



Advocating for Medication Access: How Practices Can Navigate White Bagging Mandates and Drug Authorization Restrictions



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Disclosure of Conflicts of Interest:



Jorge J. Garcia, PharmD, MS, MHA, MBA, FACHE, has the following financial relationships to disclose:

- Grant Research Support – Pharmacosmos
- Speaker – FLASCO, MED, ATOPP, ACCC
- Board of Trustees – ACCC & FLASCO

Learning Objectives:



- Discuss infusion service access barriers per payor benefits design
- Review strategies to help mitigate payor access barriers
- Discuss payment model evolution and employer opportunity to leverage value

Baptist Health South Florida



Overview

- Non-for-profit 12-hospital health system
- More than 100 outpatient centers, urgent care facilities and physician practices
- Four counties: Monroe, Miami-Dade, Broward & Palm Beach
- More than 24,000 employees
- More than 4,000 affiliated physicians
- Centers of excellence in Cancer, Cardiovascular, Orthopedics and Sports Medicine, and Neuroscience



National Recognition

- 100 Best Companies to Work For – *Fortune Magazine* (21 years)
- 100 Best Companies – *Seramount* (29 years)
- World's Most Ethical Companies – *Ethisphere Institute* (11 years)
- Most Wired Hospitals and Health Systems - *Hospital & Health Networks* (19 years)
- Magnet designation – *American Nurses Credentialing Center* (5 hospitals)
- Best Hospital Rankings with 48 High-performing Honors – *U.S News & World Report* 2021-2022



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Board of trustee member at ACCC
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Committee Chair or Member at
ASHP, APHA, ATOPP

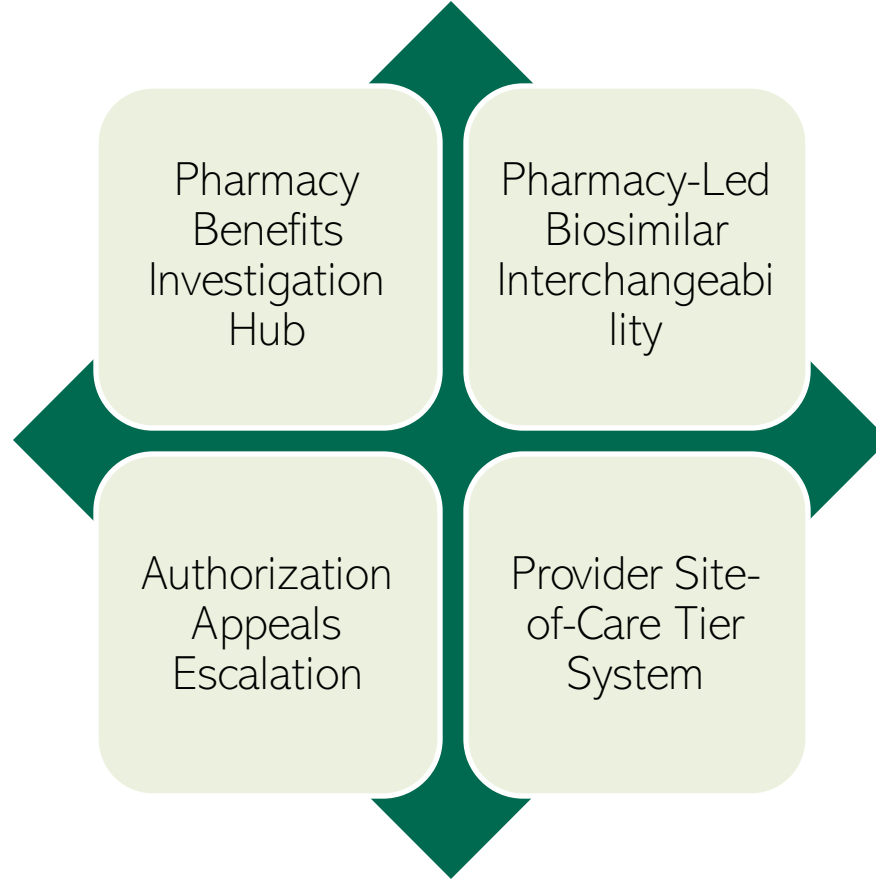
Faculty for ASHP PLA

Active with HOPA, ACHE



Pharmacy Perspective: Ensuring Equitable Access to Oncology Care

Practice Cases:



