

Managing Biosimilars in a Dynamic Landscape

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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

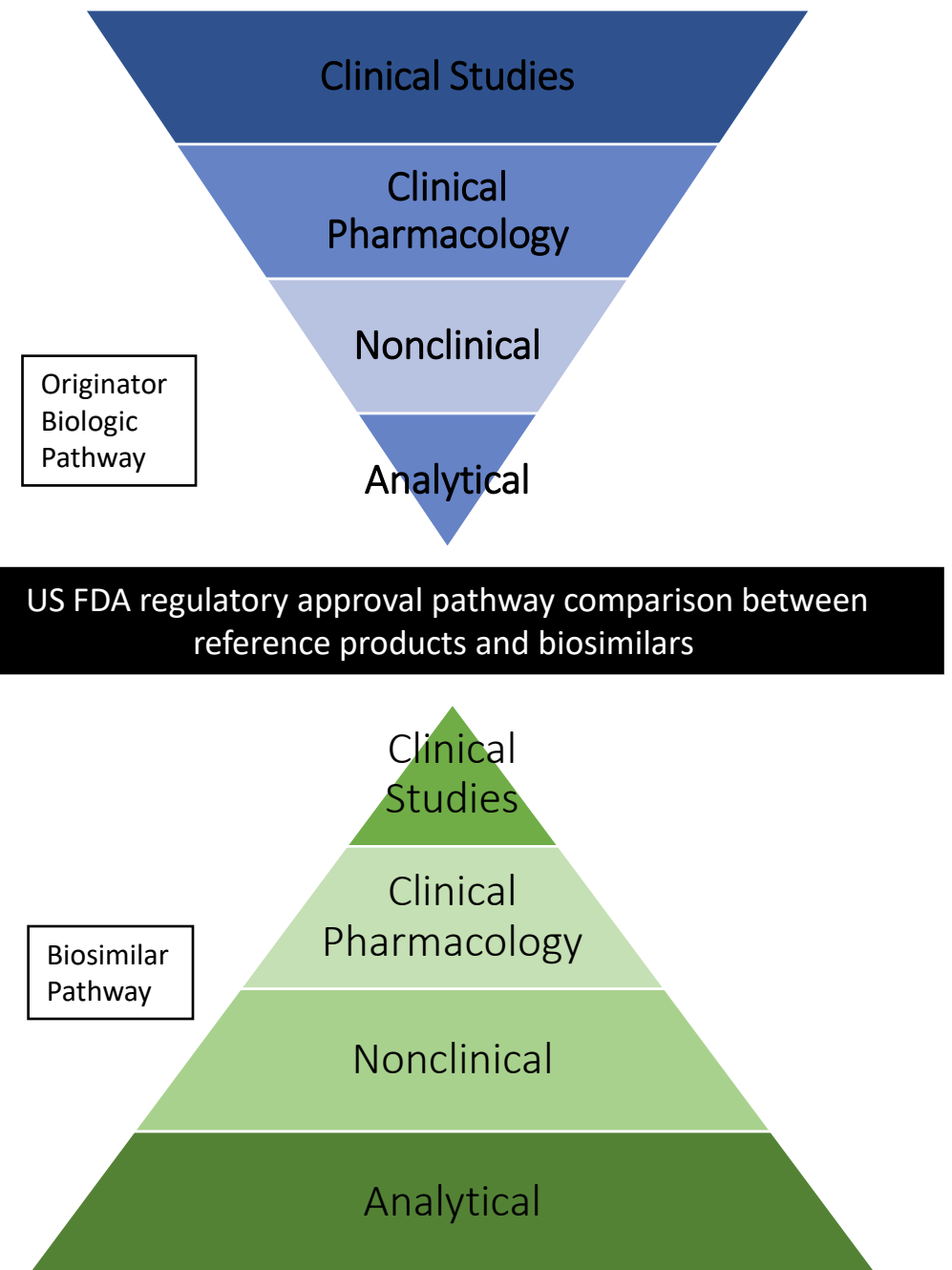
Highly similar to reference product

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



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](#)

