Improving Your Formulary and Denials Management

Zinkeng Asonganyi, PharmD
Director of Pharmacy Services-Ambulatory Operations
University of Texas Medical Branch

ACCC 2022

Objectives

- Understand the data and metrics your cancer program or practice must collect and report on to improve revenue cycle management, eliminate waste, and reduce costs.
- Gain insight on how to use these data to drive quality improvement initiatives at your cancer program or practice.
- Identify opportunities for financial navigation to support revenue optimization at your cancer program or practice.

ACCC 2022

Objectives

- Assess your denial management process and work with all members of your revenue cycle team to reduce denials.
- Review your pre-authorization process and develop strategies to make this process more efficient to better support patients and providers.

Formulary Management

- What is formulary management?
  - Process where drugs are evaluated for their safety, efficacy, and value to prevent unwarranted clinical variation and reduce unnecessary costs.
  - Major strategy to combat rising drug costs and led by chair/vice chair of the Pharmacy and Therapeutics Committee (P&T)

Formulary Management

- Open vs. Closed Formulary
  - Inpatient setting:
    - Tends to be closed formulary because of diagnosis-related group reimbursement
  - Outpatient:
    - Tends to be open formulary in accordance with guideline recommendations
    - For example, National Comprehensive Cancer Network (NCCN) Guidelines®, given that pre-approval is required by the payer

Considerations: Formulary Management in Oncology

- Oncology:
  - Between Jan. 2022 and April 6, 2022: 9 U.S. Food and Drug Administration (FDA) approvals
  - Approval of the drug with restrictions to hematology/ oncology service line
  - Cost/reimbursement is an important consideration during drug formulary review, especially when comparing to another comparable agent

Considerations: Formulary Management in Oncology

- Oncology:
  - Site of care considerations: Hospital outpatient department vs. physician clinic vs. home infusion vs. pharmacy benefits
  - Drug shortages

Biosimilar Agents and Considerations

- FDA definition:[1]

“A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product.”

