ACCC 2023

Oncology Reimbursement MEETINGS

The Oncology Pharmacy Is Your Prior Authorization Ally

Association of Community Cancer Centers

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Learning Objectives:

Collaboration between Pharmacy and Financial Advocates in Cancer Care

- Establish the roles of our patient financial advocate (PFA) teams at St. Luke's Cancer Institute.
- Discuss how pharmacy collaboration with PFAs effects prior authorization turnaround time.
- Highlight successful collaboration workflows for:
  - Biosimilar authorizations
  - Oral chemotherapy authorizations.
- Discuss the impact of pharmacy collaboration on the PFAs' ability to assist patients with out-of-pocket costs.

St. Luke's Cancer Institute
Patient Financial Advocate (PFA) Teams

1. Clinic PFA Team

- Obtain treatment prior authorization for infusion/injectable drugs.
- Identify and apply for infusion/injectable co-pay assistance for patients.
- Identify and apply other forms of assistance (internal charity, Supplemental Security Income [SSI], Medicaid, etc.) for patients.

2. Medication Assistance PFA Team

- Identify and obtain all oral chemotherapy assistance.
- Enroll into and manage patients with patient assistance programs.
- Process infusion/injectable co-pay assistance claims.

Outpatient Biosimilars

- Pharmacy and financial advocacy collaboration in the outpatient setting:
  - Our clinic PFAs identify the payer's preferred biosimilar during the prior authorization process.
    - This often eliminates the need for a prior authorization, which results in the patient receiving treatment sooner.
  - PFAs communicate payer preference to our pharmacists, who then substitute the biosimilar in the patient's treatment plan.
  - Pharmacists also offer valuable insight to our PFAs on the often-rigorous clinical questions of a prior authorization submission.
    - Some payer portals instantly authorize certain treatments if clinical questions are answered soundly; teamwork between pharmacy and PFAs is crucial.
  - Ultimately this collaboration leads to quicker prior authorization turnaround time and high-quality patient care.

Outpatient Biosimilars

- Examples of online resources that our PFAs utilize to identify a preferred biosimilar

SelectHealth:[1]

SelectHealth® offers commercial formulary coverage of the following biosimilar medications:

Reference product	Formulary status	Biosimilar	Formulary status
Filgrastim (Neupogen)	Formulary	Tbo-filgrastim (Granix)[a]	Formulary
		Filgrastim-sndz (Zarxio)	Formulary[b]
		Filgrastim-aafi (Nivestym)	Formulary[b]
Pegfilgrastim (Neulasta)	Formulary	Pegfilgrastim-cbqv (Udenyca)	Formulary
		Pegfilgrastim-jmdb (Fulphila)	Nonformulary
InFLIXimab (Remicade)	Formulary	InFLIXimab-abda (Renflexis)	Formulary[b,c]
		InFLIXimab-dyyb (Inflectra)	Nonformulary

[a]Tbo-filgrastim (Granix) is not a true biosimilar

[b]Requires prior authorization

[c]InFLIXimab-abda (Renflexis) is preferred for new starts; switching established patients to infliximab-abda (Renflexis) is strongly encouraged

Blue Cross of Idaho:[2]

Granulocyte Colony-Stimulating Factors (G-Csf)			
FULPHILA		3	SP
NEULASTA ONPRO		3	SP
NEULASTA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE		3	SP
NIVESTYM		3	SP
NYVEPRIA		3	SP
UDENYCA		3	SP
ZARXIO		3	SP
Hemoglobin S (Hbs) Polymerization Inhibitors			
OXBRYTA		4	PA; SP
Iron Combinations			
foltrin	Tricon	1	

Standard 4-Tier Formulary

AL = age limitation; PA = prior authorization; PREV = preventative drugs for HSA plans; SP = specialty medication; ST = step therapy; QL = quantity limits

Inpatient Biosimilars

- For PFAs, St. Luke's Cancer Institute's pharmacists established this table that helps PFAs understand which biosimilar will be administered during an inpatient stay.
- This mainly applies to the Blood and Marrow Transplant PFA Team; the majority of our PFA teams do not see many planned inpatient admissions.

Biosimilar Interchange Options

Originator Product (generic)	Neupogen ® (filgrastim)	Neulasta® (pegfilgrastim)	Rituxan® (Rituximab)
Outpatient Alternatives (Selected based on Insurance)	Granix (tbo-filgrastim) Nivestym (filgrastim-aafi) Zarxio (filgrastim-sndz)	Fulphila (Pegfilgrastim-jmdb) Nyvepria (pegfilgrastim-apgf) Udenyca (pegfilgrastim-cbqv) Ziextenzo (pegfilgrastim-bmez)	Riabni (rituximab-arrx) Ruxience (rituximab-pvvr) Truxima (rituximab-abbs)
Inpatient Agent Used regardless of Insurance	Granix (tbo-filgrastim)	Fulphila (Pegfilgrastim-jmdb)	Ruxience (rituximab-pvvr)