Use of biosimilars in practice

2016 European Society of Medical Oncology (ESMO)

- 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

2025 Community Oncology Alliance (COA)

- 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

2023 American Society of Clinical Oncology (ASCO)

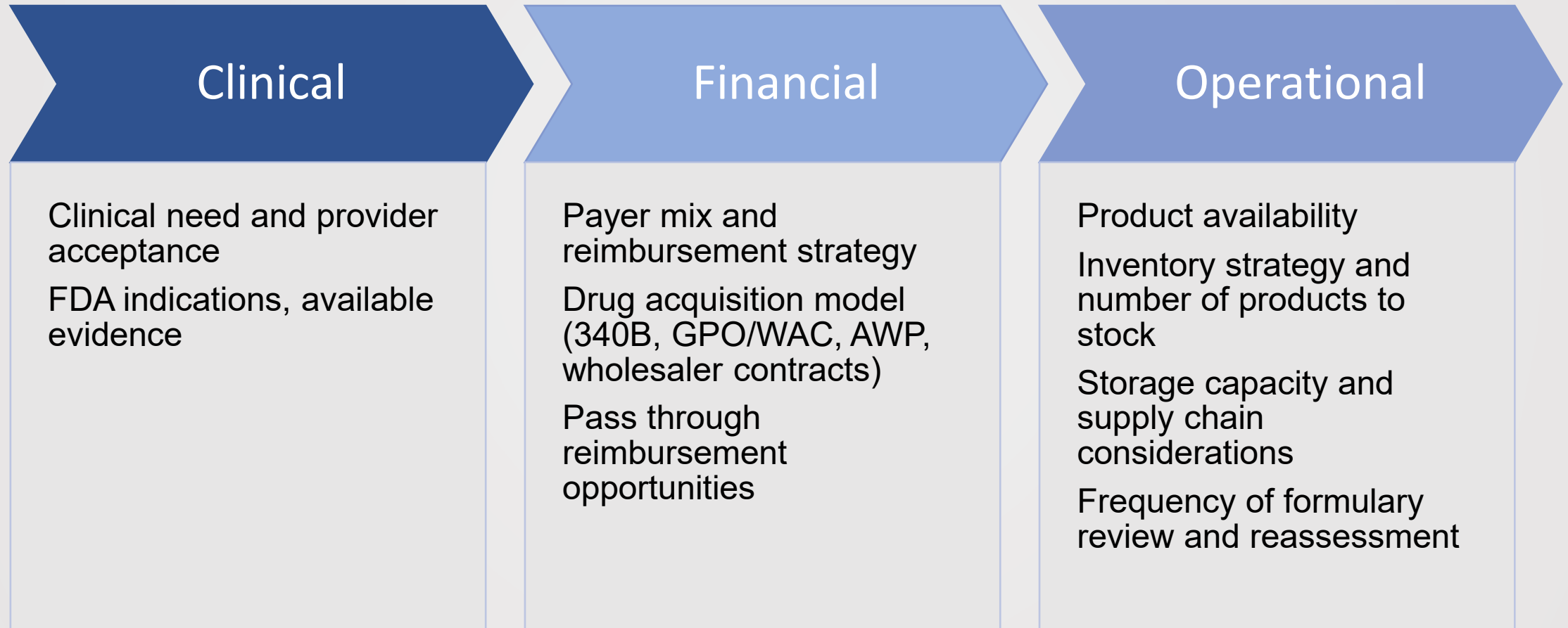
- Increase education for patients and providers to build biosimilar confidence
- Payers should provide transparent formulary decisions and reduce inventory barriers (e.g., multiple biosimilars of the same reference product)
- Substitution decisions should remain between patient and physician
- Promote regulatory pathways to encourage biosimilar market entry, including reduced data exclusivity
- Continue post-market surveillance and cost-

¹ Gladys Rodríguez et al. *JCO Oncol Pract* **19**, 411-419(2023).

