# Improving Your Formulary and Denials Management

Andre D. Harvin, PharmD, MS
Executive Director of Pharmacy, Oncology
Cone Health Cancer Center

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# Learning Objectives

- Assess the fundamentals of formulary design and denials management as it relates to oncology care
- Explain how to approach present and emerging challenges in formulary and denials management
- Justify the need to merge pharmacy and revenue cycle expertise to supercharge your revenue integrity

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# What Is a Formulary?

- *Conceptually*: An integrated patient-care process that enables physicians, pharmacists, and other healthcare professionals to work together to promote clinically sound, cost-effective medication therapy and positive therapeutic outcomes[1]
- *Definition*: A continually updated list of medications and related-products supported by current evidence-based medicine and the judgment of physicians, pharmacists, and other experts in the diagnosis and treatment of disease and preservation of health[2]

# Development and Management

- Formulary development:
  - Oversight by a Pharmacy & Therapeutics (P&T) Committee
  - Comprised of physicians, pharmacists, and healthcare professionals with relevant expertise
  - Evaluate medical and clinical trials as well as treatment guidelines to determine inclusion/exclusion from facility formulary

# Development and Management

- Formulary management:
  - Driven by the Department of Pharmacy
  - Evaluation of formulary decision after a decision has been made
  - Leverage medication-use evaluations (MUE)
  - Interlay economic data, evolving guidelines, payer mandates, etc.
  - Recommendations still approved by P&T Committee

# Location Matters

- *Open formulary*: Generally, all U.S. Food and Drug Administration (FDA)-approved drugs are available for utilization
- *Closed formulary*: Not all FDA-approved drugs are available for utilization. Restrictions at the drug, dose, or indication level
- *Value-based formulary* emphasizes the clinical effectiveness over costs

# Location Matters

- Inpatient:
  - Closed formulary
- Outpatient/Retail:
  - Open formulary
  - Transitions into value-based ongoing
- Oncology:
  - Open formulary
  - Transitions into value-based ongoing

# Inpatient Reimbursement[3]

- Medicare Severity Diagnosis Related Group (MS-DRG): A data set that represents more than 7 million discharges across more than 3,000 United States hospitals
  - It classifies Centers for Medicare & Medicaid Services (CMS) patients' hospital stay into various groups in order to facilitate payment services

# Inpatient Reimbursement[3]

- These payments cover the entirety of patients' stay in the hospital, including procedures, drugs, etc.
- The goal for inpatient formularies is to reduce drug costs so that your total spent is **less than** your anticipated MS-DRG payment

# Outpatient/Oncology Reimbursement[4]

- Hospital Outpatient Prospective Payment System (HOPPS): Sets payments for individual services using a set of relative weights, a conversion factor, and adjustments for geographic differences in input prices
  - Allots for additional payments through outlier adjustments for high-cost services and pass-through payments for new technologies

# Outpatient/Oncology Reimbursement[5]

- Physician Administered Drug Program: An outpatient drug other than a vaccine that is typically administered by a healthcare provider in a physician's office or other outpatient clinical setting

# Different Approach, Similar Results

- Inpatient:
  - Closed formulary
  - MS-DRG/bundled payment structure
  - Goal: reduce drug expenditure while maximizing patient outcomes
- Outpatient, Oncology:
  - Open or value-based formulary
  - HOPPS and Separately Payable Drug Program
  - Goal: maximize patient outcomes and strengthen reimbursement

# Living in Denial

- *Denial*: The refusal of an insurance company or carrier to honor a request by an individual (or their provider) to pay for healthcare services obtained from a healthcare professional[6]
- The average claim denial rate across the healthcare industry is between 5% to 10%[7]
  - Representing almost $300 billion annually[8]

# Living in Denial

- Other than **patient eligibility** the other most common reasons for denials include:[9]
  - Duplicate or late submissions
  - Missing or incorrect data
  - Lack of documentation or prior authorization

# Challenges in Denials Management

- **Lack of training and skill alignment:**
  - Increased administrative burden stresses staff
  - Increasing complexity and challenges require timely clinical/ operational support
- **Manual processes in a digital world:**
  - Disparate systems and processes require the use of multiple systems, not often linked digitally
  - Results in a large number of denials being unaddressed due to systems failures
- **Lack of financial and full-time equivalent (FTE) resources**

# Ongoing Oncology Accelerated Approvals

- The last few years have seen a record number of FDA approvals for cancer-related therapies
- Accelerated approvals for malignant hematology and oncology have brought **64** drugs to market prior to their original projected completion date[10]

# Ongoing Oncology Accelerated Approvals

- Cancer care is still projected to have the largest pipeline of new treatment options due to unmet needs[11]
- The proliferation of “ultra-high cost” or “ultra-expensive” drugs is set to make formulary and denials management more difficult

