



# Ten (or so) Things You Must Know About Specialty Pharmacy

First steps and key information for those seeking a career in specialty pharmacy

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# Meet The Presenter



Michael Einodshofer, RPh

President / Founder  
*MERx Consulting LLC*

*Former NASP Chairman of the Board  
Former Chief Pharmacy Officer, Optum Rx*

*Special thanks to: Jordan Almazan, PharmD, AAHIVE, BCGP who contributed much of this material.*



# SPEAKER DISCLOSURES

- Mike is a former employee of Optum Rx.
- Mike gets compensated for consultative services from a variety of clients including pharmaceutical manufacturers, pharmacies, and health plans.
- There are no conflicts of interest related to Mike's past or present experiences related to this discussion.

# LEARNING OBJECTIVES

1. How and why the pharmacy industry is shifting towards specialty drugs
2. Define 10 key terms related to specialty pharmacy
3. Learn the 2 most important things to be successful
4. Instill base knowledge about the specialty industry to enable participants to engage in meaningful conversations and continue to learn.



# What Exactly is a Specialty Drug?

Specialty drugs are often defined as being more complex than most other prescription medications and can be a biologic or traditional drug.

Defining a specialty drug can be a challenge! The FDA, employers, health plans, PBMs and trade associations each have their own definitions that may include:

1. Used to treat complex, chronic, life altering or life-threatening conditions or rare diseases
2. Have a high unit cost
3. Can be injectable, infusible, oral, inhaled, biologics or require cold chain distribution
4. Tend to be more complex to maintain, administer, and monitor than traditional small molecule drugs
5. Require significant degree of patient education, monitoring and management
6. Therapy often initiated by specialists

**Note: CMS uses a singular cost criterion for a drug to be eligible for the “specialty” tier on Part D plans.**



# Find the Specialty Drug



Drug #1

I am an oral drug, use to prevent life-threatening circulatory complications. If I'm taken incorrectly life-threatening bleeding episodes will occur. Sometimes, a blood level is necessary every day to determine the proper dose. Patients must learn about certain dietary restrictions, as simple dietary changes can create significant deviations in drug efficacy and increase risk of bleeds or clots.



Drug #2

I am an injectable medication that must be refrigerated. If I am administered in the wrong dose or to the wrong person, death can quickly result. The proper dose to be administered may change daily based on physical and dietary factors. Patients may need to be trained on how to use a separate at-home lab machine to determine the proper dose each day.



Drug #3

I am a drug that is used to as a contraceptive to lower the chances of pregnancy.

# NASP Definition of a Specialty Pharmacy

A state-licensed pharmacy, accredited by an independent, third party nationally recognized accreditor as a specialty pharmacy, ensuring consistent quality care, that solely or largely provides medications for people living with serious health conditions requiring complex therapies. These may include:

- Cancer
- Cystic Fibrosis
- Hemophilia/Other Bleeding Disorders
- Hepatitis
- HIV/AIDS
- Multiple Sclerosis
- Rheumatoid Arthritis





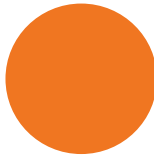

# Let's Learn the Lingo...

## *Recommended Advanced Homework*





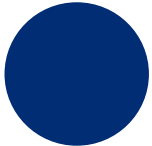
- *Gene therapy*
- *Health Systems*
- *340B*
- *Drug Distribution Channels*

- 1 Biologics
- 2 Biosimilars
- 3 Medical & Pharmacy Benefits
- 4 Infusion
- 5 Core & Enhanced Services
- 6 Limited Distribution Drugs
- 7 Hub Services
- 8 Financial Assistance
- 9 Copay Accumulators & Maximizers
- 10 Specialty Pharmacy Accreditation