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

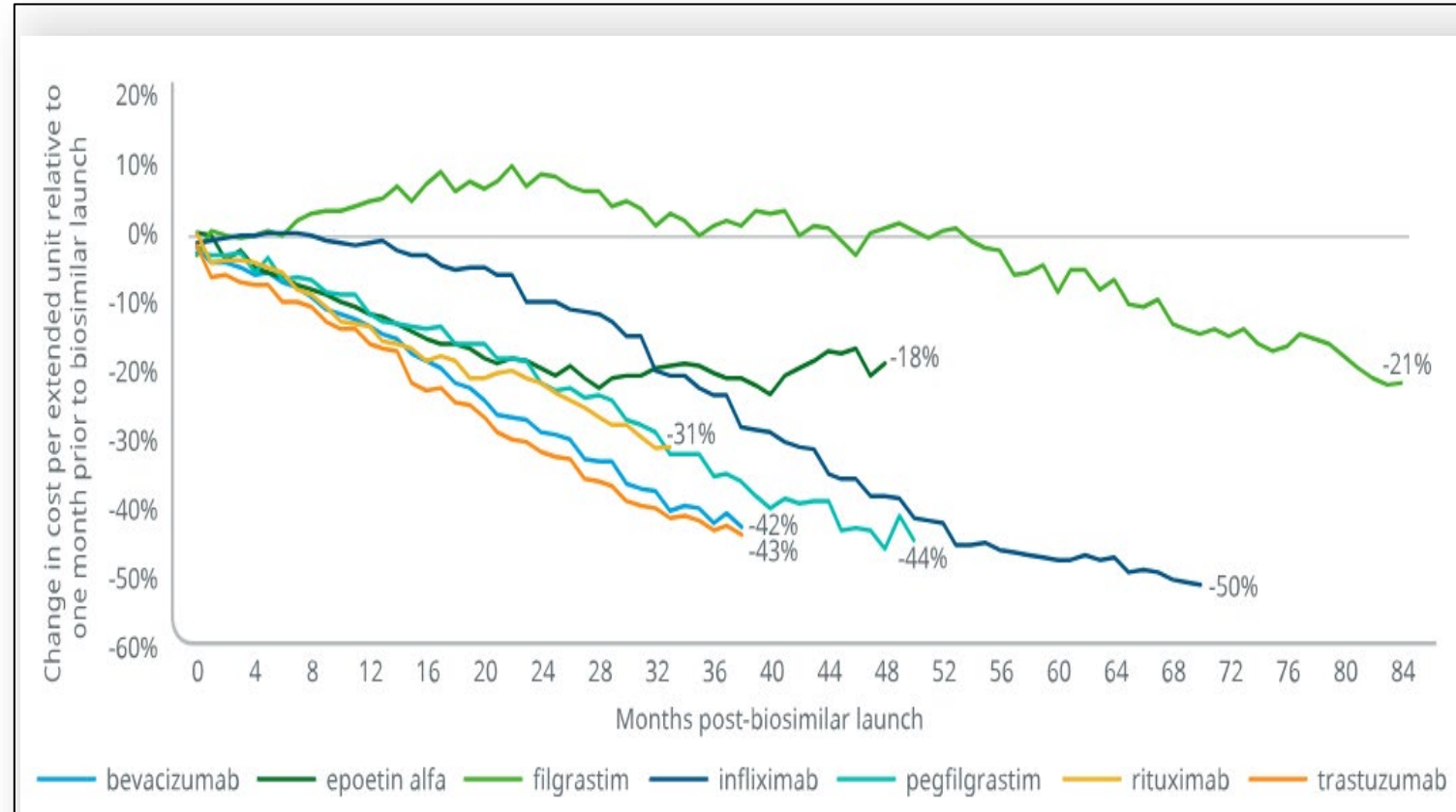
Schiestl M, Krendyukov A. *ESMO Open*, 2