# Present and Emerging Challenges

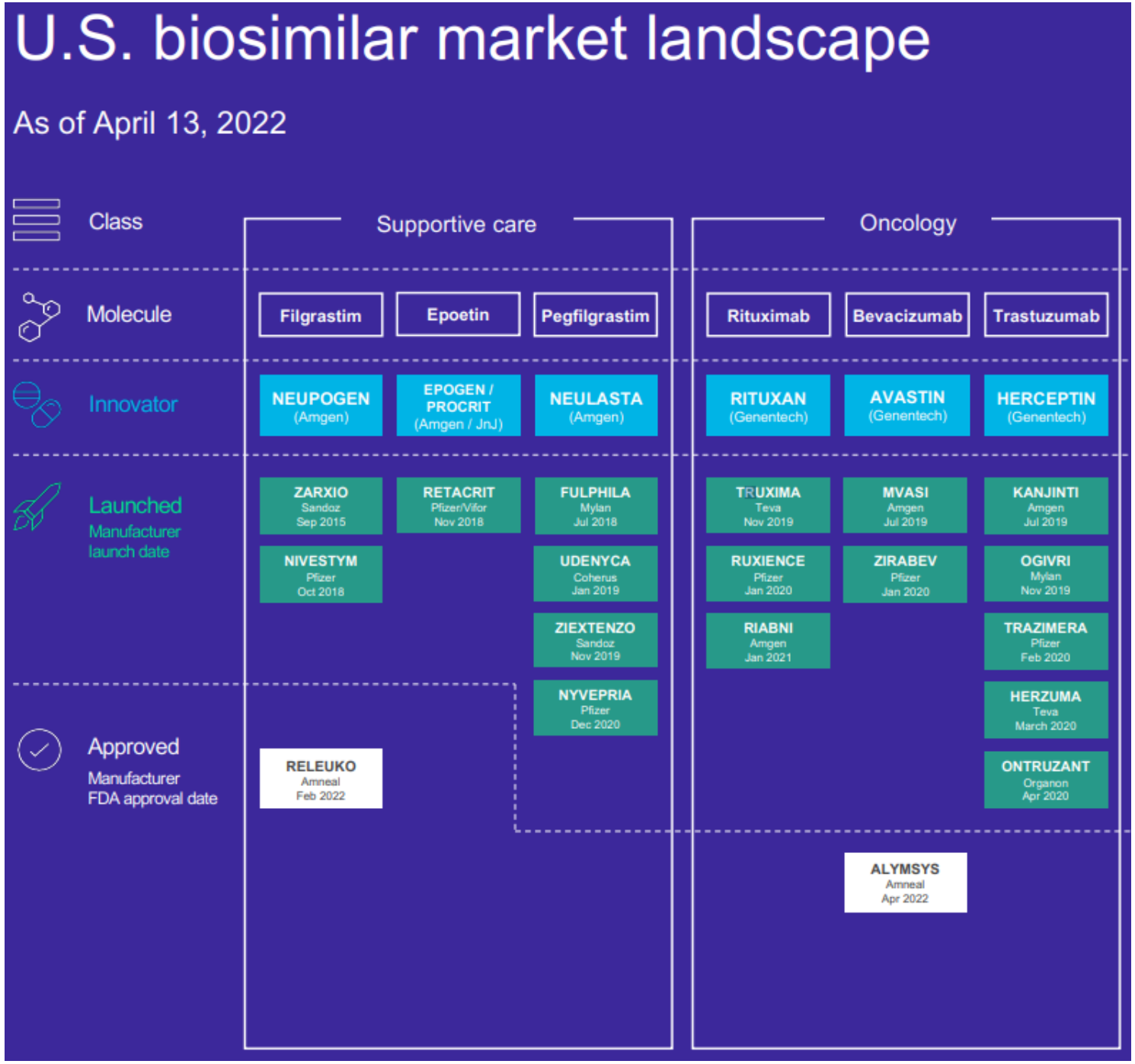
- Biosimilar integration
- Site of care restrictions
- White and brown bagging
- Adoption of value-based care arrangements
- Genetics
- Step therapy

# Biosimilars[12,13]

- FDA definition: A biosimilar product is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product
- *Highly similar*: Analysis of the structure and function of both the reference product and the proposed biosimilar. Leverages technology to compare purity, chemical identity, and bioactivity
- *Clinically meaningful*: The proposed biosimilar product has no clinically meaningful differences from the reference product in terms of safety, purity, and potency (safety and efficacy)