Oral Chemotherapy Collaboration

- Pharmacy involvement
  - Oral chemotherapy pharmacy technicians submit prior authorization and run test claims.
- PFA involvement
  - Medication assistance PFAs identify and obtain any available assistance.
  - They communicate the awarded assistance details back to oral chemotherapy for processing.
- Both teams collaborate with the prescribing provider on any denial(s) to ensure the quickest resolution.
- Overall, this collaboration with pharmacists provides PFAs with maximum bandwidth to financially advocate for St. Luke's Cancer Institute's patients and, in doing so, **minimize out-of-pocket costs and financial toxicity.**

Summary

- Established common barriers to prior authorization(s) and how the collaboration between pharmacy and PFAs combats those barriers, resulting in high-quality patient care.
  - Minimizing treatment delays by answering clinical prior authorization submission questions accurately.
  - Requesting the appropriate biosimilar based on the treatment setting.
  - Maximizing bandwidth for financial assistance to eliminate financial toxicities associated with cancer care.
- The multidisciplinary approach supports high-quality and cost-effective cancer care.

Increasing Oncology Drug Costs Challenge the Healthcare System

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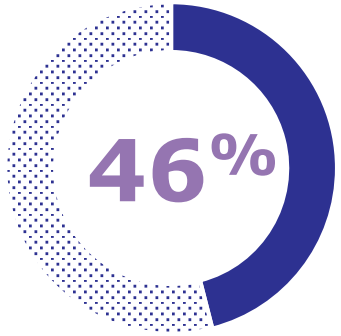
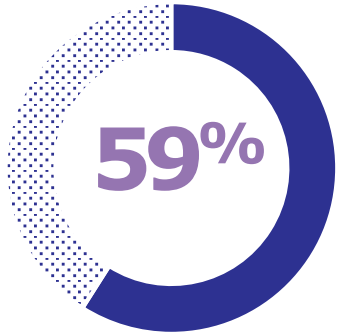
Payers[3]

In 2021, oncology and oncology supportive care drugs accounted for:



of commercial medical benefit drug spend



of Medicare Part B drug spend

Providers[4,5]

Payer cost management tools impact prescribing and may also shift financial risk[2]

- Prior authorization(s), step edits, co-pay, product tiers, formulary exclusions
- Clinical pathways, potentially tied to reimbursement
- Buy-and-bill incentives for preferred products
- Oncology Care Model → Enhancing Oncology Model, bundled payments, preferred provider networks

Oncology Patients Are Facing Higher Out-of-Pocket Costs and Increased Financial Strain

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Medicare Part B premiums and deductibles **increased by 15%** between 2021 and 2022, due in part to rising prices across the healthcare system.[6]

Annual out-of-pocket costs for Medicare patients with recently diagnosed cancer average **$2,400, but can be as high as $6,000-$7,000.**[7,a]

Patients and caregivers report that cancer costs have resulted in:[8]

- Bankruptcy
- Accumulation of debt
- Depletion of savings
- Non-adherence to anti-cancer therapy

[a]Includes medical services and prescription drugs. Based on Surveillance, Epidemiology, and End Results (SEER) Medicare data, 2007-2013.

The High Financial Toll of Cancer[9]

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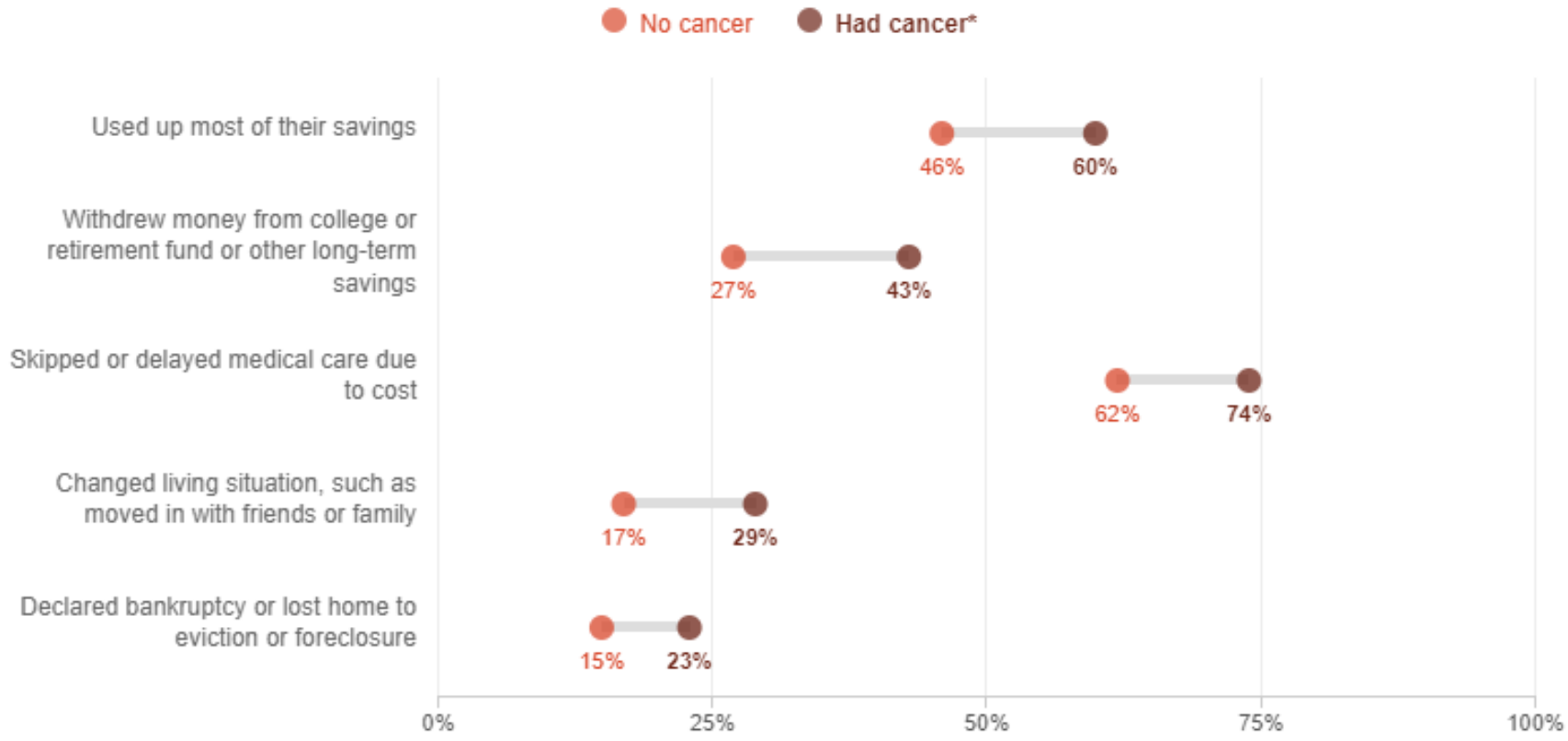
- Share of indebted adults, who say they or someone in their household have done the following due to healthcare debt



