Managing Biosimilars in a Dynamic Landscape

Rachael Morgan, PharmD, BCOP

Hem/Onc Pharmacy Research and Formulary Manager – UK Healthcare

Rebecca Champion, PharmD, MS, BCOP

Director of Pharmacy Services – Norton Cancer Institute

Anna Hitron, PharmD, MS, MBA, BCOP

Director of Pharmacy – Baptist Health Louisville

Danielle Otto, PharmD, BCOP

Hematology/Oncology Pharmacist – Evolent Health

Objectives

01

Evaluate key components for biosimilar additions to formulary including clinical and financial elements

02

Design policies and workflows to support biosimilar formularies throughout diverse hospital systems

03

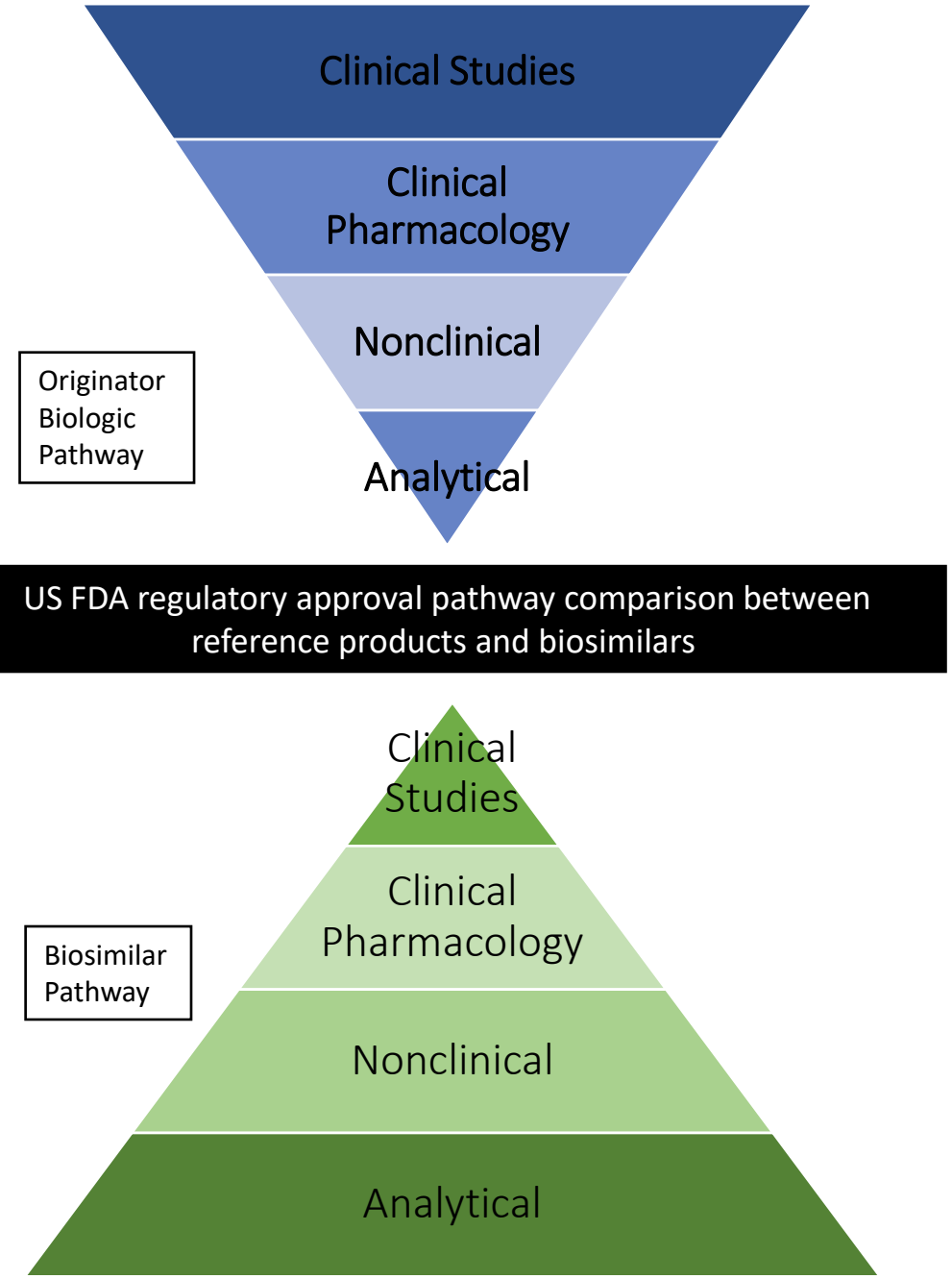
Identify common challenges among the landscape of biosimilars within institutional settings

Disclosures

Presenters have no actual or perceived conflicts of interest for this presentation

What is a biosimilar?