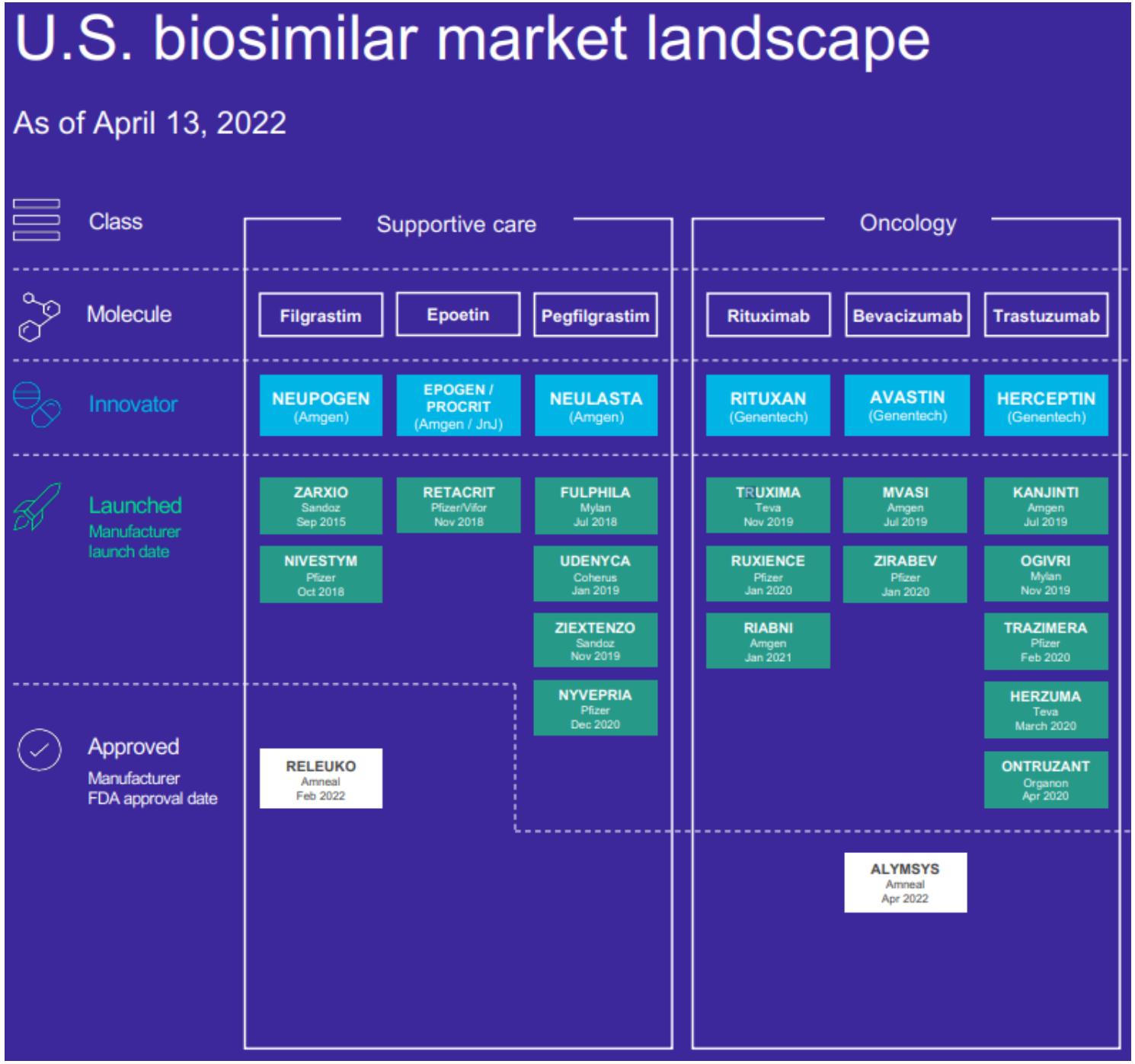
Biosimilar Agents and Considerations

- FDA definition:[1]

“An interchangeable biological product…meets additional standards for interchangeability” and “may be substituted for the reference product by a pharmacist without the intervention of the healthcare provider who prescribed the reference product.”

U.S. biosimilar market landscape

As of April 13, 2022



ACCC 2022

Biosimilars

- Forecasted to deliver over $133 billion in aggregate savings by 2025.
- Total savings to patients' out-of-pocket costs are estimated to reach up to $238 million.

Traditional Medicare, Medicare Advantage, and Average Employer Plans [3]

	TRADITIONAL MEDICARE	MEDICARE ADVANTAGE	EMPLOYER PLANS
Humira	-29.7%	-29.7%	-47.0%
Enbrel	-29.7%	-29.7%	-47.0%
Avastin	-13.4%	0.0%	-13.8%
Epogen / Procrit	-27.7%	-27.7%	-24.2%
Herceptin	-14.2%	-4.1%	-14.4%
Neulasta	-20.2%	-20.2%	-19.4%
Neupogen	-43.9%	-43.9%	-43.6%
Remicade	-41.7%	-41.7%	-38.5%
Rituxan	-7.6%	0.0%	-7.8%

Source: Author estimates based on CMS data and prescribed treatment dosages
**The biosimilar prices that compete with Humira and Enbrel are assumed because no competitors currently exist.*

Barriers to Biosimilar Adoption

- Reference drug manufacturers protecting market share by creating new formulations or giving deep discounts to payers and pharmacy benefit managers (PBMs) to maintain formulary preference
- Resistance from certain providers
- Payer formulary inclusion→ Inventory management complexities
- Regulatory issues and interchangeability
- Information technology (IT) support

Formulary Strategy for Biosimilars

- Evaluate purchase price of each biosimilar agent and compare
- Evaluate payer mix and payer preferred biosimilar for each reference drug
- Any manufacturer patient assistance programs?
- Margin analysis
- Establish biosimilar interchange policy to allow for auto substitution by pharmacists