Note: *They or an immediate family member received treatment for cancer in the past five years.

Biosimilars Are Safe, Effective, Cost-Efficient Versions of Biologic Medications[10]

Biologics

- Large, complex molecules produced in living systems
- Include therapeutic proteins, monoclonal antibodies (e.g., pegfilgrastim, adalimumab), and vaccines

Biosimilars

- A biologic product that is highly similar to and with no clinically meaningful difference from the reference biologic

Biosimilars are highly similar to reference biologics[11]

Reference product | Biosimilar

Complex manufacturing processes may lead to *clinically insignificant* differences between biosimilars and reference products, or within lots of the same biologic product.

Safety and Efficacy of Biosimilars Are well Established

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	European Medicines Agency[12,13,a]	U.S. Food and Drug Administration[12,13,a]
First biosimilar approval	**2006**	**2015**
Total number of approved biosimilars	74	40
Total number of biosimilars launched	74	27

- All approved biosimilars undergo rigorous evaluations that ensure their efficacy, safety, and quality.[14]
- More than two-thirds of oncology prescribers are likely to prescribe biosimilars for new patients or existing patients, who have had success with a reference product.[15,b]

[a]As of November 17, 2022.
[b]Based on a Cardinal Health survey of 323 oncology prescribers.

Biosimilar Competition Drives Down Oncology Costs[16]

- Oncology biosimilars have launched at prices ranging from about 3%-24% below the innovator product average sales price (ASP)
- Prices for biosimilars and reference products continue to decrease as additional biosimilars are approved