- Biological product
- Highly similar to reference product
- No clinically meaningful differences from reference product
- Still has rigorous evaluation/testing requirements
- **Examples:** Trastuzumab, bevacizumab, rituximab, pegfilgrastim, filgrastim, infliximab, denosumab
- FDA approved biosimilars continues to expand



U.S. Food and Drug Administration (FDA). Biosimilars: Overview for Health Care Professionals. Accessed July 2026.
FDA Purple Book Database. Accessed July 2026. https://purplebooksearch.fda.gov/

Interchangeable Biosimilar

Requested by manufacturer

- Must submit additional information that show the safety of switching without decrease in effectiveness

Allows the pharmacist to substitute without prescriber intervention (in certain states)

- KY allows for substitution in line with generic substitution
  - Pharmacists must communicate substitution to the patient immediately and back to the provider within 5 days
- IN law does not allow automatic substitution, unless the prescriber includes "may substitute" on prescription

FDA Purple Book Database

U.S. FDA. Interchangeable biological products. Accessed July 2026.
CardinalHealth. State regulations for biosimilar interchangeability. Accessed July 2026.
Humphreys S. *Evidence Based Oncology.* Aug 2023. 29(7):SP545-8.

Use of biosimilars in practice

2016 European Society of Medical Oncology (ESMO)	2025 Community Oncology Alliance (COA)	2023 American Society of Clinical Oncology (ASCO)
• Biosimilar use is critical to reducing drug costs • Advocates for labeling that includes immunogenicity and clinical testing data • No clear guidance on switching/interchangeability; discourages automatic substitution • Supports robust scientific study enabling extrapolation of indications	• Advocates for clinic-level biosimilar selection to improve efficiency, minimize waste, and reduce inventory costs • Warns of potential market distortion from rapid ASP and rebate changes • Acknowledges barriers around interchangeability and payor constraints • Calls for regulatory oversight to improve clinical transparency and community practice pricing	• Increase education for patients and providers to build biosimilar confidence • Payers should provide transparent formulary decisions and reduce inventory barriers (e.g., multiple biosimilars of the same reference product • Substitution decisions should remain between patient and physician • Promote regulatory pathways to encourage biosimilar market entry, including reduced data exclusivity • Continue post-market surveillance and cost-e

Gladys Rodriguez et al. *JCO Oncol Pract* **19**, 411-419(2023).
Community Oncology Alliance. (2024). *COA position statement on biosimilars.* Accessed July 2026.
Schiestl M, Krendyukov A. ESMO Open, 2