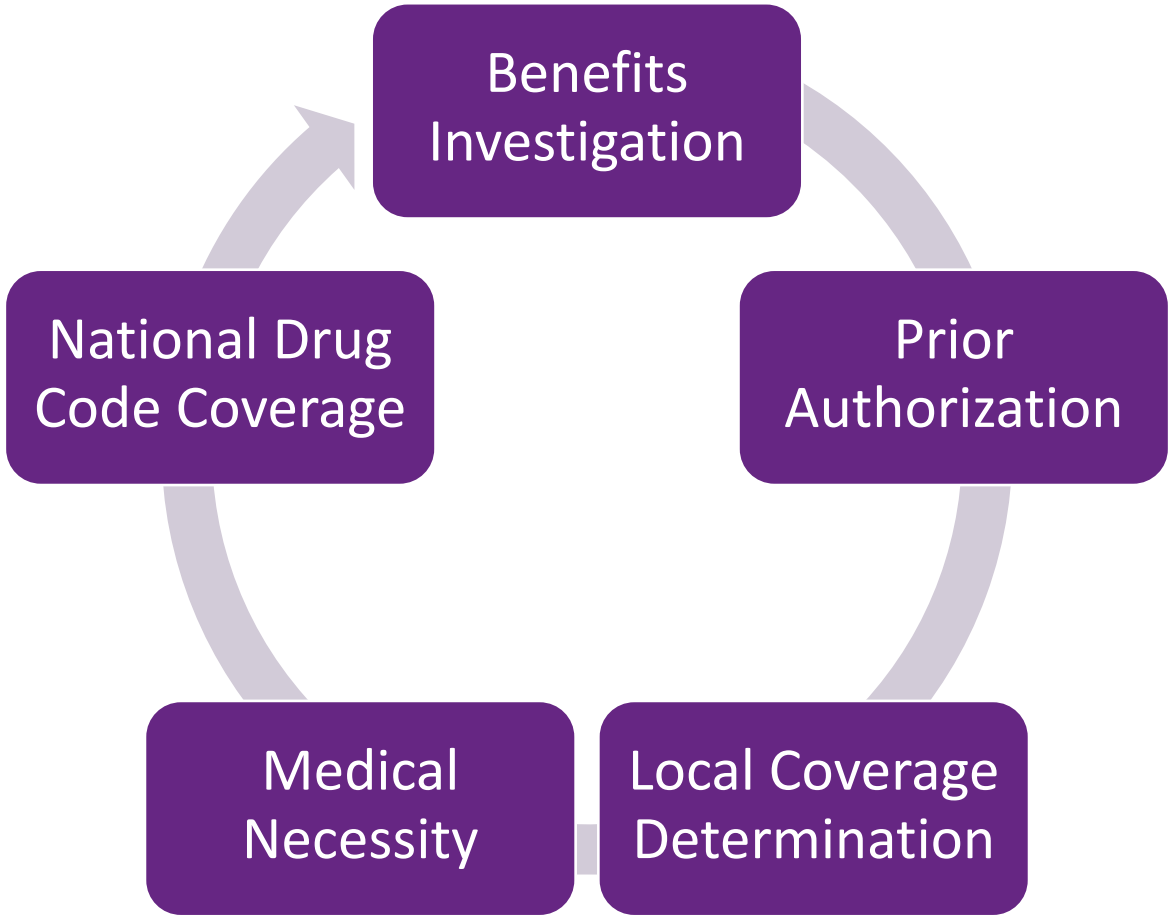
It’s More Than Just Cost Savings

- How is your organization being reimbursed for these expensive medications?
- How are you ensuring that clean claims get out to the payers in a timely fashion?
- It’s better to be right the first time, instead of chasing denials.

Payment for Drugs: Outpatient Infusion and Service

- Fee schedule:
  - Medicare's Hospital Outpatient Prospective Payment System (HOPPS)
  - Medicaid
- Fee-for-Service
  - Percentage of charges
- Capitated model: Global budget revenue
  - Flat payment

Payment for Drugs: Outpatient Infusion and Service



Payment for Drugs: Outpatient Infusion and Service

- **Benefits investigation:**
  - Verifying patients' insurance, type of coverage, and any out-of-pocket amount due
- **Prior authorization:**
  - Formulary management strategy by payer to ensure appropriate drug use (medical necessity)

Payment for Drugs: Outpatient Infusion and Service

- **Medicare process for pre-certification:**
  - No prior authorization required
  - List of drugs approved per ICD-10 code
  - Local coverage determination (LCD): Administered by local Medicare administrative contractor (MAC)
  - If drug is not on LCD, it is **NOT** approved
  - If drug is on LCD and given according to approved guidelines, it is approved

Prior Authorization

- Who owns the prior authorization process at your cancer program or practice?
- Critical process to ensure revenue integrity
  - Needs to be coordinated: complex and time consuming
- One of the top reasons for claim denials
- Use your **electronic health record (EHR)!**

ACCC 2022

Prior Authorization

- Allow appropriate time for completion, for example, provider sends order 7 days in advance
- **DO NOT** schedule patient if prior authorization is not approved
- Monitor and track expiration (e.g., reports in your EHR)