# U.S. biosimilar market landscape

As of April 13, 2022

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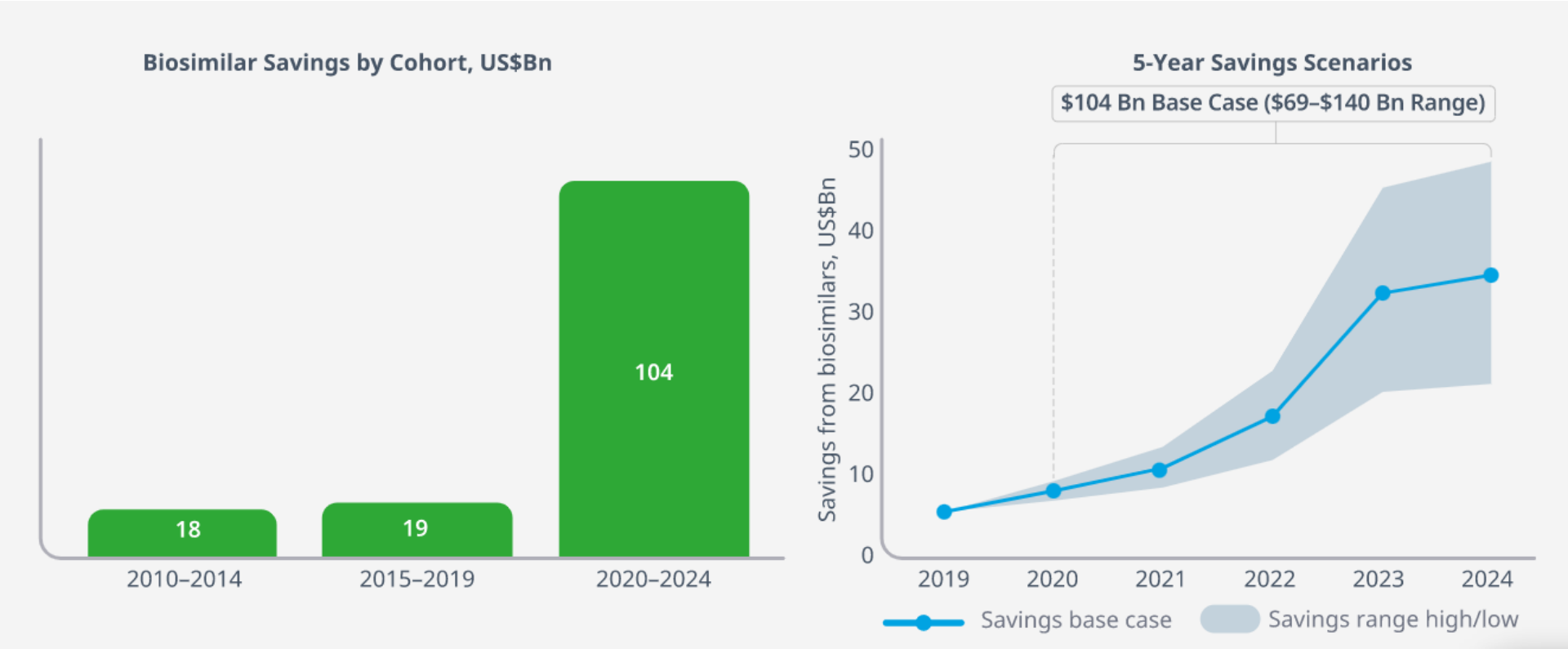
# Benefits of Biosimilars[15,16]

- By 2025:
  - Biosimilars are projected to reduce aggregate spending in the U.S. by $133 billion
  - Out-of-pocket savings for patients are set to reach $238 million
- Potential to increase patient access
- Success dependent on adoption in clinical practices

# Benefits of Biosimilars





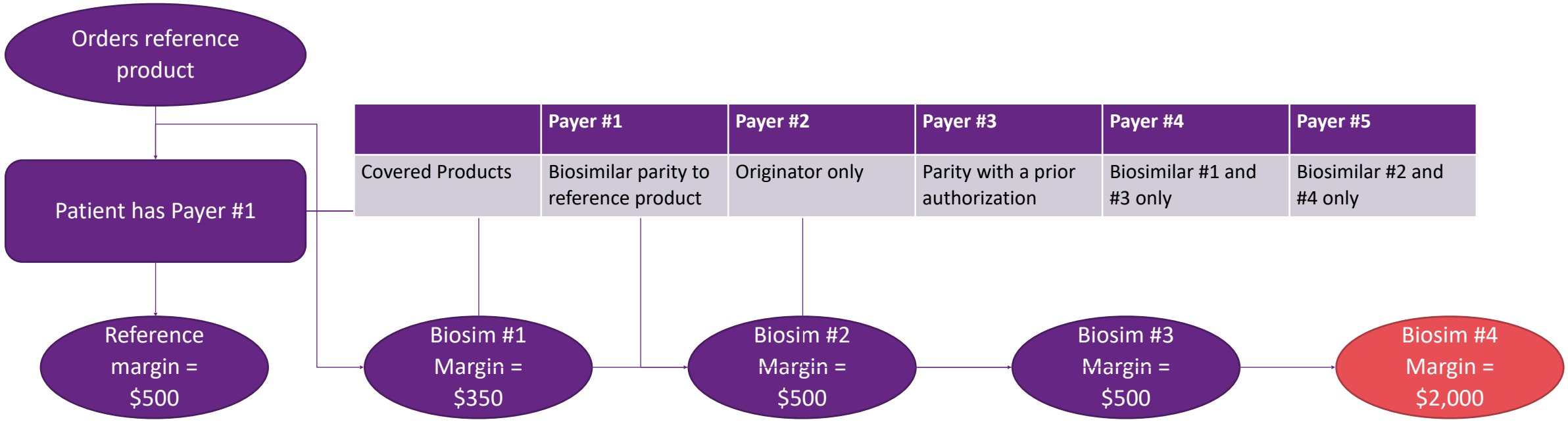
# Barriers to Adoption

- Lack of interchangeable product(s):
  - Would allow for substitution without the intervention of the healthcare professional who prescribed the reference product
- Patient and provider education:
  - Changing products could cause anxiety for patients
  - Physicians receive little education on biosimilars