Background



- Cancer drug cost is increasing at twice the rate of general healthcare cost
- Increasing drug cost is a function of unit cost and utilization
- Cost of biologic pharmaceuticals have reached an all time high
- Oncology pipeline includes >700 drugs in clinical trials

1. *Unlocking the Potential of Biosimilars*. Cigna's Newsroom. Accessed October, 5, 2021

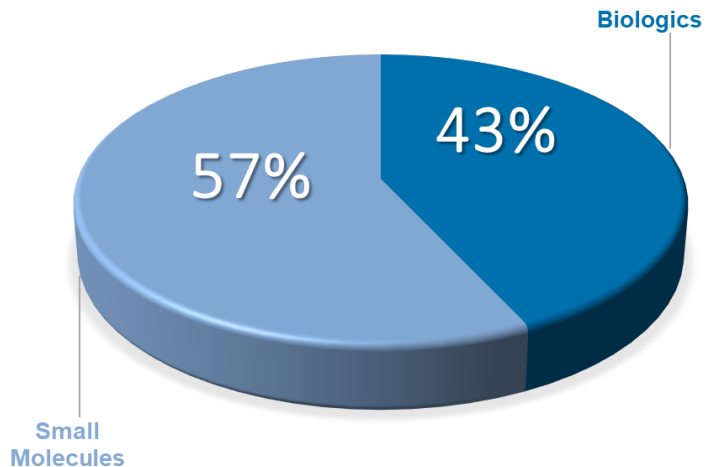
2. *Medicine Use and Spending in the U.S. A Review of 2018 and Outlook to 2023*. May 2019. IQVIA Institute for Human Data Science. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us---a-review-of-2018-outlook-to-2023.pdf?_=1602972025818. Accessed October 17, 2020.

3. Goll, G., Kvien, T. *An Opportunity Missed: Biosimilars in the United States*. *American College of Rheumatology*. Vol 72, No. 7, July 2020, 1046-1048

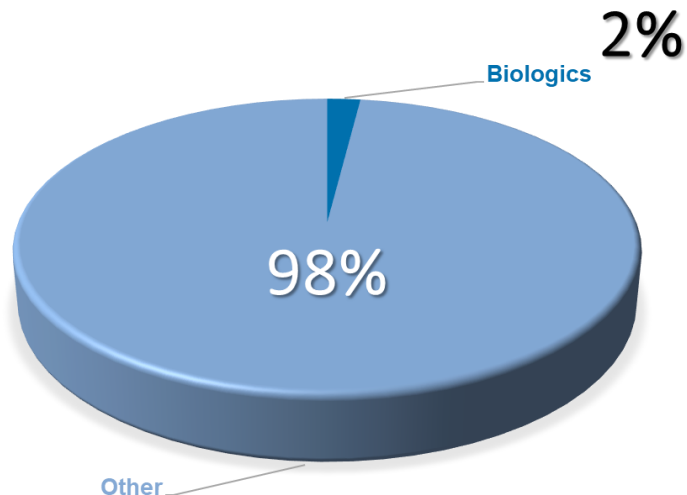
Background



2019 U.S. DRUG SPEND - \$493 BILLION



2019 U.S. PRESCRIPTION DRUG UTILIZATION



1. 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
2. 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



1.

Pharmacy Benefits Investigation Hub



- Increasing medication access barriers
- Tying-up valuable clinical pharmacy resources
- Lack of benefits investigation expertise among clinical team
- Broad scope of functions
- Inpatient & outpatient coverage