Payment for Drugs and Biologicals

New drugs not yet assigned unique Healthcare Common Procedure Coding System (HCPCS) codes	New pass-through drugs	Non pass-through separately payable drugs >$130/day	Policy packaged or lower-cost packaged products costing ≤$130/day
✓ 95% of average wholesale price (AWP)	✓ Average sales price (ASP) + 6% ✓ 46 products either keep or gain pass-through status ✓ Pass-through status expires for 28 products in CY 2020 and 26 drugs in CY 2021 ✓ All biosimilars eligible for pass-through, not just the first one for each reference product	✓ Paid at ASP + 6% if not purchased under the 340B Program ✓ Payment based on wholesale acquisition cost (WAC) + 3% until enough ASP data gathered ✓ Payment for 340B acquired drugs proposed to be reduced to ASP-28.7%	✓ No change in packaging threshold proposed from 2020 ✓ No separate reimbursement; drug costs are bundled into the service or procedure

Status Indicators

Status Indicator	Description	Paid Under HOPPS	Payment
G	Pass-through drugs and biologicals	Yes	Separate ambulatory payment classification (APC)
K	Non-pass-through drugs and biologicals	Yes	Separate APC
N	Services packaged into APC rates	Yes	No separate APC
L	Influenza and pneumococcal vaccine	No	Paid at reasonable cost
M	Services not billable to MAC	No	X
E2	Services in which pricing information and claims data are not available	No	Not paid by Medicare when submitted on outpatient claim
A	Services furnished that are paid under a fee schedule	No	Paid by MAC's under fee schedule

Pass-Through Status: Biosimilars

4	HCPCS Code	Short Descriptor	SI	APC	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment	Note: Actual copayments would be lower due to the cap on copayments at the Inpatient Deductible of $1,556.00	Drug Pass-Through Expiration during Calendar Year	* Indicates a Change
16985	Q5106	Inj retacrit non-esrd use	K	9097		$8.256		$1.66			*
16986	Q5107	Inj mvasi 10 mg	G	9329		$36.131		$7.23			*
16987	Q5108	Injection, fulphila	G	9173		$179.848		$35.97			*
16988	Q5109	Injection, ixifi, 10 mg	E2								
16989	Q5110	Nivestym	G	9193		$0.356		$0.08			*
16990	Q5111	Injection, udenyca 0.5 mg	G	9195		$183.412		$36.69			*
16991	Q5112	Inj ontruzant 10 mg	G	9382		$76.886		$15.38			*
16992	Q5113	Inj herzuma 10 mg	G	9349		$52.588		$10.52			*
16993	Q5114	Inj ogivri 10 mg	G	9341		$50.111		$10.03			*
16994	Q5115	Inj truxima 10 mg	G	9336		$53.691		$10.74			*
16995	Q5116	Inj., trazimera, 10 mg	G	9350		$51.016		$10.21			*
16996	Q5117	Inj., kanjinti, 10 mg	G	9330		$42.882		$8.58			*
16997	Q5118	Inj., zirabev, 10 mg	G	9348		$45.863		$9.18			*
16998	Q5119	Inj ruxience, 10 mg	G	9367		$49.816		$9.97			*
16999	Q5120	Inj pegfilgrastim-bmez 0.5mg	G	9345		$178.551		$35.72			*
17000	Q5121	Inj. avsola, 10 mg	G	9381		$43.290		$8.66			*
17001	Q5122	Inj. nyvepria	G	9406		$243.045		$48.61			*
17002	Q5123	Inj. riabni, 10 mg	G	9411		$56.588		$11.32			*

Denials

- Buy and Bill: A claim is sent out to the payer and payment is denied
- Could be due to several reasons:
  - No prior authorization obtained
  - Medical necessity: LCD, national coverage determination (NCD)
  - Additional documentation required
  - Coding error
  - Missing claim information
  - Non covered
  - Drug waste due to smaller vial size present commercially

It’s All About the Details

- Remittance advice:
  - Electronic data interchange that contains insurance payment explanations
  - Includes: Claim payment information, denial codes, explanation of denial
  - 835 type files

Combating Denials

- Goal is to get a clean claim out the first time
- Timely writing and submission of appeal letters with relevant information
- Allow time for prior authorization team to obtain authorization.
  - 5-7 days lead time is reasonable.