# Barriers to Adoption

- Financial impact:
  - Lower cost drugs result in lower reimbursement in the outpatient environment
- Electronic health record:
  - Complex build, as these are unique products
- Health plan formulary:
  - As more biosimilars come to market, payers create manufacturer-specific formularies

# Formulary Mismatch




| | Payer #1 | Payer #2 | Payer #3 | Payer #4 | Payer #5 |
|---|---|---|---|---|---|
| Covered Products | Biosimilar parity to reference product | Originator only | Parity with a prior authorization | Biosimilar #1 and #3 only | Biosimilar #2 and #4 only |

# Codes Galore

- Each biosimilar will have its own unique J-code or Healthcare Common Procedure Coding System (HCPCS) code
- Meaning that a single drug could have 5 to 6 possible codes, and increasing
- With each payer having their own preferred and non-preferred formularies

| Biosimilar | J-Codes | Billing Codes |
|---|---|---|
| bevacizumab | J9035 | 10 mg |
| bevacizumab-awwb | Q5107 | 10 mg |
| bevacizumab-bvzr | Q5118 | 10 mg |
| epoetin alfa, non-end-stage renal disease (ESRD) | J0885 | 1000 units |
| epoetin alfa, ESRD on hemodialysis (HD) | J0886 | 1000 units |
| epoetin alfa-epbx, non-ESRD | Q5106 | 1000 units |
| epoetin alfa-epbx, ESRD on HD | Q5105 | 1000 units |
| filgrastim | J1442 | 1 mcg |
| tbo-filgrastim | J1446 | 5 mcg |
| tbo-filgrastim | J1447 | 1 mcg |
| filgrastim-sndz | Q5101 | 1 mcg |
| filgrastim-aafi | Q5110 | 1 mcg |
| pegfilgrastim | J2505 | 6 mg |
| pegfilgrastim | J2506 | 0.5 mg |
| pegfilgrastim-jmdb | Q5108 | 0.5 mg |
| pegfilgrastim-cbqv | Q5111 | 0.5 mg |
| pegfilgrastim-bmez | Q5120 | 0.5 mg |
| pegfilgrastim-apgf | Q5122 | 0.5 mg |
| rituximab | J9310 | 100 mg |
| rituximab | J9312 | 10 mg |
| rituximab-abbs | Q5115 | 10 mg |
| rituximab-pvvr | Q5119 | 10 mg |
| rituximab-arrx | Q5123 | 10 mg |
| trastuzumab | J9355 | 10 mg |
| trastuzumab-anns | Q5117 | 10 mg |
| trastuzumab-dkst | Q5114 | 10 mg |
| trastuzumab-qyyp | Q5116 | 10 mg |
| trastuzumab-pkrb | Q5113 | 10 mg |
| trastuzumab-dttb | Q5112 | 10 mg |

# Which Biosimilar Should I Choose?

- It depends…
- What are your formulary considerations?
  - Acquisition costs of the comparable reference and biosimilar agent(s)
  - Are there discounts or rebates associated with a group purchasing organization or portfolio contract?
  - Manufacturer assistance or free drug program(s)

# Which Biosimilar Should I Choose?

- It depends…
- What are your formulary considerations?
  - Payer mix
  - Preferred biosimilar (could change over time)
  - Manufacturer reliability
  - Margin analysis
  - Pharmacy driven biosimilar interchange

# Site of Care Restrictions

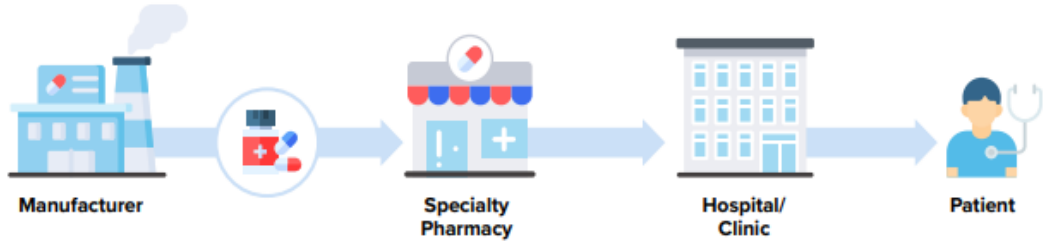
- A strategy for reducing the cost of specialty biologic medication administration; seeks to lower costs associated with certain infused or injected drugs by encouraging the use of clinically appropriate, lower cost care settings
- Previous shift from inpatient hospital administration to hospital-owned outpatient departments (HOPD)
- Recent shift from HOPD to alternative models, such as home infusion, hospital at home, and ambulatory infusion sites

# Not so Fast

- Several cancer care-focused advocacy and professional groups have resisted this specific payer driven initiative
- Statements from ACCC, American Society of Clinical Oncology (ASCO), Oncology Nursing Society (ONS), American Society of Health System Pharmacists (ASHP), and others have highlighted the risks associated with the regular administration of anti-cancer therapies in the home or non-specialized environments[18-21]
- First 30-day tactics

# White Bagging

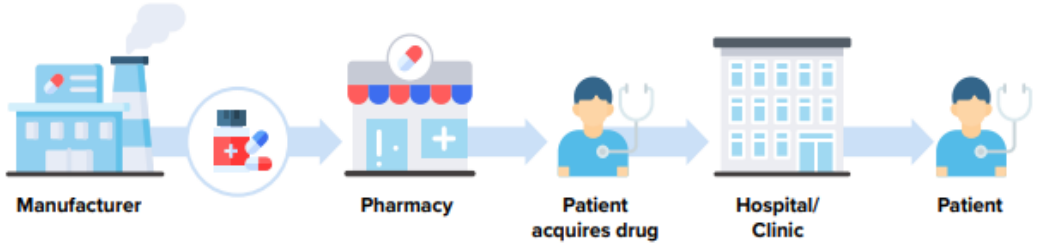
A specialty pharmacy ships a patient's prescription directly to the provider (Hospital or Clinic).