Key components for biosimilar additions to formulary

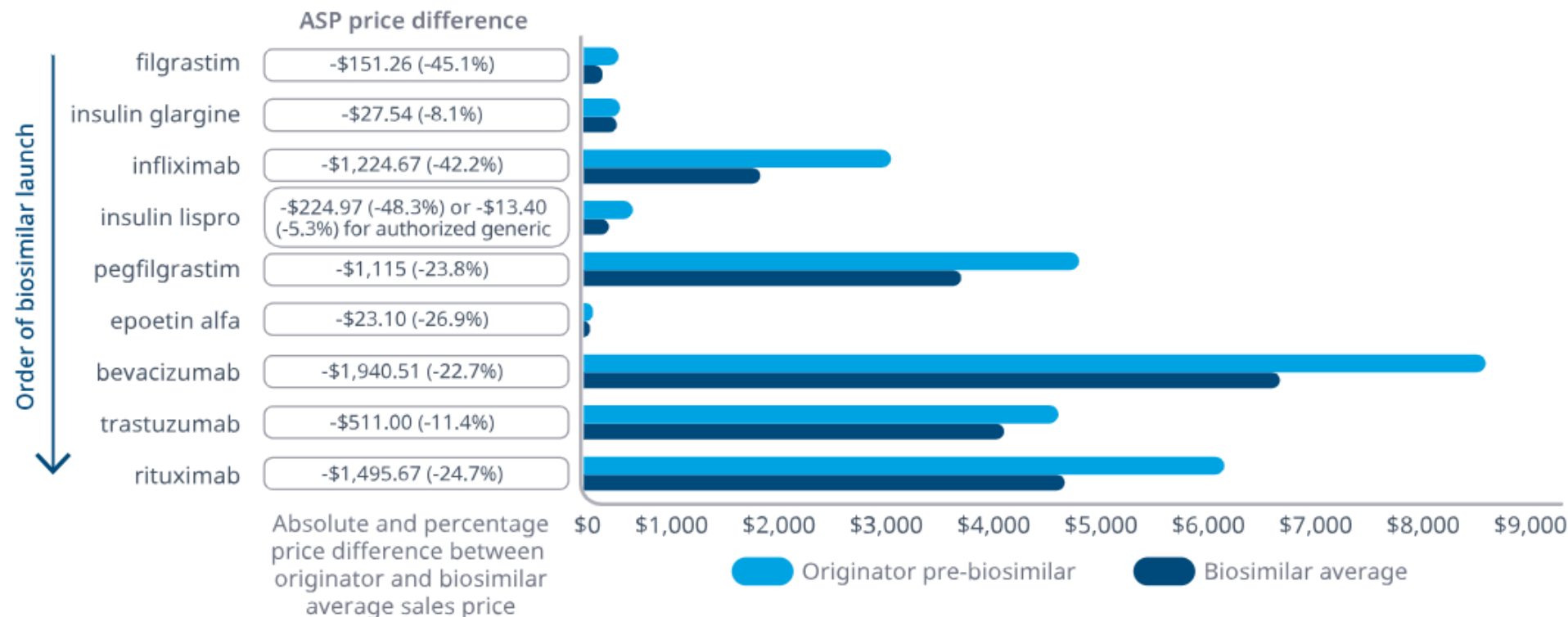


Economics of Biosimilars

- 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



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

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

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

Pre-Medications, 650 mg, Oral, Once, Starting at treatment start time, For 1 dose
Administer 30 minutes prior to rituximab.

diphenhydramINE (BENADRYL) capsule 25 mg
Pre-Medications, 25 mg, Oral, Once, Starting at treatment start time, For 1 dose
Administer 30 minutes prior to rituximab.

▼ RITUXIMAB 375 MG/M2 OFFSET BY 30 MIN

RITUXIMAB BIOSIMILAR ORDERABLE IV infusion 375 mg/m2 (Treatment Plan)
Chemotherapy, 375 mg/m2, Intravenous, Once, Starting 30 minutes after treatment start time, For 1 dose

← → Dispensable Mapping Dispensable Mapping

Orderable medication: RITUXIMAB BIOSIMILAR ORDERABLE FOR ADJUTICATION [4081308201]

#	Dispensable Drug	Patient Age	Patient Weight	Patient Rule	Dose
1	▼ RITUXIMAB BIOSIMILAR UNSPECIFIED [4081338201]			RXIV BIOSIMILAR ORDERABLE PL...	
2	▼ RITUXIMAB-ABBS IV INFUSION [4085003427]			ONCECN RITUXAN NOT BIOSIMILA...	
3	▼ RITUXIMAB IV 250 ML INFUSION [4081344491]			ONCECN NOT BIOSIMILAR RITUX...	
4	▼ RITUXIMAB IV 500 ML INFUSION [416001]			ONCECN NOT BIOSIMILAR RITUX...	
5	▲ RITUXIMAB-ABBS IV 250 ML INFUSION NCI [4081346501]			ONCECN BIOSIMILAR RITUXIMAB...	
Patient age: Patient weight: kg Order dose: mg Order mode: Inpatient Outpatient <input checked="" type="button" value="Both"/> ☐ Select based on what is authorized on the treatment or therapy plan referral Edit Medication Record to to kg to mg Patient rule: ONCECN BIOSIMILAR RITUXIM... Routes:					
6	▼ RITUXIMAB-ABBS IV 500 ML INFUSION NCI [4081348201]			ONCECN BIOSIMILAR RITUXIMAB...	
7	▼ RITUXIMAB-PVVR IV 250 ML INFUSION NCI [4081346701]			ONCECN BIOSIMILAR RITUXIMAB...	
8	▼ RITUXIMAB-PVVR IV 500 ML INFUSION NCI [4081270801]			ONCECN BIOSIMILAR RITUXIMAB...	
9	▼ RITUXIMAB-ARRX IV 250 ML INFUSION NCI [4081346801]			ONCECN BIOSIMILAR RITUXIMAB...	
10	▼ RITUXIMAB-ARRX IV 500 ML INFUSION [4081315901]			ONCECN BIOSIMILAR RITUXIMAB...	