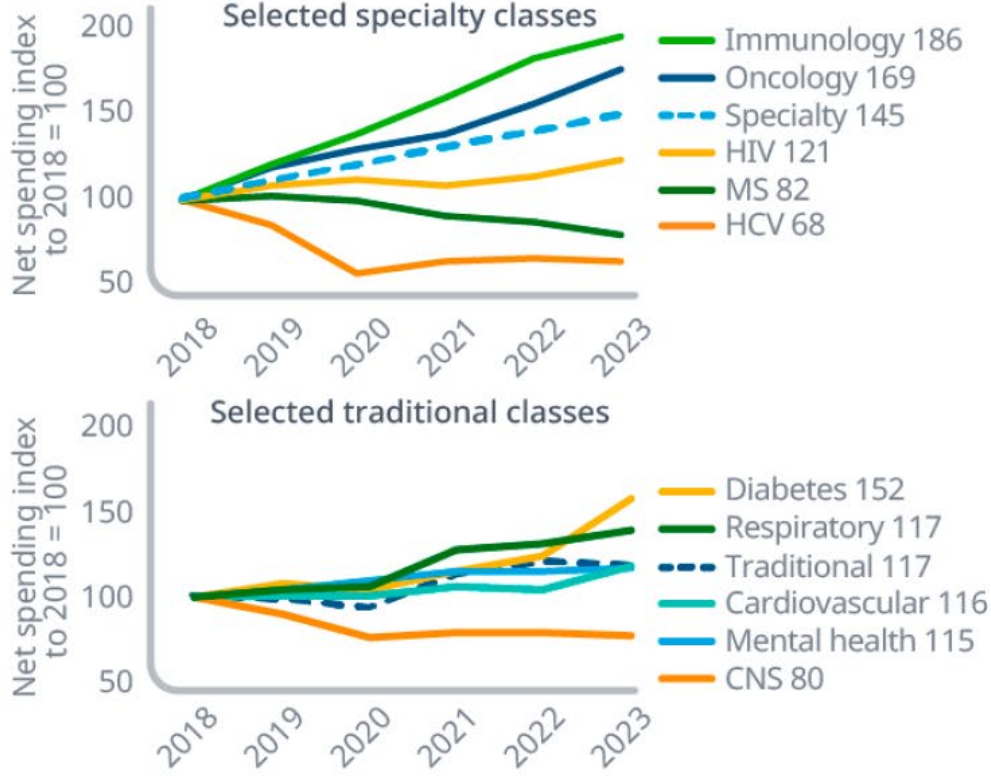
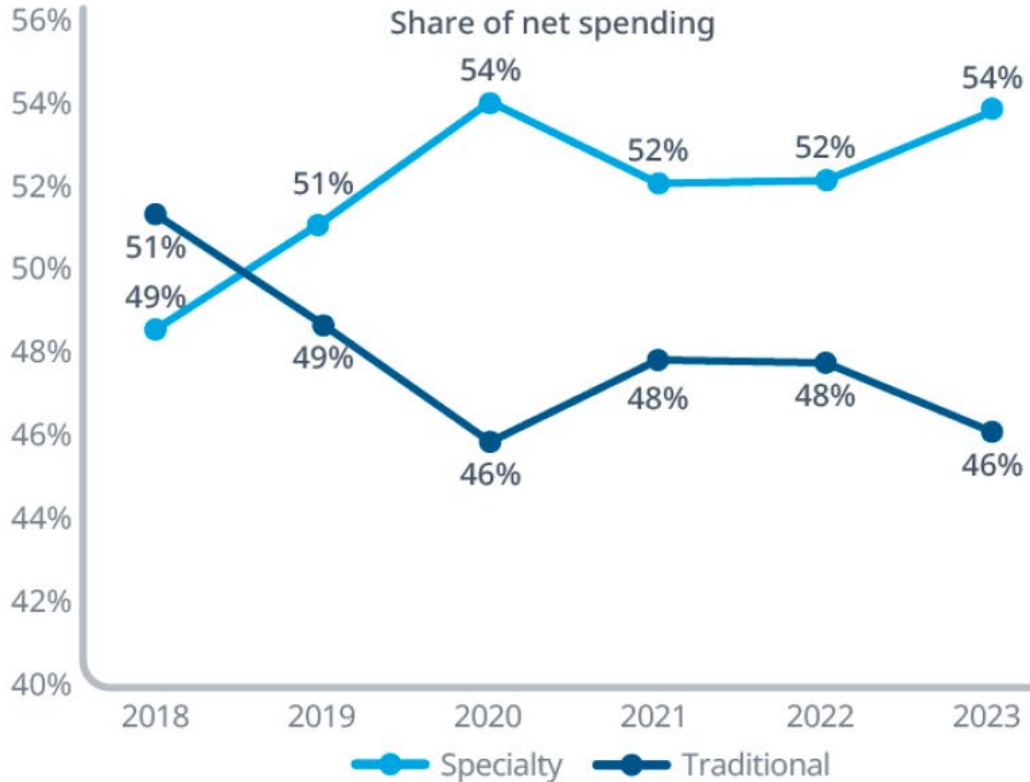


What are the two MOST important items to know about having a successful career NOT listed on the previous slide?



# Specialty medicines account for 54% of spending, lifted by immunology and oncology, while diabetes drives traditional drugs

Share of spending at estimated net manufacturer prices



Source: IQVIA Institute, Mar 2024.