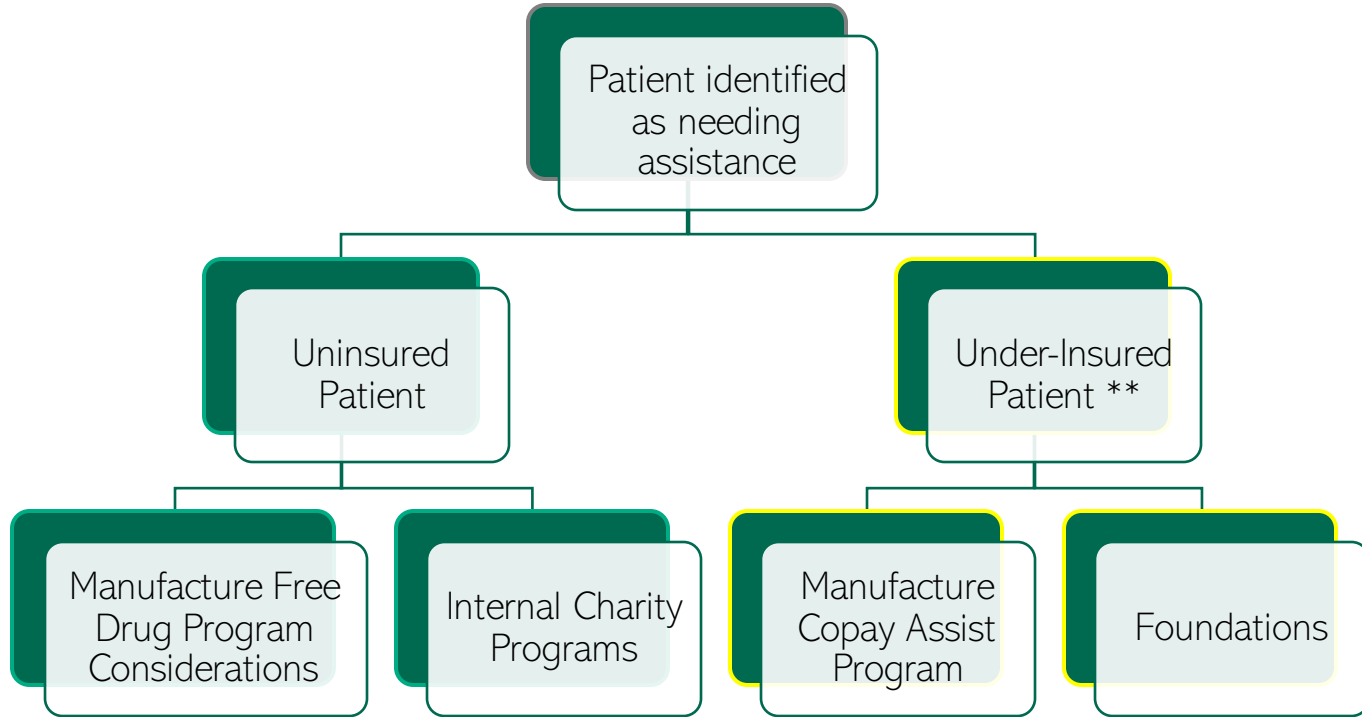
- Collaboration with Clinical Pharmacy Specialist
 - Step-therapy requirements
 - Medical necessity concerns
 - Non-standard of care justification
 - Authorization denials
 - Authorization appeals

Pharmacy Benefits Investigation Hub



- Medication access documentation
- Refer out “clean” prescriptions
 - Pharmaceutical limited distribution designation
 - Payor limited network restrictions
- Improved prescription fill turnaround time
- Improved prescription capture
- Protection of clinical resources for direct patient care functions
- Piloted and expanded to all oncology specialties

Pharmacy Benefits Investigation Hub



** Patient with inability to pay for their portion of expense after insurance Copay



2.

Pharmacy-Led Biosimilar Interchangeability

Pharmacy-led Biosimilar Interchangeability



- Biosimilars delivered intended-competition
- Payers actively managing the class
- Incongruent payor-facility formularies

Pharmacy-led Biosimilar Interchangeability



Program:

- Interchangeability policy amendment
 - Interface bridging Business Office documentation with EHR
 - Facility product preference developed
 - Pharmacy technician prospective review
 - Product selection escalation to pharmacist as needed
-
- Prescriber vs. pharmacy-led interchangeability

Pharmacy-led Biosimilar Interchangeability



Remaining opportunities:

- Same day add-on patients
- Authorizations received after pharmacy review
- Authorizations not received prior to therapy
- High charge denials



Development of Biosimilar Financial Dashboard:

- Biosimilar List
- Billing Units and Codes
- Pricing Information: ASP, WAC, GPO, 340B
- Internal Purchase History
- Internal Payor Mix Information
- Internal Reimbursement Projection

Biosimilar Financial Dashboard



Drug	Vial Size	Billing Units per Vial	HCPCS	NDC (-)	SI	ASP	ASP + 4.3%	ASP + 6%	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

Note: Drug costs and purchases above are provided for illustrative purposes only.