Norton Cancer Institute

General

Referred By/To

Treatment Plan

Diagnoses

Services

Peer to Peer

Scheduling

Appointment List

Communications

Flags

Referral Details

Authorization

HUMANA *HUMANA*

Coverage Auth



No electronic authorization requests

Manual Authorizations

Reference #Auth #

AR5571672

Service	Auth Status	Auth #	From Date	To Date	Req	Appr	Rem
J2919 - PR INJ, METHYLPRED SOD SUCC 5MG Medication: METHYLPREDNISOLONE SODIUM SUCC 125 MG IJ SOLR	—	—	—	—	—	—	0
J1308 - PR INJ, FAMOTIDINE, 0.25 MG Medication: FAMOTIDINE (PF) 20 MG/2ML IV SOLN	—	—	—	—	—	—	0
J2919 - PR INJ, METHYLPRED SOD SUCC 5MG Medication: METHYLPREDNISOLONE IV ORDERABLE	—	—	—	—	—	—	0
Q5119 - PR INJ RUXIENCE, 10 MG Medication: RITUXIMAB BIOSIMILAR ORDERABLE	✓ Authorized	AR5571672	6/17/2026	9/16/2026	13	13	13

✓ Close

↑ Previous

↓

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-arxx (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

Treatment Plan Manager - OP LYMPHOMA (CLL) RiTUXimab (Weekly X 4)

+ Add Future Plan ✖ Discontinue Plan 📧 Send Plan 💬 Share in Chat ➤ Add/Remove Views 📊 Calculator

TP Height: 167 cm Δ+0.0% ⌚ 14d ago TP Weight: 93.5 kg Δ+0.0% 🕒 yesterday TP BSA: 2.02 m² Δ+0.0% 📅 Schedule ✓ Sign Cycles 🔍 [Redacted]

📄 Lifetime Dose

+ Add ➤ Modify Dose 📄 Review Orders 🖨 Print Labels ⌵ Show 🗓 Current Day 🔦 Spotlight 📊 Calculator

▼ **OP LYMPHOMA (CLL) RiTUXimab (Weekly X 4)** Actions ▼

🔗 Start Date: 7/20/2026, Treatment Goal: Curative, Plan Provider: [Redacted]

▼ Treatment Plan Approval Order — 7/18/2026, Planned			Sign	Actions ▼	🗑
▼ 📄 Treatment Plan Approval, Treatment Plan Approval Order — Planned for 7/18/2026			Sign	Release	Actions ▼ 🗑
▼ Provider Communication			Sign	Release	Actions ▼ 🗑
Provider Communication 3 ⓘ Treatment plan reviewed and approved. Proceed with orders per protocol.			Sign	Release	Actions ▼ 🗑
> Pre-Treatment Orders — 7/19/2026, Planned			Sign	Actions ▼	🗑
▼ Cycle 1 — 7/20/2026 through 8/16/2026 (28 days), Planned			Sign	Actions ▼	🗑
▼ 📄 Day 1, Cycle 1 — Planned for 7/20/2026			Sign	Actions ▼	🗑
> Labs & Appointments			Sign	Actions ▼	🗑
> Nursing Orders			Sign	Actions ▼	🗑
> Flush Solution			Sign	Actions ▼	🗑
> Sensitivity Medications			Sign	Actions ▼	🗑
▼ Chemotherapy			Sign	Actions ▼	🗑
RiTUXimab-arx (RIABNI) 760 mg in sodium chloride 0.9 % 326 mL IVPB ⓘ 760 mg (rounded from 757.5 mg = 375 mg/m ² × 2.02 m ² Treatment Plan BSA from Recorded weight), Intravenous, Once, Starting 45 minutes after treatment start time, For 1 dose ⓘ 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 been selected as insurance preferred product. ⓘ Corbin, Richmond - Diluent Prime Line			Sign	Actions ▼	🗑
> Emergency Medications			Sign	Actions ▼	🗑