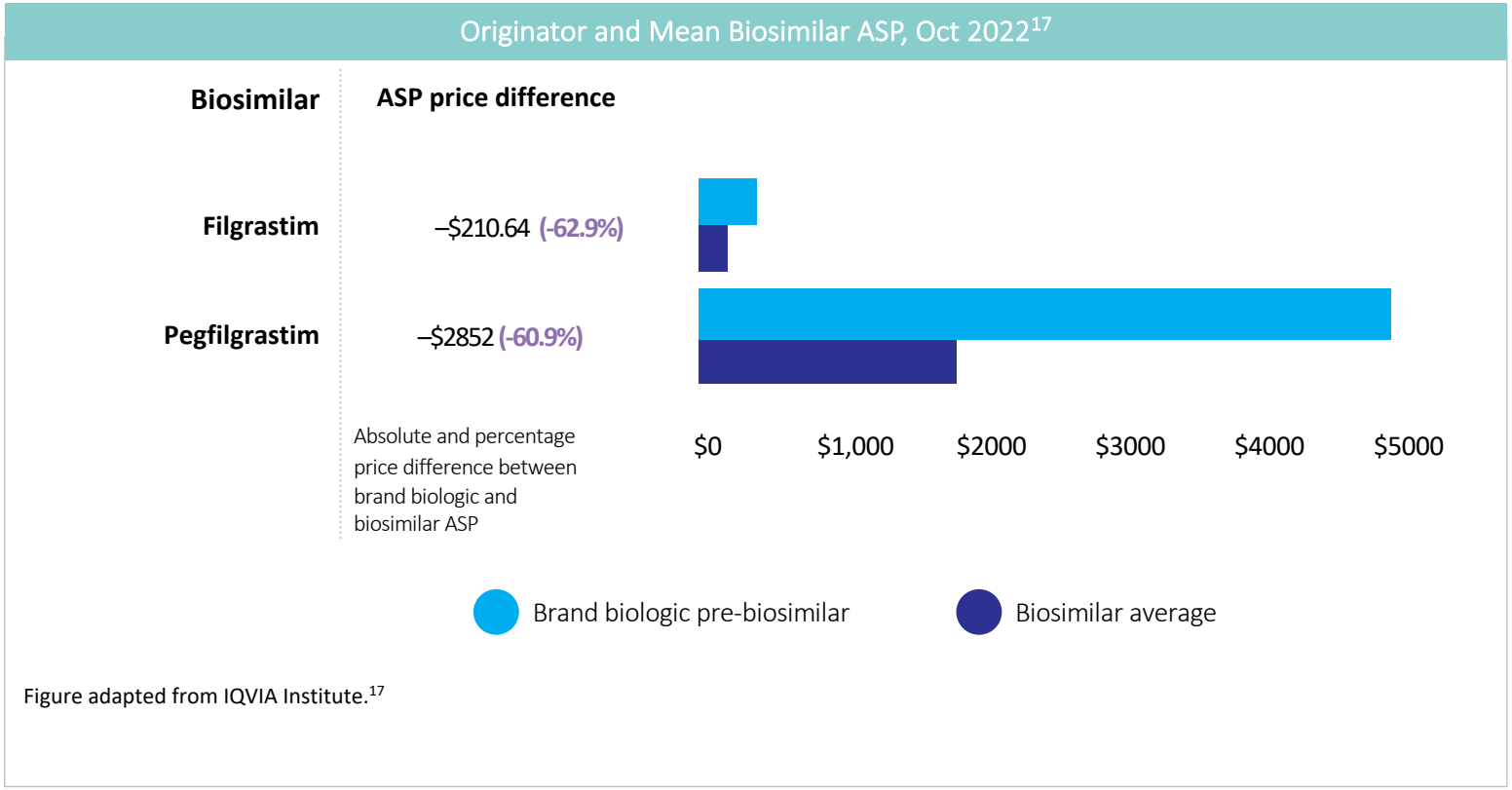
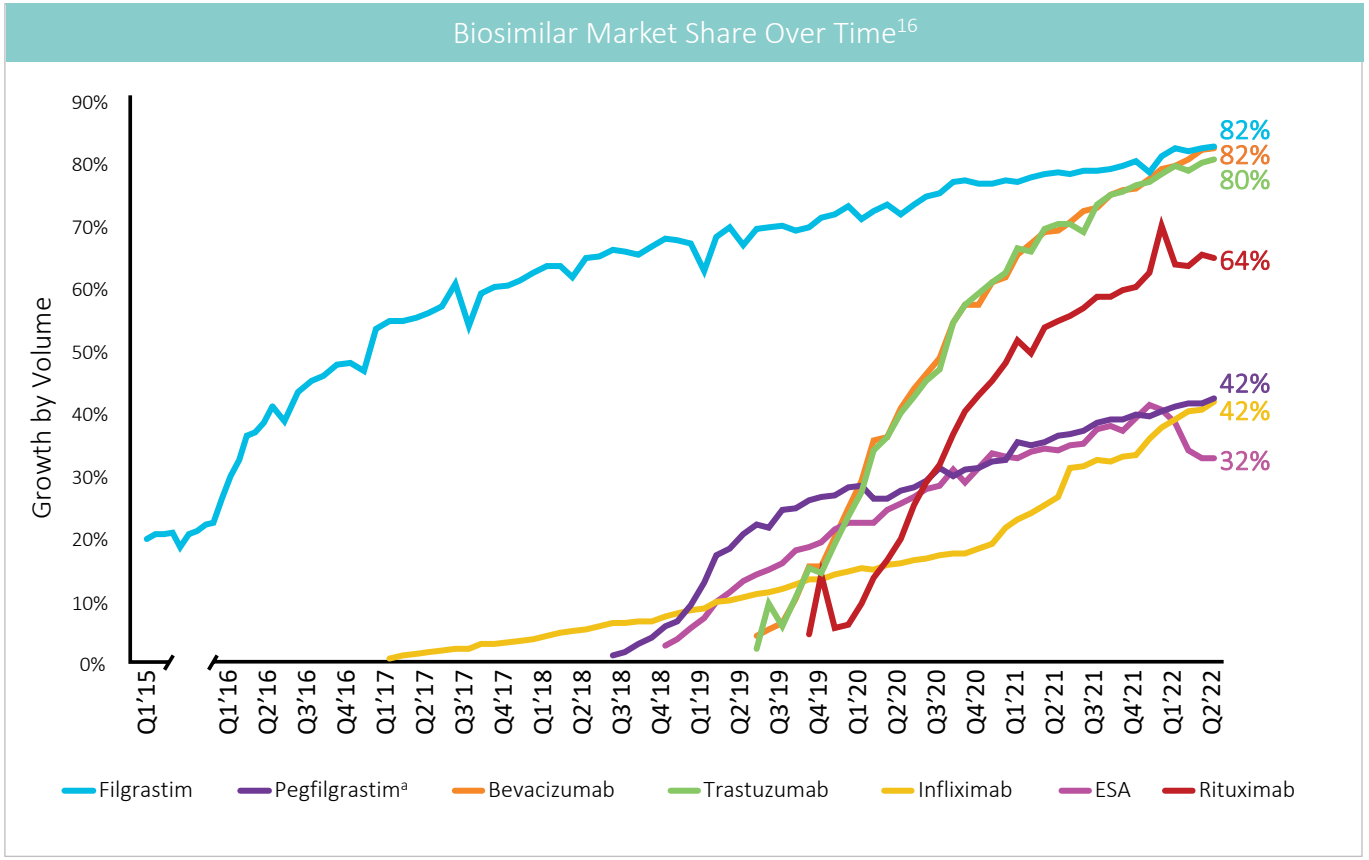


Figure adapted from IQVIA Institute.[17]

Biosimilar Use in the U.S. Is Increasing



- Adoption of biosimilars has been strongest in oncology.[15]
- Despite improvement in adoption rates, **barriers continue to exist**.[15]

[a]Excludes on-body injector for pegfilgrastim syringes, biosimilar market share is 78%.