Key components for biosimilar additions to formulary

Clinical

- Clinical need and provider acceptance
- FDA indications, available evidence

Financial

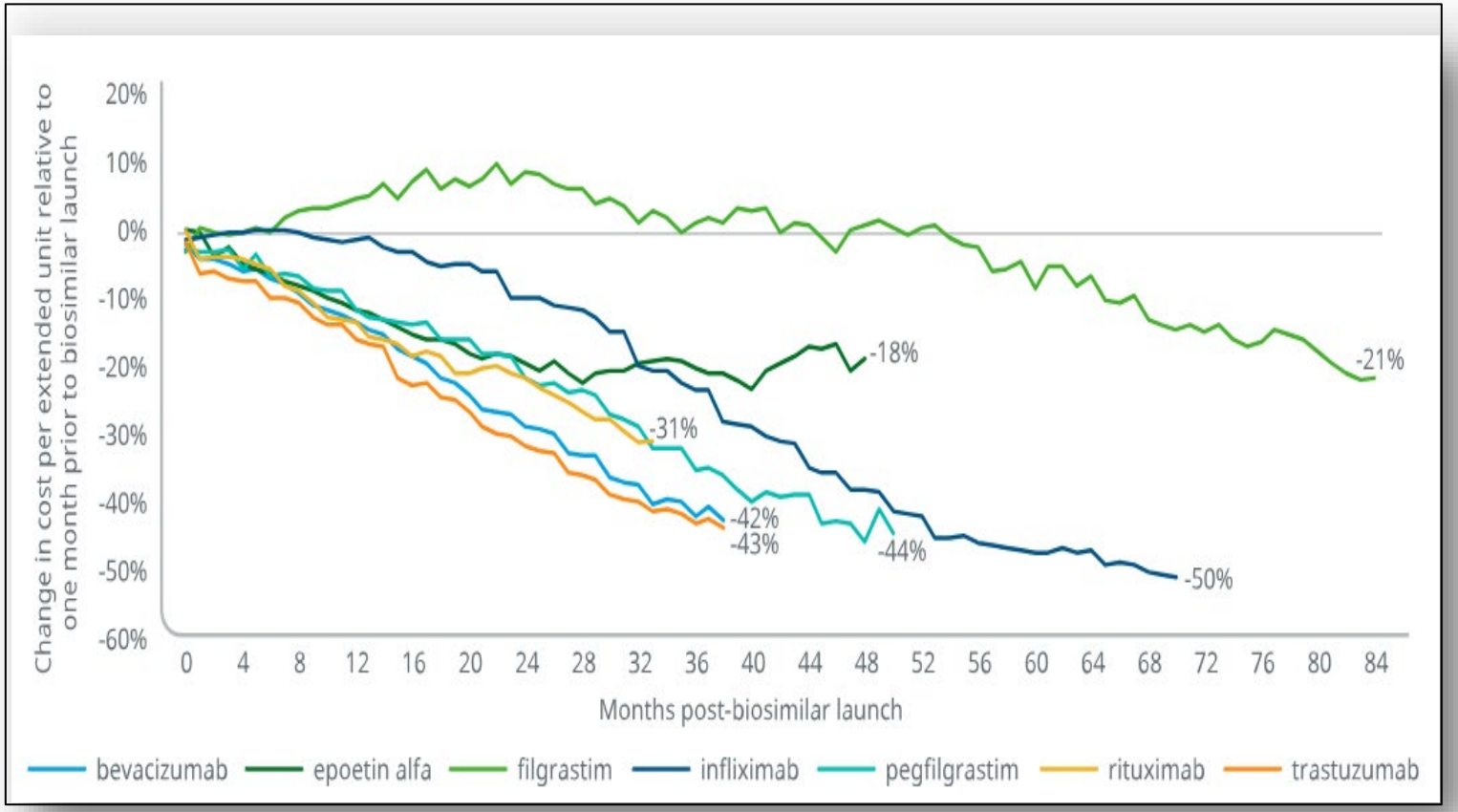
- Payer mix and reimbursement strategy
- Drug acquisition model (340B, GPO/WAC, AWP, wholesaler contracts)
- Pass through reimbursement opportunities

Operational

- Product availability
- Inventory strategy and number of products to stock
- Storage capacity and supply chain considerations
- Frequency of formulary review and reassessment

Economics of Biosimilars

- Biologic medications represent 47% of US drug spending
  - Only 2% of overall sales
- Average sales price for biosimilar is 15-50% lower than reference drug
  - Potentially can result in significant savings, especially over time