Transportation of drugs problematic. Drugs can be sent from anywhere, arrive late, etc. Issue is fragmentation of care and negative patient experience. Multiple steps in the process.

# Brown Bagging

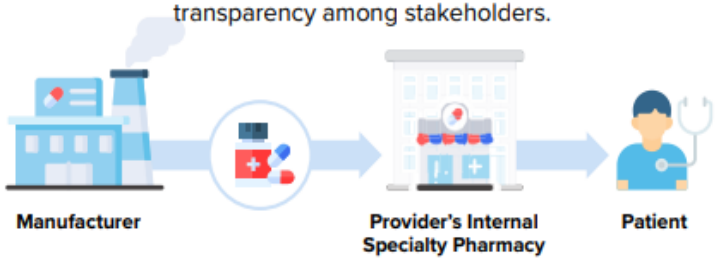
The practice of patients acquiring pharmaceuticals, through their pharmacy benefit and bringing the drugs to a physician's office or hospital to have them administered.




No longer legal in most places. Multiple failure points.

# Clear Bagging

A health system's internal specialty pharmacy fulfills the patient's prescription, then transports the product to the location of drug administration. Effectively depicts transparency among stakeholders.




Functional solution but lacks holistic healthcare approach; widget movement only.

# Gold Bagging

Incorporates transparent clear bagging approach AND emphasizes the gold standard of care. Correlates to Olympic gold medal performance through improved care process leading to better patient outcomes.


Holistic, best practice approach. SP dispenses drug from their inventory to their clinic for their patient. More controlled, fewer failure points, patients' physicians and EMR all available and updated. Promotes health equity. Gold Bagging acknowledges essential value in the pharmacy process steps, which are typically not reimbursable. Clinical pharmacist steps include: lab value monitoring and sterile infusion preparation.

# Secure the Bag

- Denials can occur if a payer mandates that a drug must be procured through an alternative bagging model (e.g., white, brown, clear)
- Communication between prior authorization team and pharmacy often breaks down with patient-specific requirements

# Secure the Bag

- Prior authorization teams can push back on payers that require bagging
- Restrict at the organization level
- Advocate at the state and federal level to prevent the practice

# Transition to Value-Based

- Payment models that favor care quality and outcomes over quantity of services provided
  - Initial model was the Center for Medicaid and Medicare Innovation's Oncology Care Model
  - Next-generation model (Oncology Care First) will put greater emphasis on enhanced collaboration, cost containment, and total cost of care
- Drug formularies and revenue cycle teams will need to rapidly adapt to new models and information to optimize therapy decisions