Biosimilar Challenges

- Payer coverage
- Provider financials
- Patient access

Coverage Shifts: Pegfilgrastim

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	Oct 2019	Jan 2020	Mar 2020	Aug 2021	Oct 2022
Payer #1					
Pegfilgrastim	P	P	P	P	P
Pegfilgrastim-jmdb	P	P	P	NP	NP
Pegfilgrastim-cbqv	P	P	P	P	P
Pegfilgrastim-bmez	N/A	N/A	NP	NP	NP
Pegfilgrastim-apgf	N/A	N/A	N/A	NP	NP

	Oct 2019	Jan 2020	Mar 2020	Aug 2021	Oct 2022
Payer #2					
Pegfilgrastim	P	P	P	P	P
Pegfilgrastim-jmdb	NP	NP	NP	NP	P
Pegfilgrastim-cbqv	NP	NP	NP	NP	P
Pegfilgrastim-bmez	N/A	N/A	P	P	NP
Pegfilgrastim-apgf	N/A	N/A	N/A	NP	NP

	Oct 2019	Jan 2020	Mar 2020	Aug 2021	Oct 2022
Payer #3					
Pegfilgrastim	P	P	P	NP	NP
Pegfilgrastim-jmdb	NP	P	P	NP	NP
Pegfilgrastim-cbqv	P	P	P	P	P
Pegfilgrastim-bmez	N/A	N/A	P	P	P
Pegfilgrastim-apgf	N/A	N/A	N/A	NP	NP

	Oct 2019	Jan 2020	Mar 2020	Aug 2021	Oct 2022
Payer #4					
Pegfilgrastim	P	P	P	P	P
Pegfilgrastim-jmdb	NP	NP	NP	NP	NP
Pegfilgrastim-cbqv	NP	NP	P	P	P
Pegfilgrastim-bmez	N/A	N/A	NP	NP	NP
Pegfilgrastim-apgf	N/A	N/A	N/A	NP	NP

Preferred
Non-preferred
No data

Commercial vs. Advantage: Pegfilgrastim

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	Oct 2019	Jan 2020	Mar 2020	Aug 2021	Oct 2022
Payer #4, commercial					
Pegfilgrastim	P	P	P	P	P
Pegfilgrastim-jmdb	NP	NP	NP	NP	NP
Pegfilgrastim-cbqv	NP	NP	P	P	P
Pegfilgrastim-bmez	N/A	N/A	NP	NP	NP
Pegfilgrastim-apgf	N/A	N/A	N/A	NP	NP

	Oct 2019	Jan 2020	Mar 2020	Aug 2021	Oct 2022
Payer #4, Medicare Advantage					
Pegfilgrastim	P	P	P	P	P
Pegfilgrastim-jmdb	P	P	NP	NP	NP
Pegfilgrastim-cbqv	NP	NP	NP	NP	NP
Pegfilgrastim-bmez	N/A	N/A	P	P	P
Pegfilgrastim-apgf	N/A	N/A	N/A	NP	NP

Preferred
Non-preferred
No data

Biosimilar-Related Cost Savings Are Expected to Increase Over the Next Several Years[17]

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2013-2022

The U.S. has saved

$56 billion

on biologic medications by using biosimilars[a]