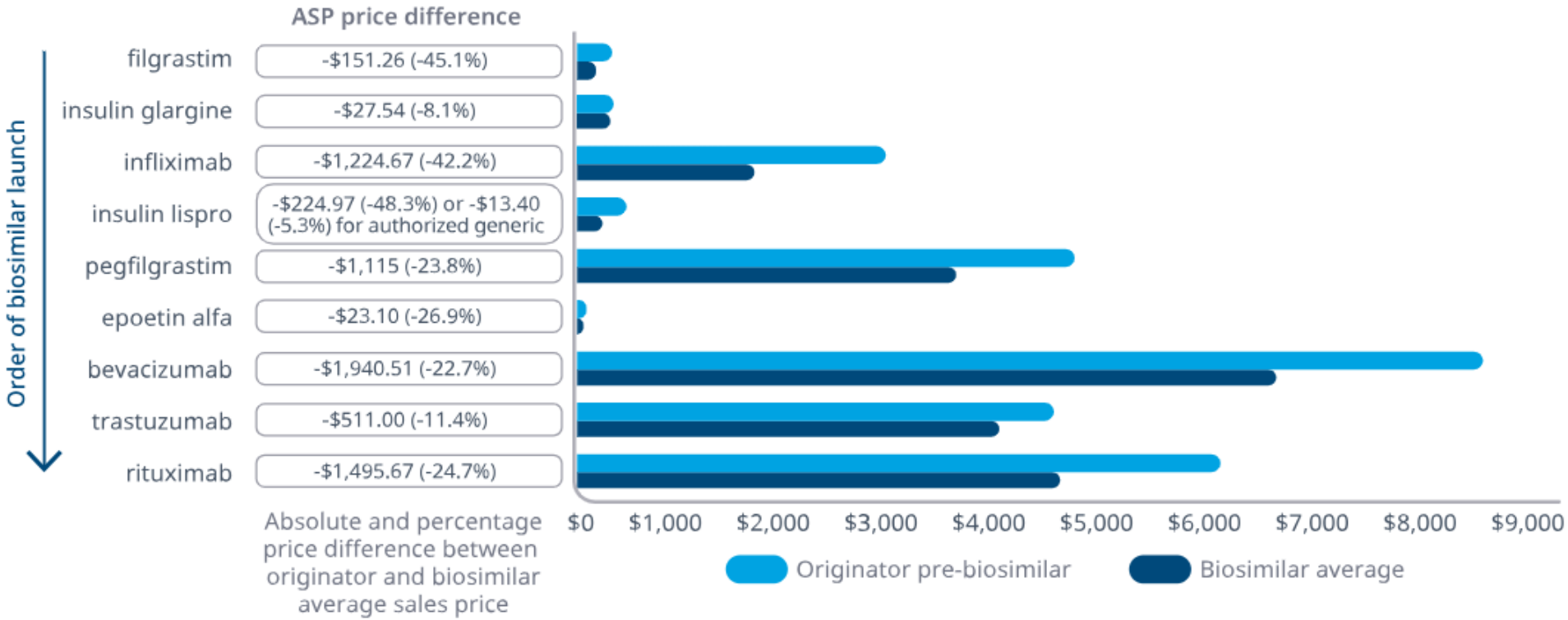
Schiestl M, Krendyukov A. ESMO Open, 2

Community Oncology Alliance. (2024). *COA position statement on biosimilars.* Accessed July 2026.

Association for Accessible Medicines (AAM). *2024 U.S. Generic & Biosimilar Medicines Savings Report*. Published 2024.

Report: Biosimilar in the United States 2023-2027: Competition, Saving, and Sustainability. IQVIA Institute for Human Data Science. January 2023.

Originator and Mean Biosimilar Average Sales Price (ASP) in US$, July 2020



Source: CMS ASP Jul 2020 accessed Sep 2020; IQVIA National Sales Perspectives, Jul 2020; IQVIA Institute, Sep 2020

Exhibit Notes: Average sales price (ASP) costs have been normalized to standardized dosing for each medicine to calculate comparable costs. Insulins use IQVIA invoice prices. ASP for biosimilars was calculated from the CMS website using July 2020 values and period pre-biosimilar entry for each medicine as accessed September 2020: filgrastim 5mcg/kg, insulin glargine, and insulin lispro 5-pen pack 100units/ml 3ml, infliximab 5mg/kg, pegfilgrastim 6mg per chemotherapy cycle, epoetin alfa 100 units/kg, bevacizumab 15mg/kg, trastuzumab 6mg/kg, rituximab 375mg per meter-squared body surface area. Standard body weight was considered 70kg and standard body surface area 1.7 meters squared. *IQVIA Institute LAAD data.

Report: Biosimilars in the United States 2020–2024: Competition, Savings, and Sustainability. IQVIA Institute for Human Data Science, October 2020

IQVIA Institute. *Biosimilars in the United States 2020-2024*. Published October 2020.
Gladys Rodriguez et al. *JCO Oncol Pract* **19**, 411-419(2023).

Realizing cost savings

- Pharmacist-led implementation accelerates biosimilar uptake
- Standardized workflows and EMR optimization improve consistency
- Continued review of biosimilars necessary to ensure optimal outcomes

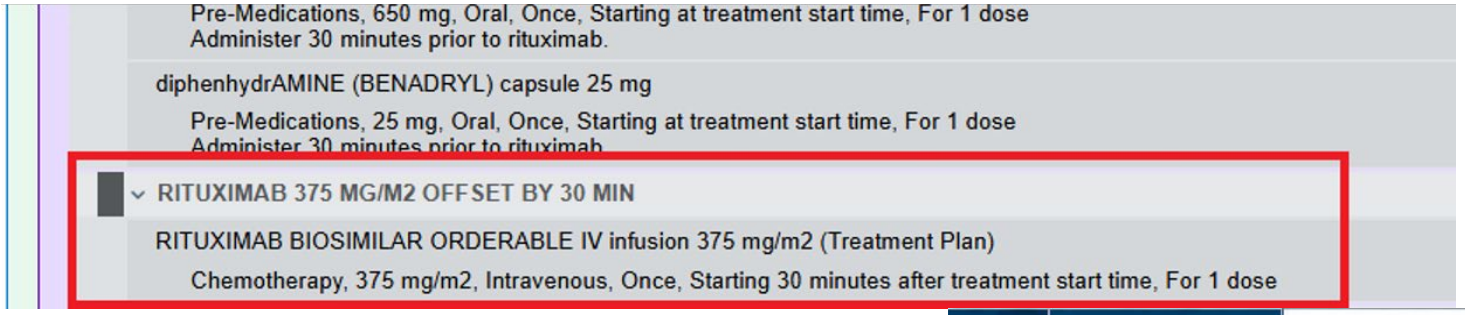
Bourbeau B, et al. JCO Oncol Pract. 2023.
Chang M, et al. J Clin Oncol. 2023 (ASCO Abstract 6516).
Gilmore JW, et al. J Clin Oncol. 2025 (ASCO Abstract 11033).