Notes: Specialty and traditional medicines are defined by IQVIA. Specialty medicines — those that treat chronic, complex or rare diseases, and possess additional distribution, care delivery and/or cost characteristics which require special management by stakeholders. Includes all medicines in both pharmacy and institutional settings, and all brands and generics. Totals may not sum due to rounding.

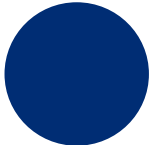




Report: The Use of Medicines in the U.S. 2024: Usage and Spending Trends, and Outlook to 2028. IQVIA Institute for Human Data Science, April 2024.



# What is a Biologic Drug?



# 1. Biologics

- Pharmaceutical products derived from a biological source
  - Generally larger and structurally more complex than chemically-derived medicines
  - Special considerations for storage and handling, adverse events, patient counseling, and administration
  - Common biologics include:
    - Insulin
    - TNF inhibitors
    - IL inhibitors
- 
- 
- 
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# Biologics vs Traditional Drugs

## Biologics

- Come from living organisms
- Complex structure, larger molecules and are not easily reproduced.
- Difficult to characterize by testing methods
- Must ensure the manufacturing process remains the same over time
- Many cause immunosuppression

## Traditional Drugs

- Typically manufactured through chemical synthesis
- Well-defined chemical structure
- Can be analyzed to determine components
- The drug manufacturer can change the manufacturing process extensively

# Select Pre-Market Requirements

	Biologics	Traditional Drugs
Authorization	Licensure	Approval
Submission	Biologics License Application (BLA)	New Drug Application (NDA)
Clinical Trial	Yes	Yes
Standard of Evidence	Safe, pure and potent	Substantial evidence of effectiveness and adequate tests of safety
Compliance with cGMPs	Yes	Yes





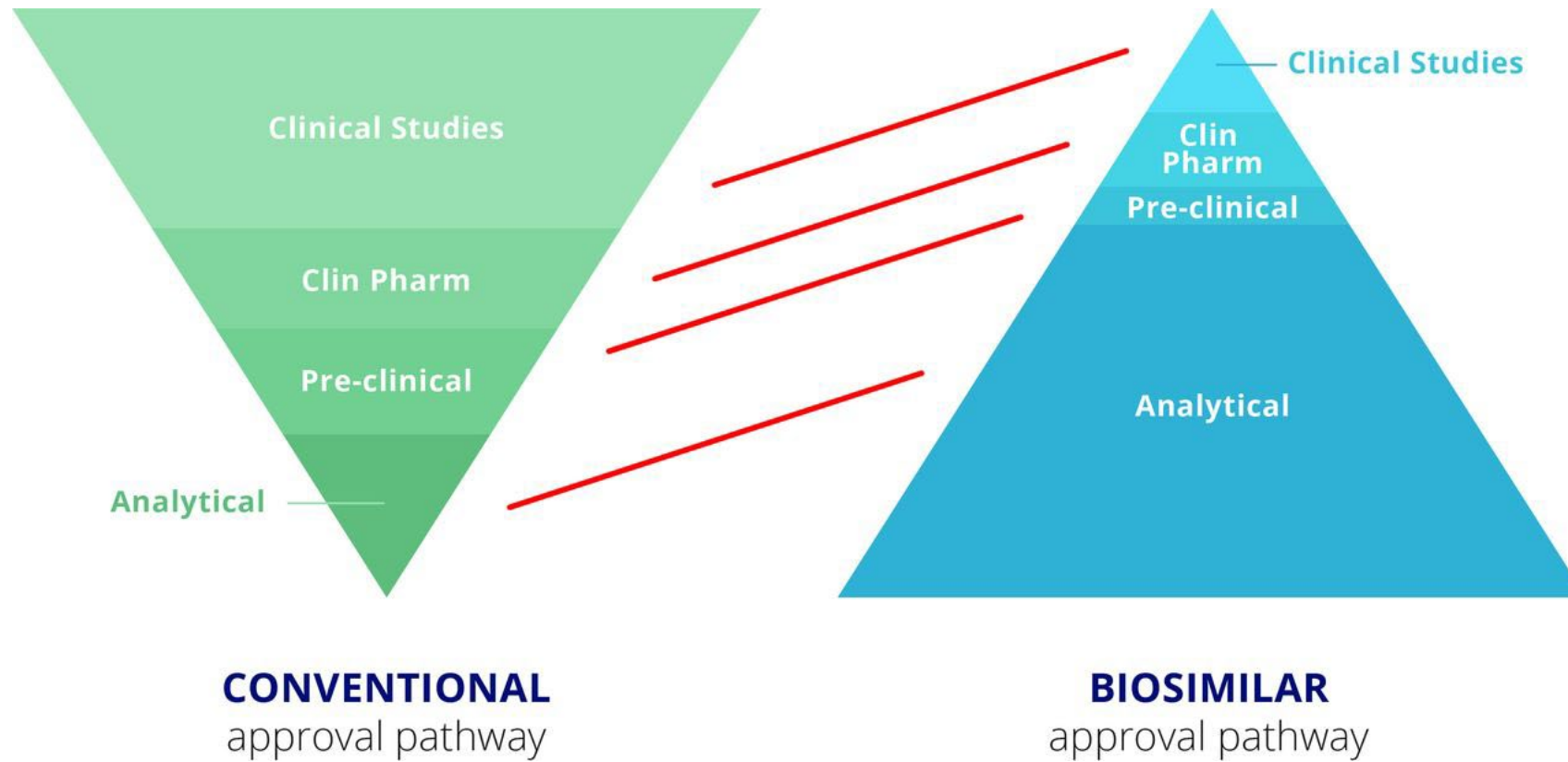
## What is a Biosimilar Drug?