Biosimilar Financial Dashboard



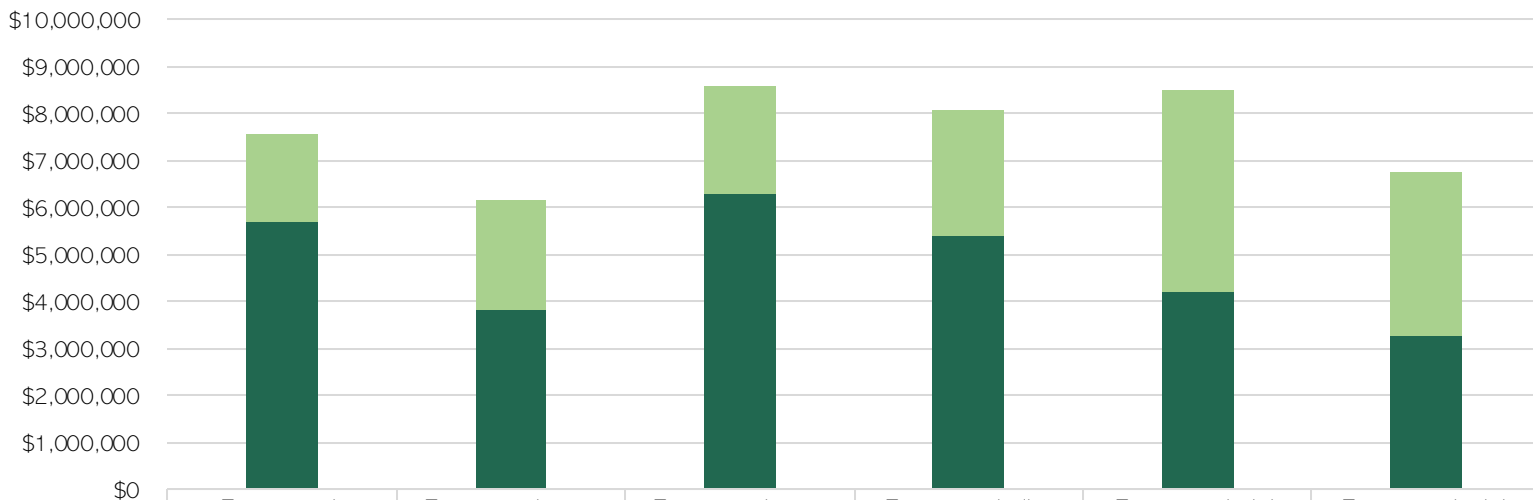
Drug	Vial Size	Billing Units per Vial	HCPCS	NDC (-)	SI	Medicare (1 248 Vials)	HMO (2 122 Vials)	PPO (2 371 Vials)	Total Projected Reimbursement
Trastuzumab	150 MG	15	J9355	50242-0132-01	K	\$1,229,230	\$2,545,920	\$3,793,920	\$7,569,070
Trastuzumab-qyyp	150 MG	15	Q5116	00069-0308-01	G	\$1,103,918	\$2,036,736	\$3,035,136	\$6,175,790
Trastuzumab-anns	150 MG	15	Q5117	55513-0141-01	G	\$979,618	\$3,055,104	\$4,552,704	\$8,587,426
Trastuzumab-dkst	150 MG	15	Q5114	67457-0991-15	G	\$1,103,457	\$2,800,512	\$4,173,312	\$8,077,281
Trastuzumab-dttb	150 MG	15	Q5112	00006-5033-02	G	\$1,225,836	\$2,927,808	\$4,363,008	\$8,516,652
Trastuzumab-pkrb	150 MG	15	Q5113	63459-0303-43	G	\$1,055,508	\$2,291,328	\$3,414,528	\$6,761,364

Note: Drug costs and purchases above are provided for illustrative purposes only.