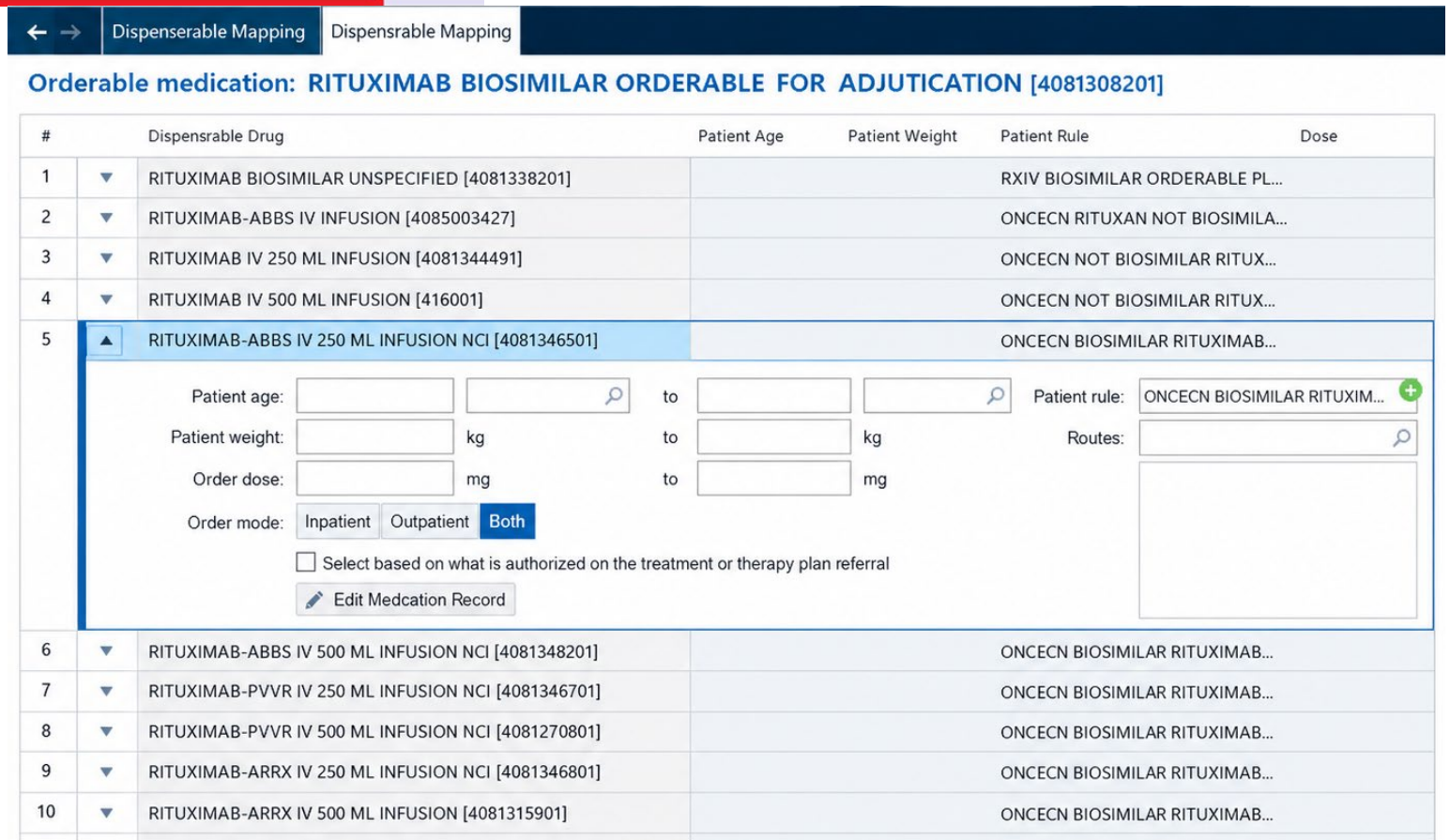
Summary of Challenges/Future Directions

- Continued growth of biologic agents and biosimilar pipeline as patents expire
- Role of payors and the rebate system on market competition
- Impact of site of care challenges
- Expansion beyond oncology