# Example Strategy

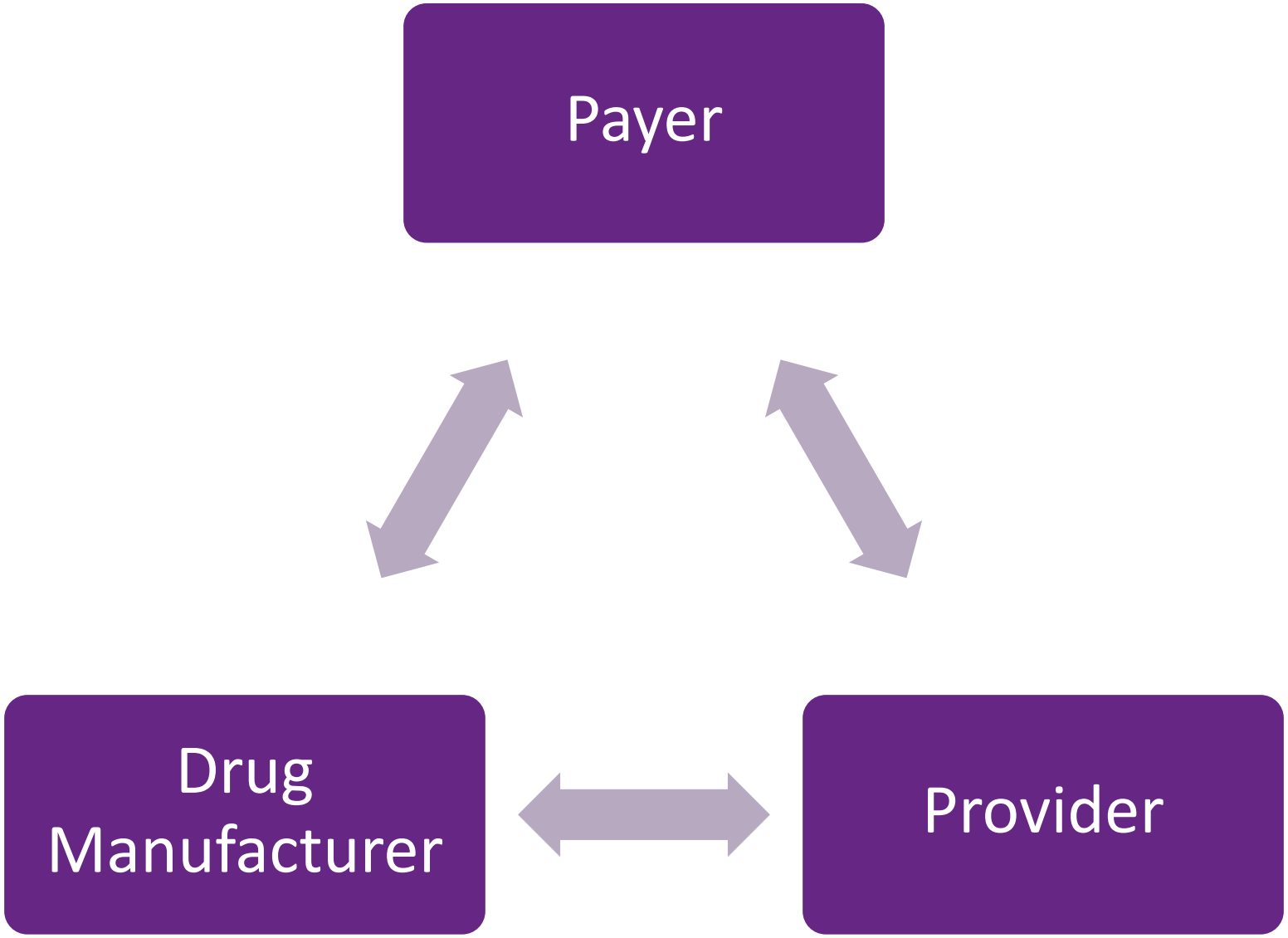
- Novel product “X” gained FDA approval as a pre-chemotherapy supportive medication that could reduce the use of other expensive supportive therapy medications and reduce emergency department (ED) visits for specific patients
- Based on the above information would you add this to your inventory?
- Would your decision change if you learned that product “X” was priced at three times the cost of standard-of-care supportive drugs? Five times? More?

# Example Strategy

- Product “X” was added to your formulary and utilized based on its FDA approval. After a year of utilizing product “X,” you find that ED visits for patients on product “X” shows no statistical difference from your previous standard of care. What do you do?

- It depends…
  - Evaluate practice and comparable patients
  - Reduce utilization of other healthcare resources

# Shared Risk Payment Models



# Cell and Gene Therapy[23,24]

- *Gene therapy*: The use of genetic material in the treatment or prevention of disease. The genetic material changes how a single protein or group of proteins is produced by a cell
- *Cell therapy*: The transfer of intact, live cells into a patient to help lessen or cure a disease. The cells may originate from the patient (autologous cells) or a donor (allogeneic cells)
- The FDA predicts 10 to 20 genetic or cell therapy approvals per year by 2025

# Costly Future

- Some of these therapies are expected to exceed $1 million in total spending, per patient
- Requirements for some portions of the therapy to be completed inpatient with others in the outpatient
- Requirements for specific genetic testing  prior to therapy initiation
- Potential to accelerate costs for pharmaceuticals while potentially eliminating certain diseases

