br> – *large B-cell lymphoma* <br> – *Chronic lymphocytic leukaemia* <br> – *Follicular lymphoma* |
| *trastuzumab** <br> **including quality-assured biosimilars* | ***Powder for injection:*** *60 mg; 150 mg; 440 mg in vial.* <br> *Early stage HER2-positive breast cancer* <br> *Metastatic HER2-positive breast cancer* |
| *pegfilgrastim** <br> **including quality-assured biosimilars* | ***Injection:*** *6 mg/0.6 mL in pre-filled syringe.* <br> – *Primary prophylaxis in patients at high risk for developing febrile neutropenia associated with myelotoxic chemotherapy* <br> – *Secondary prophylaxis for patients who have experienced neutropenia following prior myelotoxic chemotherapy* <br> – *To facilitate administration of dose dense chemotherapy regimens* |

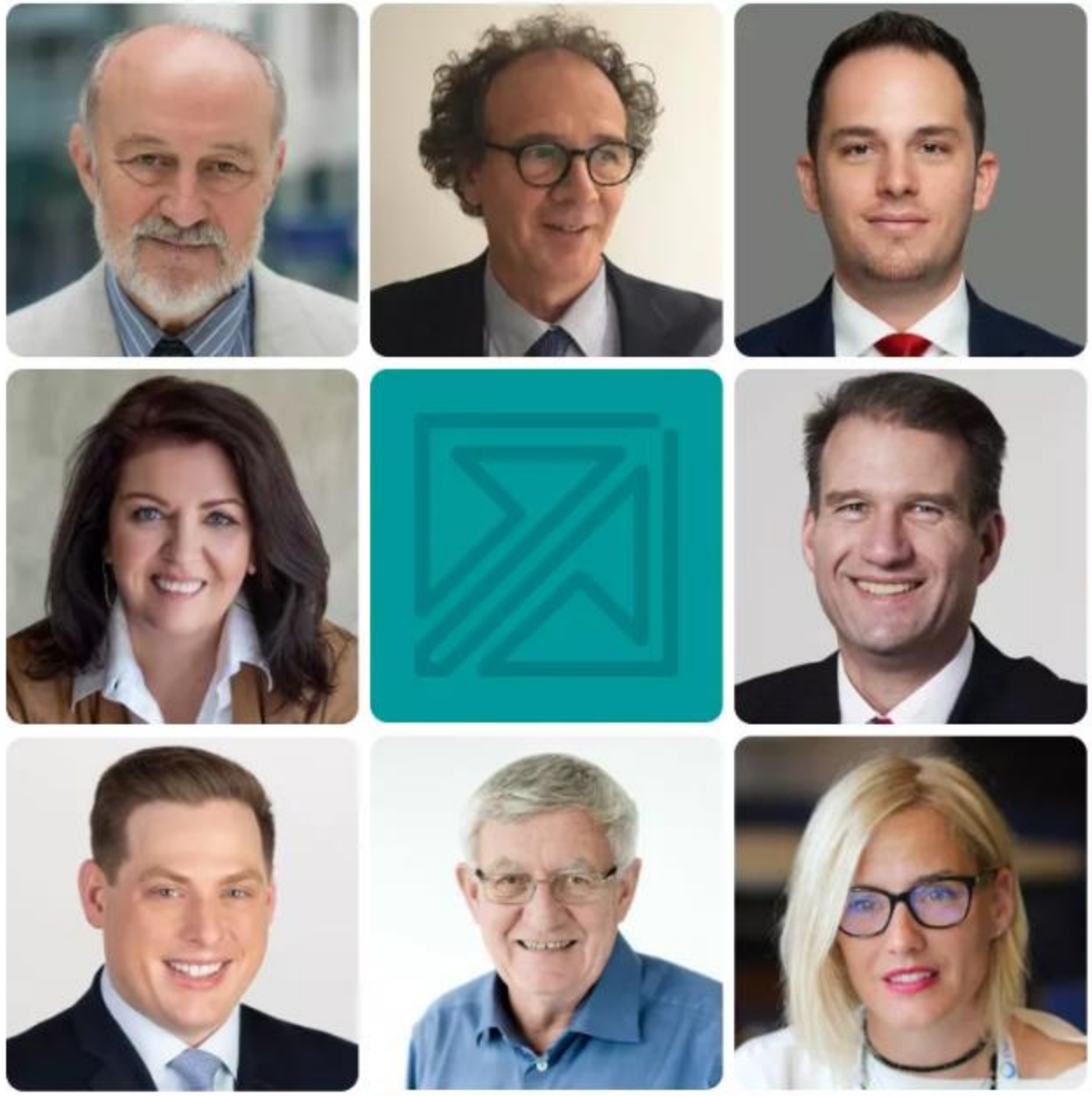
1. https://iris.who.int/bitstream/handle/10665/371090/WHO-MHP-HPS-EML-2023.02-eng.pdf?sequence=1 Accessed January, 2025

# Act4Biosimilars Global Initiative

## Act4Biosimilars Steering Committee

Act4Biosimilars is led by a multidisciplinary Steering Committee o patient advocacy leaders, healthcare professionals, biosimilar experts and industry leaders from around the world. It is supported by founding sponsor, Sandoz.



1. Act4Biosimilars Global Initiative. www.act4biosimilars.com Accessed Sept. 15, 2022.

# Summary

- Biologics have revolutionized the treatment of serious health conditions over the last few decades
- Biologic innovation and marked utilization increases have led to a significant increase in healthcare spending
- Biosimilars offer high quality treatment alternatives at a fraction of the cost
- Biosimilars provide a strong cost savings value proposition which helps practices achieve better performance in value-based payment models

# Summary

- Many pre- and post-marketing implementation barriers exist leading to slow adoption of biosimilar utilization in the U.S.
- Biosimilars are a tool at our disposal presenting one of the most important healthcare cost mitigation opportunities
- To reap the potential economic benefit biosimilars must be utilized
- Biosimilar utilization is influenced by provider/practice economics
- Healthcare professionals uniquely positioned to promote the evaluation of the growing body of evidence and enable biosimilar utilization where there is evidence supporting safe and effective use.

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