Combating Denials

- Pre-certification built into infusion regimen (therapy plan/ treatment plan in EHR)
  - If an order is signed or a change to regimen occurs, a referral is dropped in a work queue.
  - Medicare: Have clinical staff (nurse or pharmacist) review LCD/NCD
  - If no prior authorization is required, clinical staff should review payer medical necessity guidelines
  - Target denials by volume of reason codes.
    - Reason code may not represent the actual reason for denial

Combating Denials

- Ensure accurate drug build
  - NDC
  - Accurate HCPCS (Healthcare Common Procedures Coding System) code and revenue code
  - Using appropriate unclassified HCPCS code (C9399 vs. J3490)
- Comprehensive charge capture
  - Barcoded medication administration
  - Dispense prep/dispense prep workflow (in EHR)
  - Waste billing: Use appropriate vial sizes to generate the least waste

Medical Necessity

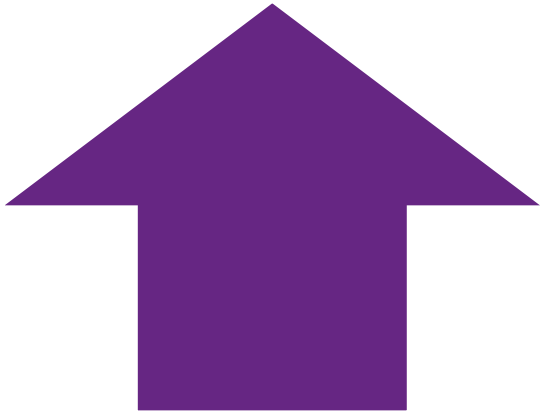
1. Complete prior authorization (PA) and told by payer "No PA required."
2. Get a denial after given for medical necessity.
3. Payer website has medical polices and requirement by coverage.

Site of Care

- Choice of physical location for infusion administration
  - Hospital: inpatient/outpatient
  - Home infusion
  - Physician office
  - Free standing infusion suite
- Payer might allow patient to receive a few doses in a hospital outpatient infusion center but mandates patient to go to a cheaper site of service for subsequent infusions.
- If you don't keep track of site of care restrictions→ increased denials

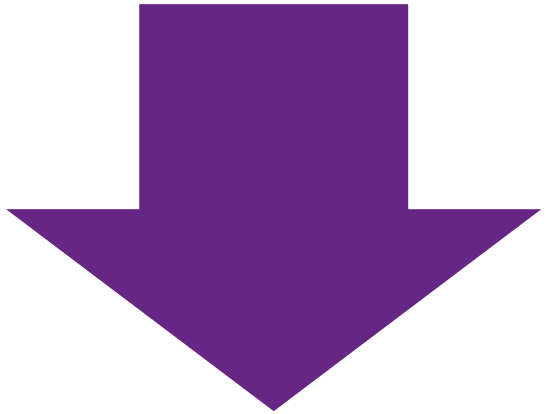
Why Is Site of Care So Important?

- Payers shifting services to a lower cost of care setting
  - Expensive specialty medication and biologics



21-Inpatient Hospital

21-Outpatient Hospital Department



11-Office

12-Home

49-Independent Clinic

Medical vs. Pharmacy Benefits

- Specialty drugs may be covered under medical and/or pharmacy benefits
- Medical benefit:
  - Buy-and-bill model under medical benefit

Medical vs. Pharmacy Benefits

- Pharmacy benefit:
  - Buy and bill under the pharmacy benefit
  - Can be self-administered or taken to site of care for administration
    - White bagging
    - Brown bagging
    - Clear bagging

Questions?

References

1. U.S. Food and Drug Administration. Biosimilar and interchangeable products. Published October 23, 2017. Accessed April 26, 2022. https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products
2. AmerisourceBergen. U.S. biosimilar report. Published April 13, 2022. Accessed May 2, 2022. https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/biosimilars-page/sgs-biosimilars-usmarketlandscape-041422.pdf?la=en&hash=DC34E27B09855CFD4F85BFE61F878CF2EFA6127B
3. Winegarden W. Promoting biosimilar competition to reduce patients' out-of-pocket costs. Published March 2020. Accessed April 2022. https://www.pacificresearch.org/wp-content/uploads/2020/03/BiosimilarReduceOutofPocket_Fweb.pdf
4. American Society of Health-System Pharmacists. 2021: upheavals in drug payment, drug pricing, and more! Published December 9, 2020. https://www.eventscribe.com/2020/midyear/fsPopup.asp?Mode=presInfo&PresentationID=770129
5. Centers for Medicare & Medicaid Services. Addendum D1—proposed payment status indicators. Accessed May 2, 2022. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS1392P_Addendum_D1.pdf