Biosimilar Dashboard



Trastuzumab Drug Margin



	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

■ Drug Spend
 ■ Estimated Drug Margin
 Total Projected Reimbursement

Note: Drug costs and purchases above are provided for illustrative purposes only.

Biosimilar Financial Dashboard



- Total at-a-glance biosimilar comparison
- Develop projections inclusive of payor preference
- Trend ASP and drug cost over time
- Trend purchase history and utilization over time
- Negotiate manufacturer contracts and rebates based on organizational data



3.

Authorization Appeals Escalation

Authorization Appeal Escalation



- Authorization denial for clinical vs. operational reasons
- Focused on site-of-care and white bagging mandates
- Executive level escalation *in writing*
- Regulatory policy
 - Florida Board of Pharmacy
 - Florida Legislation



4.

Provider Site-of-Care Tier System

Provider Site-of-care Tier System



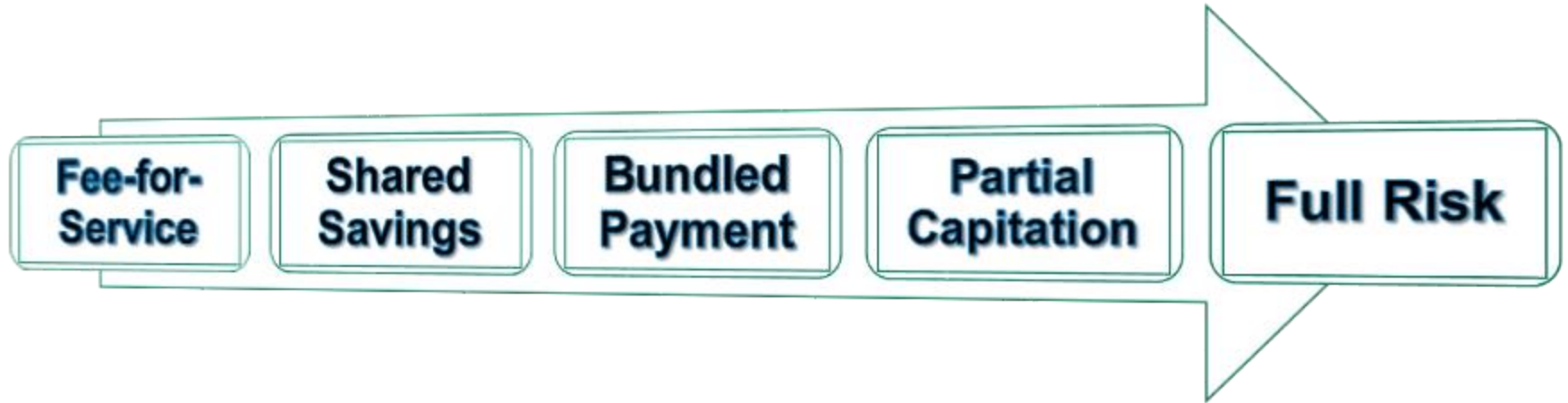
- Payor access design increasing sophistication
- Expansion of services across site-of-care continuum
 - Acute hospital services
 - Ambulatory hospital-based services
 - Physician-based services
 - Specialty pharmacy
 - Home health

Provider Site-of-care Tier System



- Authorization denial mitigation:
 - Appeal authorization denial
 - Offer non-hospital base infusion where available
 - Consider a clear bag
 - Consider a white bag
 - Consider home health
 - Consider criteria for patient assistance programs
 - Consider therapy charge write-off

Payment Model Evolution



Employer Leverage



- 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
- Employers can align incentives at point-of-purchase:
 - Getting system-owned specialty pharmacy in network
 - At-parity biosimilar coverage
 - Site-of-care access

Summary



- Increasing cost of care is expected to continue to increase payer cost containment strategies
- Providers need to closely monitor benefit design evolution to strategize and negotiate access accordingly
- Employers can align incentives at health insurance point-of-purchase



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Discussion & Questions:



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