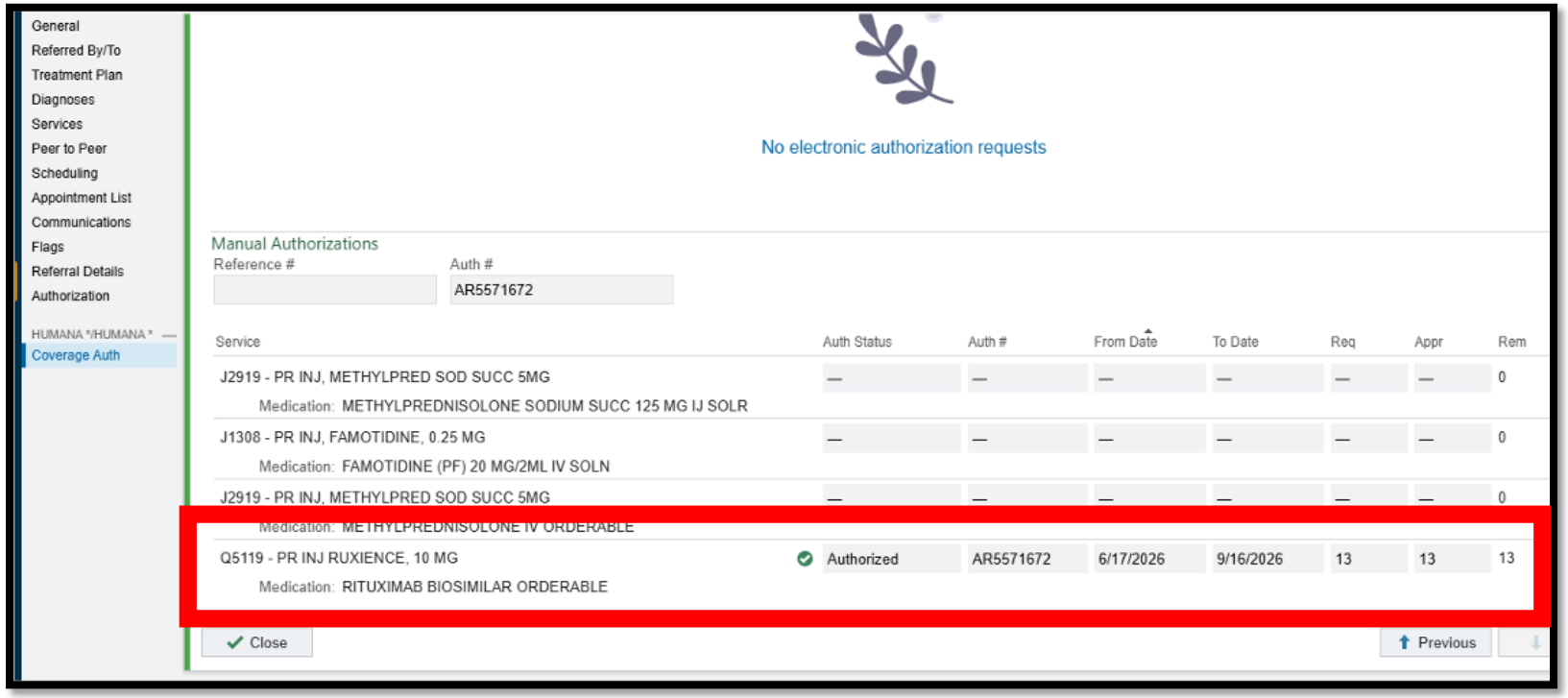
Q & A Time

Norton Cancer Institute





Norton Cancer Institute



Baptist Health

Order Group Start: ONC CHEMO RITUXIMAB / RITUXIMAB BIOSIMILARS 375 MG/M2 (45M OFF) (INITIAL DOSE) (Single-Select)

Chemotherapy

◉ **riTUXimab-abbs (TRUXIMA) 375 mg/m2 in sodium chloride 0.9 % 250 mL IVPB**
Weight: Treatment plan weight
375 mg/m2, Intravenous, Once, Starting 45 minutes after treatment start time
Start initial infusion at 50 mg/hr. If there is no reaction, increase the rate by 50 mg/hour increments every 30 minutes, to a maximum rate of 400 mg/hour. Start subsequent infusions at 100 mg/hr. If there is no reaction, increase the rate by 100 mg/hour increments every 30 minutes, to a maximum rate of 400 mg/hour. Monitor patient for hypersensitivity/infusion reaction.
Biosimilar Use Indication: defaulted medication has be selected as insurance preferred product.
Corbin, Richmond - Diluent Prime Line

☐ **riTUXimab (RITUXAN) 375 mg/m2 in sodium chloride 0.9 % 250 mL IVPB**
Weight: Treatment plan weight
375 mg/m2, Intravenous, Once, Starting 45 minutes after treatment start time
Start initial infusion at 50 mg/hr. If there is no reaction, increase the rate by 50 mg/hour increments every 30 minutes, to a maximum rate of 400 mg/hour. Start subsequent infusions at 100 mg/hr. If there is no reaction, increase the rate by 100 mg/hour increments every 30 minutes, to a maximum rate of 400 mg/hour. Monitor patient for hypersensitivity/infusion reaction.
Biosimilar Use Indication: defaulted medication has be selected as insurance preferred product.
Corbin, Richmond - Diluent Prime Line