## 2. Biosimilars

- Biological products which have the same clinical function as a biologic
- Established similarity in safety, purity, and potency compared to its parent biologic
- Reviewed and approved by the FDA under the 351(k) pathway
- Expected to be less costly compared to branded biologics
- Common biosimilars include:
  - Adalimumab-atto (aka Amjevita by Amgen)
  - Filgrastim-sndz (aka Zarxio by Sandoz)

# Biosimilars Track to Approval



# Biosimilar Approval Process

## Biosimilars Approval Process

- Must demonstrate that the biosimilar is highly similar to the reference product, except for minor differences in clinically inactive components
- No clinically meaningful differences in terms of the safety, purity, and potency of the product (i.e., safety and effectiveness)
- Animal and clinical studies are required

## Generics Approval Process

- Must demonstrate, among other things, that the generic is bioequivalent to the brand-name drug
- Active ingredient must be identical in strength, dosage form, and route of administration
- No animal or clinical studies are required

# Biosimilar Strategies are Creating New Manufacturer, Payer, and Pharmacy Relationships

## Manufacturer

The manufacturer develops and produces the medication, directly influencing pricing and availability.

## Payer/PBM

The payer negotiates drug prices and manages patient benefits, impacting coverage and accessibility.

## Pharmacy

The pharmacy dispenses medication and manages patient adherence, contributing to clinical outcomes and patient satisfaction.

e.g. Accredo is owned by Express Scripts

e.g. Quallent is a biosimilar company owned by Cigna, which owns Express Scripts.



# U.S. biosimilar market landscape

Available at: [Biosimilars pipeline report: A guide for understanding the growing market \(amerisourcebergen.com\)](https://www.amerisourcebergen.com)

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As of September 1, 2024

Class	Supportive care	Oncology	Insulin	Ophthalmology
<b>Molecule</b>	Filgrastim   Epoetin   Pegfilgrastim	Rituximab   Bevacizumab   Trastuzumab	Insulin Glargine   Insulin Lispro	Ranibizumab   Aflibercept
<b>Reference Products</b> Manufacturer	NEUPOGEN Amgen	RITUXAN Genentech	LANTUS Sanofi	LUCENTIS Genentech
<b>Biosimilar Products</b> Manufacturer Launch date or Approval date	ZARXIO Sandoz Sep 2015	TRUXIMA Teva Nov 2019	SEMGLLEE Bionon Nov 2021	BYOOVIZ Biogen Jul 2022
	RETACRIT Pfizer-Vifor Nov 2018	MVASI Amgen Jul 2019	REZVOGLAR Eli Lilly Apr 2023	YESAFILI Bionon May 2024
	FULPHILA Bionon Jul 2018	KANJINTI Amgen Jul 2019		OPUVIZ Biogen May 2024
	NIVESTYM Pfizer Oct 2018	RUXIENCE Pfizer Jan 2020		CIMERLI Coherus Oct 2022
	UDENYCA Coherus Jan 2019	ZIRABEV Pfizer Jan 2020		AHZANTIVE Formycon Jun 2024
	RELEUKO Amneal Nov 2022	RIABNI Amgen Jan 2021		ENZEEVU Sandoz Aug 2024
	NYPOZI Tanvex Jun 2024	ALYMSYS Amneal Oct 2022		PAVBLU Amgen Aug 2024
	ZIEXTENZO Sandoz Nov 2019	TRAZIMERA Pfizer Feb 2020		
	NYVEPRIA Pfizer Dec 2020	VEGZELMA Callitron Apr 2023		
	STIMUFEND Fresenius Feb 2023	HERZUMA Teva March 2020		
	FYLNETRA Amneal May 2023	AVZIVI Sandoz Dec 2023		
		ONTRUZANT Organon Apr 2020		
		HERCESSI Accord May 2024		
<b>Follow-on biologics</b> Manufacturer Launch date or Approval date			BASAGLAR Eli Lilly Dec 2016	ADMELOG Sanofi Dec 2017