2023-2027

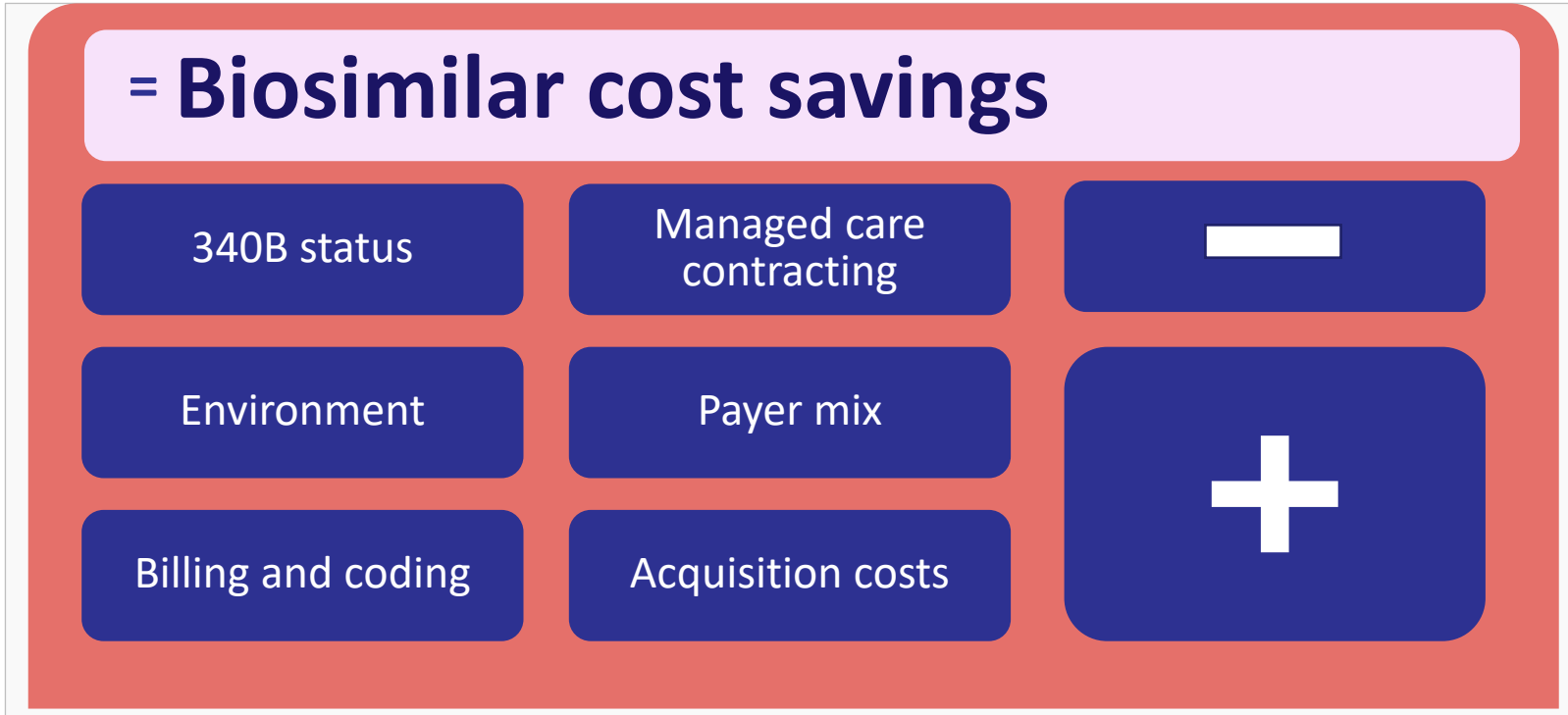
Potential savings of

$181 billion

(range, $125billion to $237 billion) with increasing biosimilar use[b]

[a]Calculated by comparing actual molecule spend to projected spending if total molecule volume had been at originator *pre-expiry* prices.
[b]Based on estimated continuing impact of biosimilar events in progress, as well as expected expiries. The range of savings includes assumptions for high, low, and average biosimilar volume uptake and price discounts relative to originators.

There Is no "One-Size-Fits-All" to Calculate Biosimilar Cost Savings[18]



Multiple factors affect the cost-savings potential of biosimilars

Changes to 340B Reimbursement: 2023

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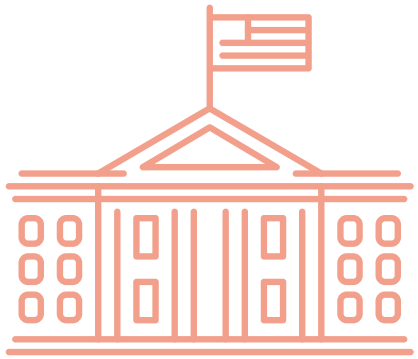
Inflation Reduction Act 2022[19]

Biosimilars: ASP+8% (reference product ASP)

- Previously ASP+6%
- Guarantees reimbursement rate for 5-year period
- Oct. 1, 2022, to Dec. 31, 2027, for existing biosimilars



Department of Health and Human Services (HHS) & Supreme Court ruling: June 15, 2022[20]

- Previous cuts to 340B payments (ASP-22.5%) deemed unlawful
- Reference product CMS payment: ASP+6%
- All other separately payable CMS payments: ASP+6%

Commercial Payers

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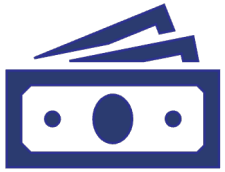


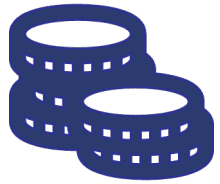
Fee schedule

Like CMS, separately payable fee schedule where there is an agreed upon reimbursement rate per Healthcare Common Procedure Coding System (HCPCS) code.

Percent of charges

Providers are reimbursed based on charges associated with the HCPCS code.

More expensive medications may net increased revenue.



Value-based arrangements

Fastest growing reimbursement strategy.

Could be bundled payments, capitation, or shared risk.