Selection conditions: Select Rituxan if patient's primary insurance is in the grouper

☐ **riTUXimab-arrx (RIABNI) 375 mg/m2 in sodium chloride 0.9 % 250 mL IVPB**
Weight: Treatment plan weight
375 mg/m2, Intravenous, Once, Starting 45 minutes after treatment start time
Start initial infusion at 50 mg/hr. If there is no reaction, increase the rate by 50 mg/hour increments every 30 minutes, to a maximum rate of 400 mg/hour. Start subsequent infusions at 100 mg/hr. If there is no reaction, increase the rate by 100 mg/hour increments every 30 minutes, to a maximum rate of 400 mg/hour. Monitor patient for hypersensitivity/infusion reaction.
Biosimilar Use Indication: defaulted medication has be selected as insurance preferred product.
Corbin, Richmond - Diluent Prime Line

Selection conditions: Select Riabni if patient's primary insurance is in the grouper

☐ **riTUXimab-pvvr (RUXIENCE) 375 mg/m2 in sodium chloride 0.9 % 250 mL IVPB**
Weight: Treatment plan weight
375 mg/m2, Intravenous, Once, Starting 45 minutes after treatment start time
Start initial infusion at 50 mg/hr. If there is no reaction, increase the rate by 50 mg/hour increments every 30 minutes, to a maximum rate of 400 mg/hour. Start subsequent infusions at 100 mg/hr. If there is no reaction, increase the rate by 100 mg/hour increments every 30 minutes, to a maximum rate of 400 mg/hour. Monitor patient for hypersensitivity/infusion reaction.
Biosimilar Use Indication: defaulted medication has be selected as insurance preferred product.
Corbin, Richmond - Diluent Prime Line

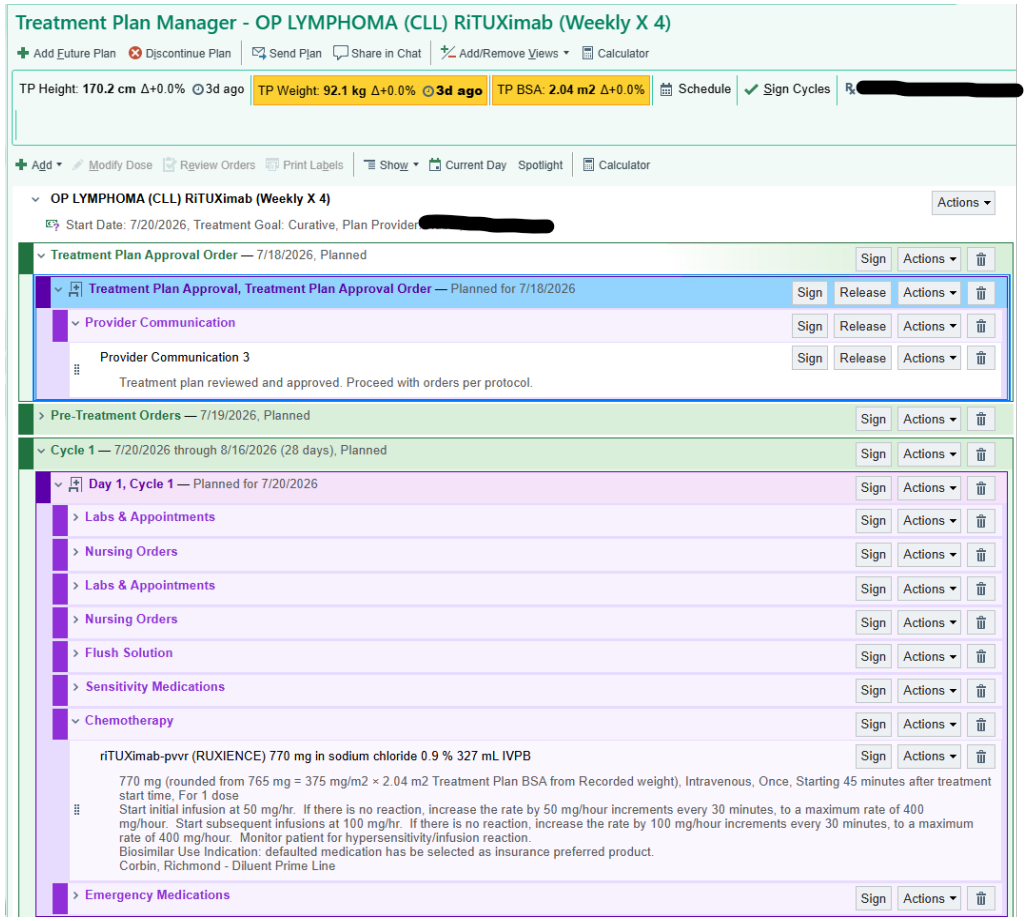
Selection conditions: Select Ruxience if patient's primary insurance is in the grouper