# Step Therapy Challenges

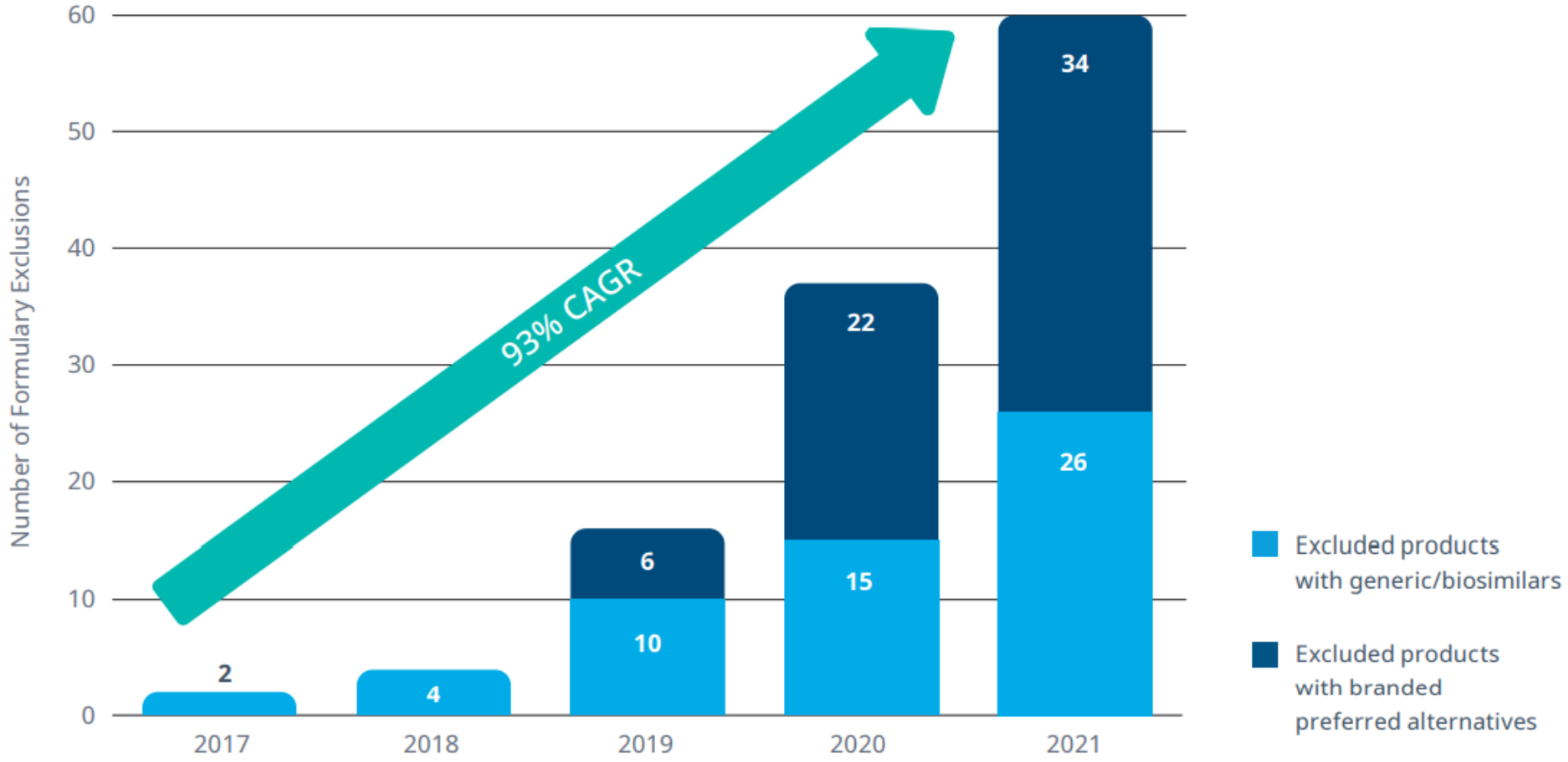
- Known as a “fail first” or “try and fail” tactic, where a patient is required to try an alternative, typically cheaper, product (medicine, therapy, or service) before the one their physician prescribed[25]
- Most often used for ancillary, supportive care medications used in the treatment of side effects like nausea, vomiting, and neutropenia

# Step Therapy Challenges

- Response by insurers to slow drug costs
- Lack of real-world evidence in comparison to standard of care for new therapies will create a difficult environment in the immediate future

# Number of National Formulary Exclusions

## (Top National Payers, Commercial Insurance, Oncology)[26]

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# All About the Denials

- Get it right the first time!
- Timely resubmission of denials with required information
- Start from the beginning:
  - Require prior authorization before any procedure
  - Align practices with National Comprehensive Cancer Network or third-party clinical pathways

# All About the Denials

- Get it right the first time!
- Timely resubmission of denials with required information
- Start from the beginning:
  - Review payer medical necessity guidelines even if payers do not require prior authorization
  - Ensure electronic health record is built correctly with billing codes
  - Evaluate your comprehensive charges to ensure you meet your allowable billing rates

# Teamwork Wins the Day

- There is no one team that is accountable for formulary and denials management
- Siloed operations will lead to underperformance and the inability to meet future challenges
- Communication between pharmacy, prior authorization, and revenue cycle teams will be critical for future practice
- Denials often require additional clinical (trials, guidelines, testing, etc.) or operational (vial size, rounding, waste documentation, etc.) information that can be found with your pharmacy team

# Next Steps?

- Evaluate your P&T Committee(s):
  - Do you have one specifically for oncology?
  - Does the committee have the expertise required?
  - Is it multidisciplinary?
- Understand how your upstream and downstream denials process works:
  - Do you have a prior authorization process?
  - Are pharmacy or medical oncologists integrated into the denials process?
- Do you have the right data available to be successful?