▲ Unbranded version is also available

● Interchangeability approval by the FDA. For more details on interchangeability, please visit <https://www.fda.gov/media/151094/download>

Approved but yet to launch

Continued on next page

# U.S. biosimilar market landscape

As of September 1, 2024

Class	Immunomodulators							Bone health		
Molecule	Infliximab	Etanercept	Adalimumab		Natalizumab	Tocilizumab	Ustekinumab	Eculizumab	Denosumab	
Reference Products Manufacturer	REMICADE J&J	ENBREL Amgen	HUMIRA AbbVie		TYSABRI Biogen	ACTEMRA IV/SC Genentech	STELARA IV/SC J&J	SOLIRIS Alexion	PROLIA Amgen	XGEVA Amgen
Biosimilar Products Manufacturer Launch date or Approval date	INFLECTRA Pfizer Nov 2016	Ongoing litigation forecasted launch 2028/2029	AMJEVITA Amgen Jan 2023	YUSIMRY Coherus Jul 2023	TYRUKO Sandoz Aug 2023	TYENNE Fresenius Apr 2024	WEZLANA Amgen Oct 2023	BKEMV Amgen May 2024	JUBBONTI Sandoz Mar 2024	WYOST Sandoz Mar 2024
RENFLLEXIS Organon Jul 2018	▲ CYLTEZO BI Jul 2023		HADLIMA Organon Jul 2023	TOFIDENCE Biogen May 2024	SELARSDI Teva Apr 2024	EPYSQLI Samsung Jul 2024				
AVSOLA Amgen July 2020	▲ HULIO Biocon Jul 2023		▲ IDACIO Fresenius Jul 2023	PYZCHIVA Sandoz Jun 2024						
NOT LAUNCHING IN U.S.  IXIFI Pfizer Dec 2017	ERELZI Sandoz Aug 2016		▲ HYRIMOZ Sandoz Jul 2023	YUFLYMA Celltrion Jul 2023						
	ETICOVO Samsung Apr 2019	● ABRILADA Pfizer Oct 2023	● SIMLANDI Teva May 2024							

[View detailed landscape of Adalimumab products](#)

Available at: [Biosimilars pipeline report: A guide for understanding the growing market \(amerisourcebergen.com\)](https://www.amerisourcebergen.com)