Active Insurance as of 7/20/2026

HUMANA MEDICARE REPLACEMENT - Humana Medicare Advantage GROUP
PPO

Treatment Plan Manager - OP LYMPHOMA (CLL) RiTUXimab (Weekly X 4)

+ Add Future Plan ✖ Discontinue Plan 📧 Send Plan 💬 Share in Chat ✂ Add/Remove Views 📊 Calculator

TP Height: **170.2 cm** Δ+0.0% ⌚ 3d ago TP Weight: **92.1 kg** Δ+0.0% ⌚ 3d ago TP BSA: **2.04 m²** Δ+0.0% 📅 Schedule ✓ Sign Cycles R ██████████

+ Add ✎ Modify Dose 📋 Review Orders 🖨 Print Labels ☰ Show 🗓 Current Day 🔍 Spotlight 📊 Calculator

▼ OP LYMPHOMA (CLL) RiTUXimab (Weekly X 4) Actions ▼

🔑 Start Date: 7/20/2026, Treatment Goal: Curative, Plan Provider: ██████████

▼ Treatment Plan Approval Order — 7/18/2026, Planned Sign Actions ▼ 🗑

▼ [🔒] Treatment Plan Approval, Treatment Plan Approval Order — Planned for 7/18/2026	Sign Release Actions ▼ 🗑
▼ Provider Communication	Sign Release Actions ▼ 🗑
Provider Communication 3 ⋮ Treatment plan reviewed and approved. Proceed with orders per protocol.	Sign Release Actions ▼ 🗑

> Pre-Treatment Orders — 7/19/2026, Planned Sign Actions ▼ 🗑

▼ Cycle 1 — 7/20/2026 through 8/16/2026 (28 days), Planned Sign Actions ▼ 🗑

▼ [🔒] Day 1, Cycle 1 — Planned for 7/20/2026	Sign Actions ▼ 🗑
> Labs & Appointments	Sign Actions ▼ 🗑
> Nursing Orders	Sign Actions ▼ 🗑
> Labs & Appointments	Sign Actions ▼ 🗑
> Nursing Orders	Sign Actions ▼ 🗑
> Flush Solution	Sign Actions ▼ 🗑
> Sensitivity Medications	Sign Actions ▼ 🗑
▼ Chemotherapy	Sign Actions ▼ 🗑
riTUXimab-pvvr (RUXIENCE) 770 mg in sodium chloride 0.9 % 327 mL IVPB ⋮ 770 mg (rounded from 765 mg = 375 mg/m ² × 2.04 m ² Treatment Plan BSA from Recorded weight), Intravenous, Once, Starting 45 minutes after treatment start time, For 1 dose 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 been selected as insurance preferred product. Corbin, Richmond - Diluent Prime Line	Sign Actions ▼ 🗑
> Emergency Medications	Sign Actions ▼ 🗑

Active Insurance as of 7/20/2026

PASSPORT HEALTH BY MOLINA - PASSPORT BY MOLINA

UK - Markey

 Hospital Medications

Name	Dose	Route	Frequency	Phase of Care
 bevacizumab (biosimilar orderable) IV		Intravenous	Once	

Orderable medication: BEVACIZUMAB IV BIOSIMILAR ORDERABLE [40850014]

Dispensable Drug		Patient Age	Pati
1	⌵ BEVACIZUMAB CHEMO IVPB [410002]		
2	⌵ BEVACIZUMAB-ADCD CHEMO IVPB [408610006]		
3	⌵ BEVACIZUMAB-AWWB CHEMO IVPB [40850162]		
4	⌵ BEVACIZUMAB-BVZR CHEMO IVPB [40850108]		

	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

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