# QUESTIONS?

# Resources


1. Academy of Managed Care Pharmacy. Most popular. Accessed June 13, 2022. https://www.amcp.org/most-popular#:~:text=Formulary%20management%20is%20an%20integrated,therapy%20and%20positive%20therapeutic%20outcomes.
2. Academy of Managed Care Pharmacy. Formulary management. Published November 2009. Accessed June 13, 2022. https://www.amcp.org/sites/default/files/2019-03/Formulary%20Management.pdf
3. Centers for Medicare & Medicaid Services. MS-DRG classifications and software. Updated May 24, 2022. Accessed June 13, 2022. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software
4. Centers for Medicare & Medicaid Services. Hospital outpatient PPS. Updated March 3, 2022. Accessed June 13, 2022. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS
5. NC Medicaid Division of Health Benefits. Physician administered drug program. Accessed June 13, 2022. https://medicaid.ncdhhs.gov/providers/programs-and-services/prescription-drugs/physician-administered-drug-program
6. Healthinsurance.org. Denial of claim. Accessed June 13, 2022. https://www.healthinsurance.org/glossary/denial-of-claim/
7. American Academy of Family Physicians. Five key metrics for financial success in your practice. Accessed June 13, 2022. https://www.aafp.org/dam/AAFP/documents/practice_management/admin_staffing/FiveKeyMetricsPresentation.pdf
8. Harmony Healthcare. New Harmony Healthcare survey of hospital leaders finds more than 30% of hospitals near danger zone of denial rates. Published June 1, 2021. Accessed June 14, 2022. https://www.prweb.com/releases/new_harmony_healthcare_survey_of_hospital_leaders_finds_more_than_30_of_hospitals_near_danger_zone_of_denial_rates/prweb17964890.htm
9. Reiner G. Success in proactive denials management and prevention. Published May 18, 2022. Accessed June 14, 2022. https://www.hfma.org/topics/hfm/2018/september/61778.html
10. U.S. Food and Drug Administration. Ongoing, cancer accelerated approvals. Updated June 1, 2022. Accessed June 14, 2022. https://www.fda.gov/drugs/resources-information-approved-drugs/ongoing-cancer-accelerated-approvals
11. Journal of Hematology Oncology Pharmacy. The oncology pipeline overview: recent approvals and hear-term drugs. Published December 2021. Accessed June 14, 2022. https://jhoponline.com/jhop-issue-archive/2021-issues/december-2021-vol-11-no-6/19096-the-oncology-pipeline-overview-recent-approvals-and-near-term-drugs

# Resources


12. U.S. Food and Drug Administration. Biosimilar and interchangeable products. Updated October 23, 2017. Accessed June 13, 2022. https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products

13. U.S. Food and Drug Administration. Biosimilar development, review, and approval. Updated October 20, 2017. Accessed June 13, 2022. https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval

14. 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

15. Association for Accessible Medicines. The U.S. generic & biosimilar medicines savings report. Published October 2021. Accessed June 13, 2022. https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf

16. Hunter H. Biosimilars 2022: realizing the potential in the year ahead. Accessed June 13, 2022. https://newsroom.cardinalhealth.com/2022-02-21-Biosimilars-2022-Realizing-the-potential-in-the-year-ahead

17. Iqvia. Biosimilars in the United States 2020-2024: competition, savings, and sustainability. Published September 29, 2020. Accessed June 13, 2022. https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024

18. Association of Community Cancer Centers. ACCC principles to preserve provider and patient choice in cancer treatment. Published April 29, 2022. Accessed June 14, 2022. https://www.accc-cancer.org/home/news-media/news-releases/news-template/2022/04/29/accc-principles-to-preserve-provider-and-patient-choice-in-cancer-treatment

19. American Society of Clinical Oncology. American Society of Clinical Oncology position statement: home infusion of anticancer therapy. Published June 2020. Accessed June 13, 2022. https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020_Home-Infusion-Position-Statement.pdf

20. Oncology Nursing Society. Infusion of antineoplastic therapies in the home. Published August 2020. Accessed June 13, 2022. https://www.ons.org/make-difference/ons-center-advocacy-and-health-policy/position-statements/infusion-antineoplastics-in-home#:~:text=Investigational%20non%2DU.S.%20Food%20and,is%20conducive%20to%20home%20infusions


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# Resources


21. American Society of Health-System Pharmacists. ASHP guidelines on home infusion pharmacy services. Accessed June 13, 2022. https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/home-infusion-pharmacy-services.ashx

22. Health System Owned Specialty Pharmacy Alliance. “Gold bagging” is the newest emerging terminology in the health system-owned specialty pharmacy arena…and it’s gaining steam. Published May 20, 2021. Accessed June 13, 2022. https://hospalliance.org/gold-bagging-is-the-newest-emerging-terminology-in-the-system-owned-specialty-pharmacy-arena/

23. American Society of Gene + Cell Therapy. Gene and cell therapy FAQ’s. Accessed June 13, 2022. https://asgct.org/education/more-resources/gene-and-cell-therapy-faqs

24. Stanton D. Celle and gene therapies: FDA expects 10 to 20 approvals per year by 2025. Published January 16, 2019. Accessed June 13, 2022. https://bioprocessintl.com/bioprocess-insider/regulations/cell-and-gene-therapies-fda-expects-10-to-20-approvals-per-year-by-2025/#:~:text=Upstream-,Cell%20and%20gene%20therapies%3A%20FDA%20expects%2010%20to,approvals%20per%20year%20by%202025&text=The%20US%20FDA%20predicts%20it,staff%20to%20review%20these%20products.

25. Targeted News Service. Alliance for transparent & affordable prescriptions issues public comment to FTC. Published June 2, 2022. Accessed June 13, 2022. https://insurancenewsnet.com/oarticle/alliance-for-transparent-affordable-prescriptions-issues-public-comment-to-ftc

26. Drug Channels. Drug Channels news roundup, October 2021: PBMs’ oncology exclusions, biosimilar boom, BCBS vs. hospitals, U.S. vs. the world, and CRISPR comedy. Published October 28, 2021. Accessed June 13, 2022. https://www.drugchannels.net/2021/10/drug-channels-news-roundup-october-2021.html