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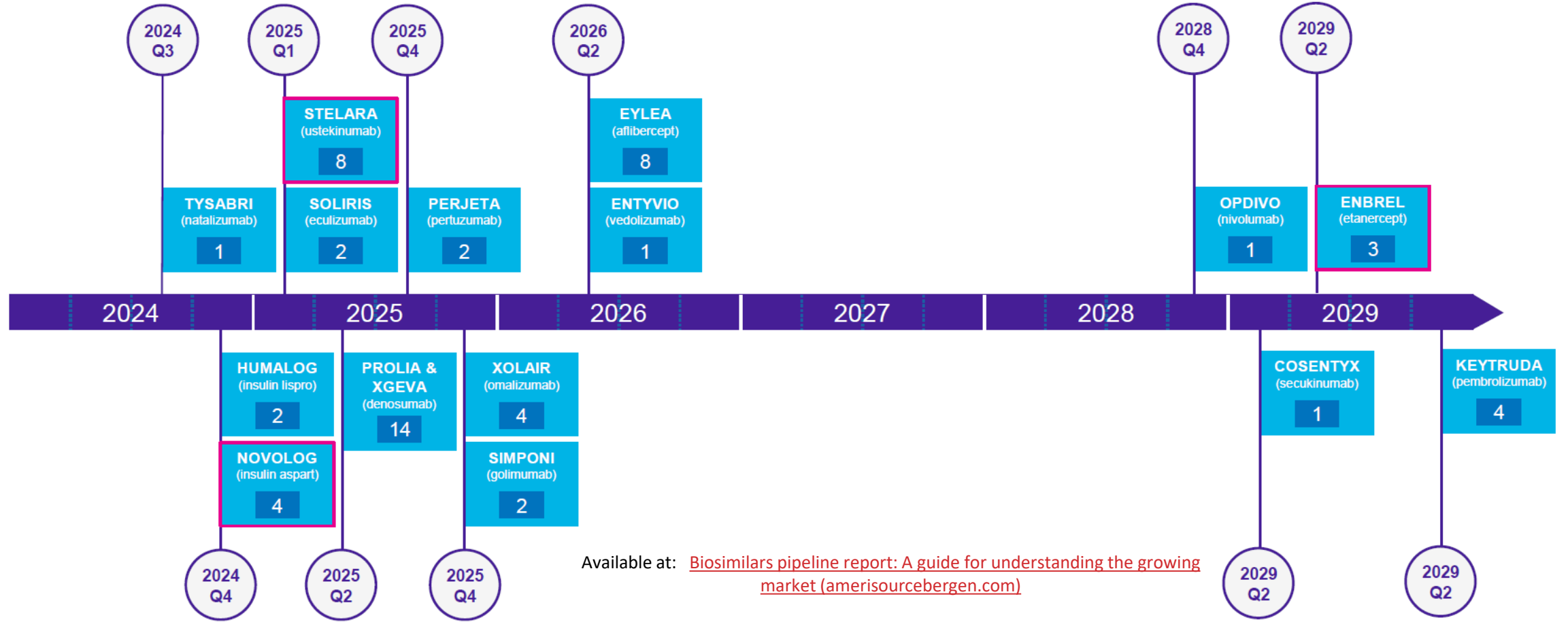
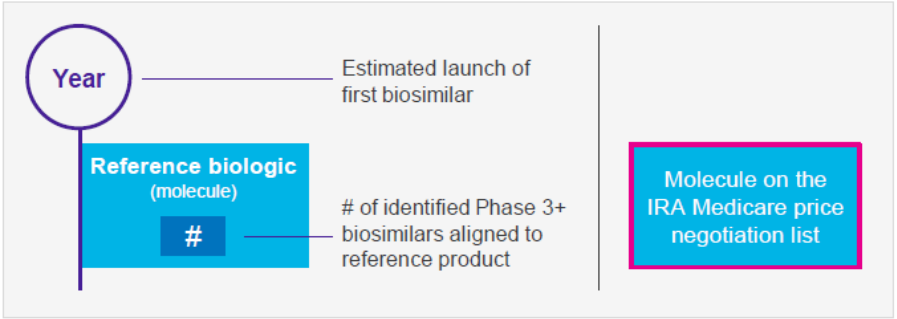
● Interchangeability approval by the FDA. For more details on interchangeability, please visit <https://www.fda.gov/media/151094/download>

Approved but yet to launch

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# New biosimilar launches

Reference products included have no marketed biosimilars



Available at: [Biosimilars pipeline report: A guide for understanding the growing market \(amerisourcebergen.com\)](https://www.amerisourcebergen.com/resources/biosimilars-pipeline-report)

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## Medical vs. Pharmacy Benefit: How do drugs get paid for?



### 3. Medical Benefits vs Pharmacy Benefits – How Are Drugs Paid For?

Refers to how medications and services are paid for by an insurance plan.



#### Medical Benefits

- Cover visits to medical settings and services provided in these settings
- *Sometimes* cover dispensing and administration of certain medications
- Report billing for drugs as J-codes
- Are controlled by insurance companies



#### Pharmacy Benefits

- Cover dispensing of medications
- *Sometimes* cover administration of vaccines and other injectable products
- Report billing for drugs as NDCs
- Are controlled by PBMs (pharmacy benefit managers)

# Medical Benefits vs. Pharmacy Benefits

	Medical Benefit	Pharmacy Benefit
Administration	Intravenous infusions, injections	Self-administered injections
Dispensing Channel	Physician, infusion center, home health	Specialty pharmacy dispenses drug and delivers to patient
Billing Term	“Buy and Bill”	“Bill and dispense”
Claims Submission	Batch or real-time using HCPCS codes	Online using NDC
Utilization Management	Prior authorization (PA)/medical review process	PA, step therapies, concurrent DUR, formularies
Member Cost-Share	Copayment for office visit, coinsurance for drug product	Copayment or coinsurance for drug