Order Group End: ONC CHEMO RITUXIMAB / RITUXIMAB BIOSIMILARS 375 MG/M2 (45M OFF) (INITIAL DOSE) (Single-Select)

Baptist Health

Active Insurance as of 7/20/2026

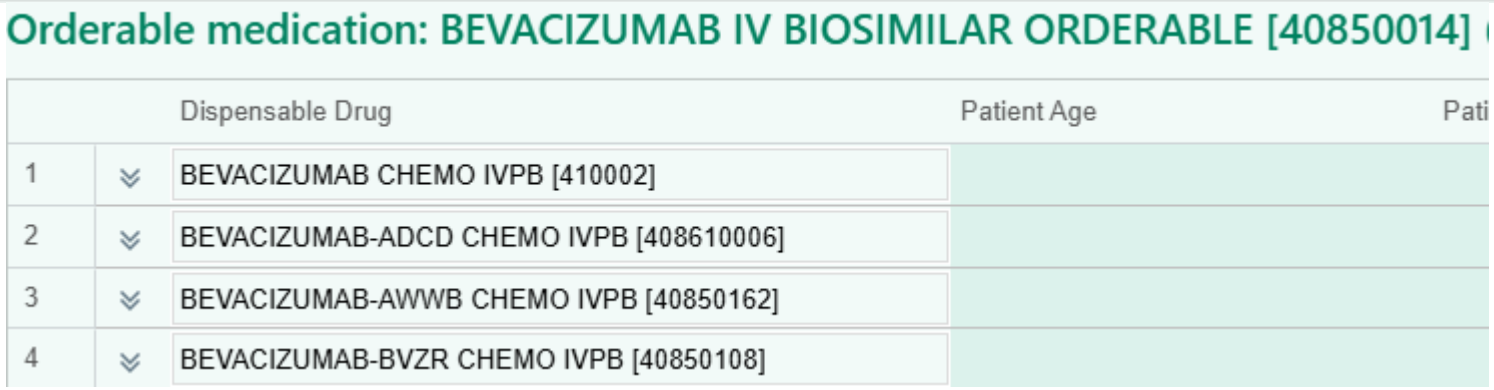
HUMANA MEDICARE REPLACEMENT - Humana Medicare Advantage GROUP PPO



Active Insurance as of 7/20/2026

PASSPORT HEALTH BY MOLINA - PASSPORT BY MOLINA

UK - Markey



	UK Preferred	Anthem	Humana	United	Cigna	Aetna/CVS Health	WellCare	Passport	Traditional Medicare
Bevacizumab Products	Mvasi	Avastin/ Mvasi	Mvasi and Zirabev	**Commercial & MCO (not Medicare Advantage plans):** Mvasi preferred	Mvasi and Zirabev	Mvasi, Zirabev, Avastin	MCO prefers Mvasi and Zirabev	Mvasi	Alymsys

References

- Gilmore, J. W., Indurlal, P., Rainey, A. M., Sabo-Wagner, S., Rahman, A., & Swart, S. (2025, May 30–June 3). Cost-effective cancer care: The role of oncology biosimilars in generating cost savings [Poster presentation]. 2025 ASCO Annual Meeting, Chicago, IL, United States. https://doi.org/10.1200/JCO.2025.43.16_suppl.11033
- Bourbeau, B., Lyman, G. H., Lei, X. J., Jones, L., Rosenthal, J., Kozlik, M. M., Oettel, K. R., Tinger, A., & Page, R. (2023). Biosimilar use among 38 ASCO PracticeNET practices, 2019–2021. JCO Oncology Practice, 19(7), 516–522. https://doi.org/10.1200/OP.22.00618
- Chang, M., Li, J., Peters, B., Winegar, B., Carr, R., Rodriguez, C., Gerber, A. K., Connor, D., Freeman, T., & Brown, K. (2023). Biosimilar uptake and cost savings analysis before and after implementation of a pharmacist-driven substitution program within a National Community Oncology Network: One-year follow-up [Poster discussion session]. 2023 ASCO Annual Meeting, Chicago, IL, United States. Journal of Clinical Oncology, 41(16_suppl), Abstract 6516.