Payer Models of Biosimilar Reimbursement[3]

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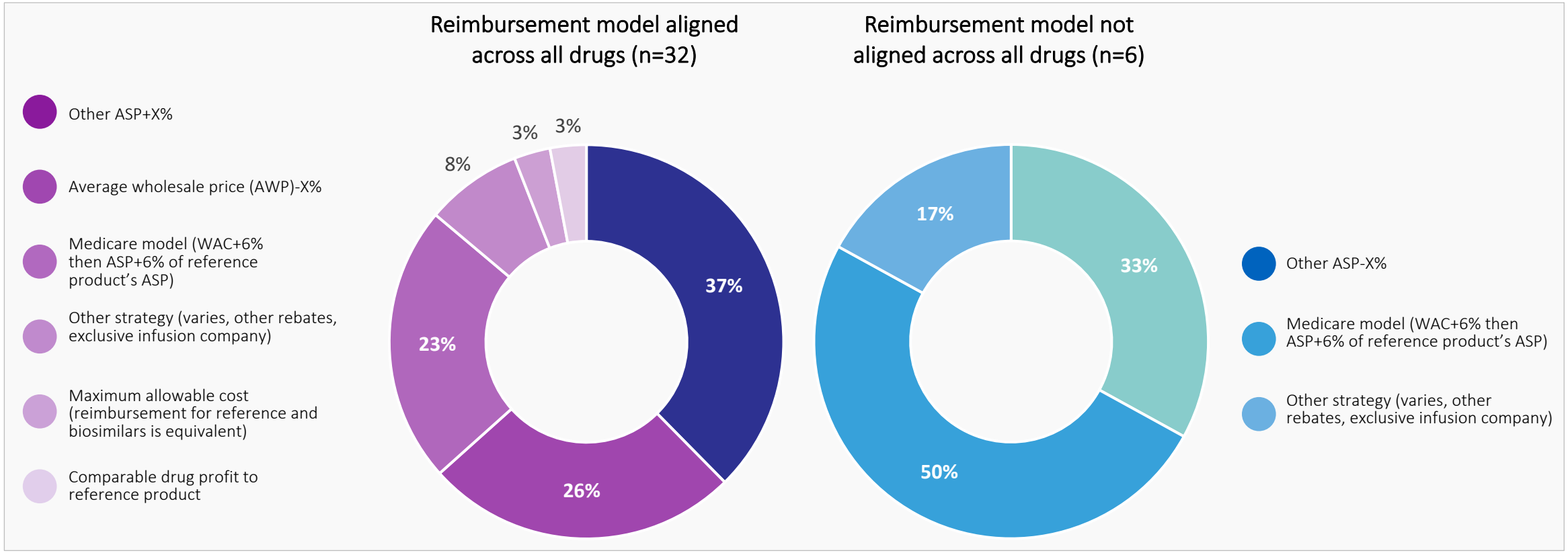
Payers reported innovative approaches to incentivize biosimilar use, such as lowering patient cost-share and providing focused education.



Magellan 2022

Putting it all Together: Assessing Net Cost Recovery (NCR)

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Scenario: You are evaluating 2 pegfilgrastim biosimilars to potentially add to your formulary for your 340B inpatient hospital. How might you begin this process?

1. Assess acquisition costs including variables, such as rebates and tiered contracts
2. Define reimbursement (% of charges, fee schedules)
3. Plug into payers and calculate NCR

Product	Cost per vial (6mg)	Billing unit	Per billing unit cost	Payer 1: Preferred product (Y/N)	Payer 1: Fee schedule	NCR Payer 1
Biosimilar A	$540	0.5mg	$45	Yes	$171	$126
Biosimilar B	$300	0.5mg	$25	Yes	$75	$50
Reference product	$600	0.5mg	$50	No	$170	$120

While both biosimilars are covered by the payer, biosimilar A has the largest NCR.

Putting it all Together: Assessing NCR

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Scenario: You are evaluating 2 pegfilgrastim biosimilars to potentially add to formulary for your 340b inpatient hospital. How might you begin this process?

1. Assess acquisition costs including variables such as rebates and tiered contracts
2. Define reimbursement (% of charges, fee schedules)
3. Plug into payers and calculate NCR

Product	Cost per vial (6mg)	Billing unit	Per billing unit cost	Payer 2: Preferred product (Y/N)	Payer 2: % of charges	NCR Payer 2
Biosimilar A	$540	0.5mg	$45	Yes	71.3%	$32.09
Biosimilar B	$300	0.5mg	$25	Yes	71.3%	$17.83
Reference product	$600	0.5mg	$50	No	71.3%	$35.65

Although the reference product has the largest NCR, it is not covered by payer 2; biosimilar A has the higher NCR of the 2 biosimilars.

Putting it all Together: Assessing NCR

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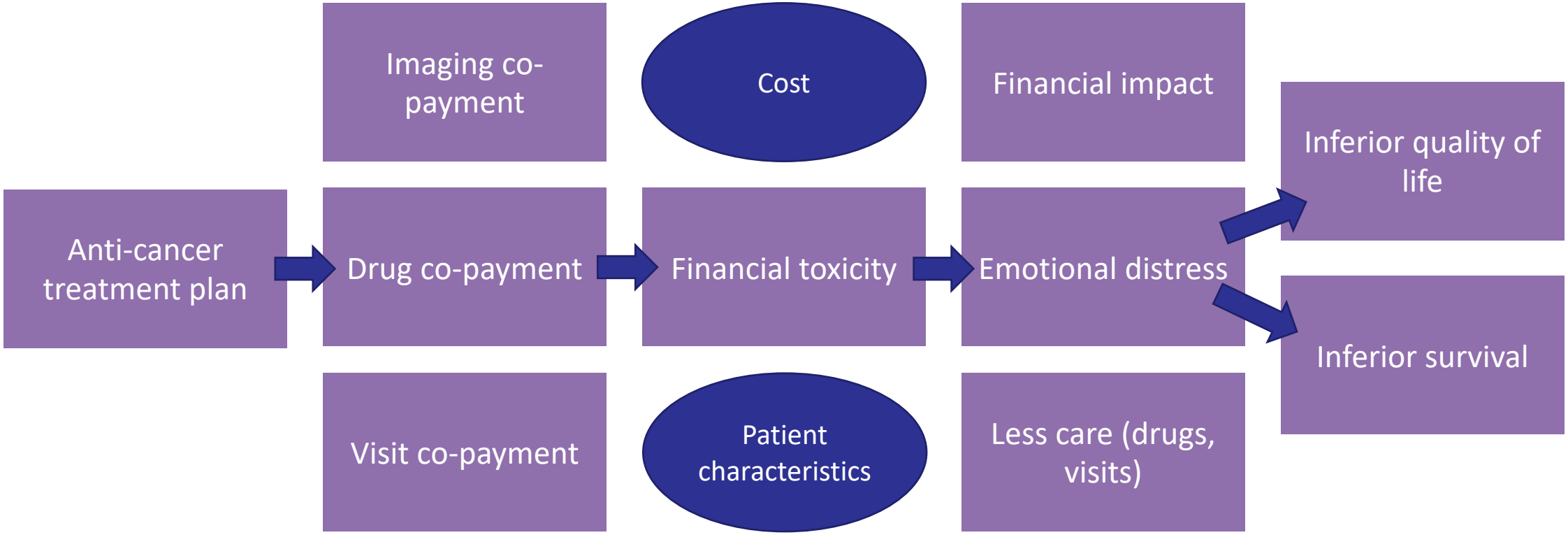
Scenario: You are evaluating 2 pegfilgrastim biosimilars to potentially add to formulary for your 340b inpatient hospital. How might you begin this process?

1. Assess acquisition costs including variables such as rebates and tiered contracts
2. Define reimbursement (% of charges, fee schedules)
3. Plug into payers and calculate NCR

Product	Cost per vial (6mg)	Billing unit	Per billing unit cost	Medicare Fee schedule	NCR Medicare
Biosimilar A	$540	0.5mg	$45	$66	$21
Biosimilar B	$300	0.5mg	$25	$48	$23
Reference product	$600	0.5mg	$50	$62	$12

In this scenario with Medicare, biosimilar B has the lowest cost and largest NCR.

Patient Access and Advocacy[21]



Specialty Pharmacy[22]

Outcome	Time frame	Method for polytherapy	Measurements	Internal specialty pharmacy	External specialty pharmacy	*P* value
Proportion of days covered (PDC)	Prescription-based measure	Calculate PDC per medication and average PDC per patient	Sample size	360	189	—
			Median (IQR)	0.99 (0.89-1.00)	0.91 (0.76-0.98)	<0.01
			PDC > 80%	299 (83%)	130 (69%)	<0.01
Medication possession ratio (MPR)	Prescription-based measure	Calculate MPR per medication and average MPR per patient	Sample size	360	189	
			Median (IQR)	1.00 (0.90-1.00)	0.93 (0.76-1.00)	<0.01
			MPR > 80%	305 (85%)	134 (71%)	<0.01
Time to treatment (TTT), days	Prescribing date to first fill date	Calculation only for initial fill	Sample size	517	241	—
			Median (IQR)	5 (2-3)	27 (2-82)	<0.01

IQR = interquartile range

Non-Malignant Hematology Clinic

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Active ingredient	Dosing	Administration guidelines	Number of recommended doses
Sodium ferric gluconate	125mg diluted in 100mL NS	Intravenous (IV) infusion over 1 hour	8 doses given weekly
	Max: 250mg diluted in 250mL NS	IV infusion over 2 hours	4 doses given weekly
Iron sucrose	200mg diluted in 100mL NS	IV infusion over 15 minutes	5 doses
	300mg diluted in 250mL NS	IV infusion over 90 minutes	3 doses
	400mg diluted in 250mL NS	IV infusion over 2.5 hours	
Ferric carboxymaltose	750mg diluted in 250mL	IV infusion over 15 minutes	2 doses at 7-day interval
Ferumoxytol	510mg diluted in 100mL NS	IV infusion over 15 minutes	2 doses, 8 days apart
Iron isomaltoside 1000	1000mg diluted in 250ml of NS If <50kg: 20mg/kg actual BW	IV infusion over 20 minutes	1 dose
LMW iron dextran	< 1g diluted in 500mL NS	IV infusion over 2-4 hours	1-4+ doses at 7-day interval
	>1g to <2g diluted in 1,000ml NS	IV infusion over 4-6 hours	
	> 2g diluted in 1,000mL NS	IV infusion over 6 hours	

Stage IV Breast Cancer Clinic

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- Found a unique service that reduced provider burden, while maintaining quality of care
- Allows providers to open additional slots for new patients
- Pharmacists given limited prescribing authority through a collaborative practice agreement
- Assessing ability to expand to other malignancies

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Oncology Pharmacy

- Clinical
- Operations
- Finance

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Questions?

Association of Community Cancer Centers

Thank you!