# Medical Billing: Coding



## Current Procedural Terminology (CPT) codes

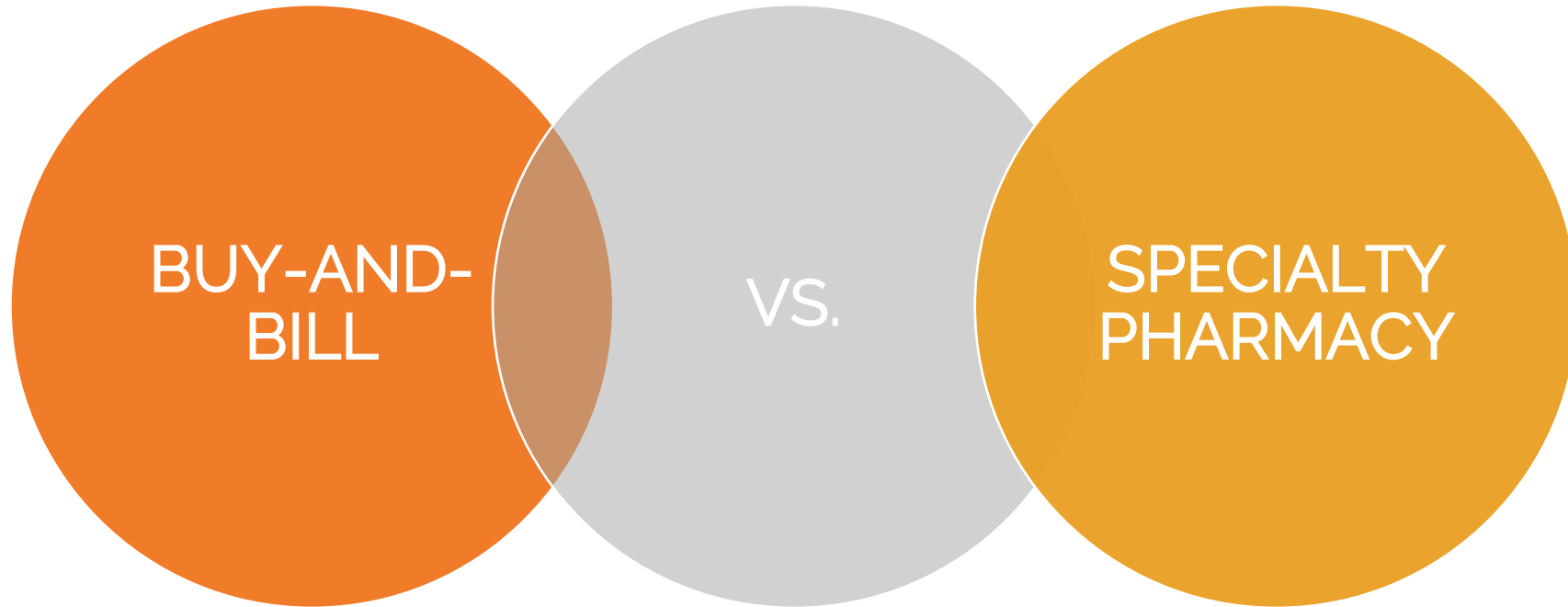
Are used to classify most medical procedures done in an HCP's office (e.g. 96360-96361)



## Healthcare Common Procedure Coding System (HCPCS) Codes

C-codes: temporary codes for outpatient drugs  
J-codes: HCP-administered drugs

# Specialty Drug Acquisition Models



# Buy-and-Bill



HCP purchases the drug from a specialty distributor, allowing the product to be available on-hand.



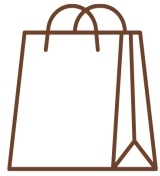
Typically, not self-administered by patient, usually administered in the office by a nurse.



Healthcare provider bills health plan (and subsequently patient) for:

- Drug Reimbursement
- Drug Administration

# Specialty Pharmacy Distribution of Non-Self-Administered Drugs



Brown Bagging



White Bagging



Clear Bagging





## Infusion Drugs

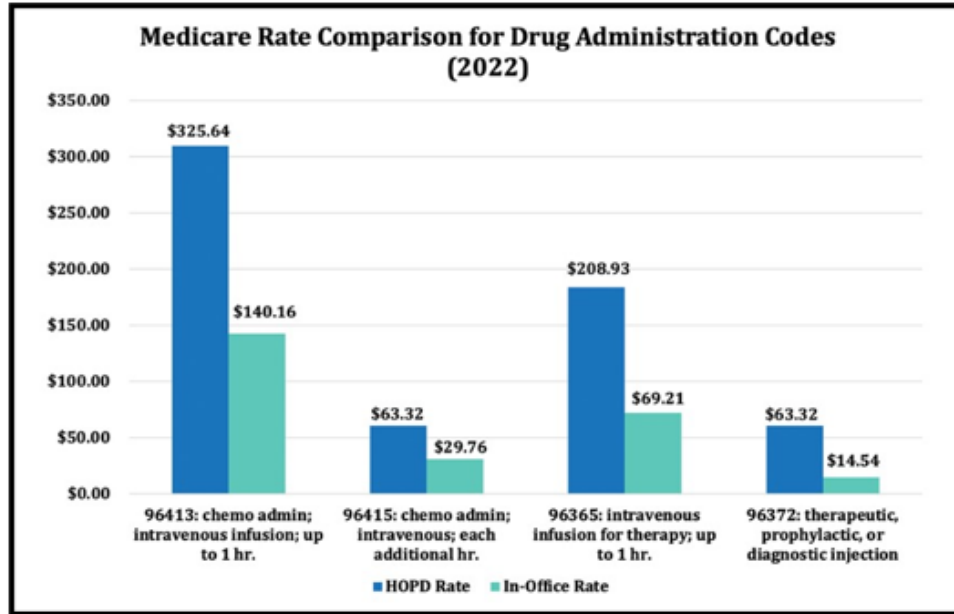
# 4. Infusion Therapies

- Administration of a medication through a needle or catheter
- Advantage: immediate bioavailability
- Examples of infusion products: antibiotics, parenteral nutrition, immunoglobulin, and oncology medications
- Viable alternative when oral medications are no longer effective
- Locations:
  - Hospital infusion centers
  - At-home infusions
  - Outpatient infusion centers





# Hospital vs. In-Office Infusions



Non-self-administered drugs are typically billed in 2 parts.

1. A CPT code for administration "How long was the infusion?"
2. A HCPCS (J-Code) representing the drug. "What was infused/administered?"

While administration costs are higher in Institutional (hospital) settings, it's also important to understand that the cost of the drug itself billed by the hospital can be up to 50-200%+ more expensive vs. other sites of care.

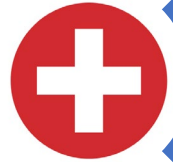
FIGURE 109: 2019 COMMERCIAL TOP 25 DRUGS COST TRENDS BY SITE OF SERVICE

Rank	HCPCS	Brand	COST PER CLAIM			COST PER UNIT			MARKET SHARE BY SOS		
			HOME	HOSPITAL OP	PHYSICIAN	HOME	HOSPITAL OP	PHYSICIAN	HOME	HOSPITAL OP	PHYSICIAN
1	J1745	Remicade	\$6,185	\$7,975	\$3,991	\$128	\$170	\$81	12%	29%	59%

[www1.magellanrx.com/documents/2021/05/2020-mrx-medical-pharmacy-trend-report.pdf/](http://www1.magellanrx.com/documents/2021/05/2020-mrx-medical-pharmacy-trend-report.pdf/)



# Alternative Sites of Administration



Infusion Centers Already Part of a System or Local Hospital



Stand-Alone Infusion Centers



Home Health Providers



Specialty Providers  
Accepting Outside Referrals



# Core and Enhanced Services of Specialty Pharmacies

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# 5. Core vs Enhanced Services at Specialty Pharmacies

Core Services	Enhanced Services
<ul style="list-style-type: none"><li>• Basic offerings that the pharmacy provides without the compensation of a third party</li><li>• Consistent with a standard of care for pharmacy practice and regulatory requirements</li></ul>	<ul style="list-style-type: none"><li>• Offerings that the pharmacy provides with the compensation of a third party, typically a manufacturer</li><li>• Allow the specialty pharmacy to improve adherence and provide intensive clinical care and monitoring</li></ul>
<p>Examples:</p> <ul style="list-style-type: none"><li>• Dispensing</li><li>• Patient counseling</li><li>• Medication usage monitoring</li><li>• Benefits investigation</li><li>• Financial assistance</li></ul>	<p>Examples:</p> <ul style="list-style-type: none"><li>• Data sharing for Phase IV clinical trials</li><li>• Hub offer and warm transfer services</li><li>• High-touch benefits investigation</li><li>• Clinical/laboratory monitoring (e.g. LFTs, blood pressure)</li></ul>



# Core v. Enhanced Services

- Manufacturers provide a request for proposal
- Sections of the proposal
  - Data and information services that the pharmacy would agree to provide to the manufacturer
  - Explanation of the clinical services that the pharmacy would provide to the patient
- The pharmacy can determine whether it will offer core or enhanced services





# Limited Distribution Drugs

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# 6. Limited Distribution Drugs

- Medications which are dispensed only by a limited number of pharmacies, as determined by the manufacturer
- LDDs generally require enhanced clinical oversight
- Include therapies for cancer, rare diseases, and other conditions
- Limited distribution networks
  - Are established by pharmaceutical manufacturers
  - Include pharmacies which meet specific criteria
  - Differ from drug to drug
  - Are expected to increase quality of clinical care
  - May increase cost and reduce access

# LDDs (continued)

Sample criteria for selection:

- Qualified care coordination team
- National accreditation
- Efficient tracking and reporting
- Management of tools and services
- Payable coverage
- 24/7 call centers available for clinical support
- National coverage

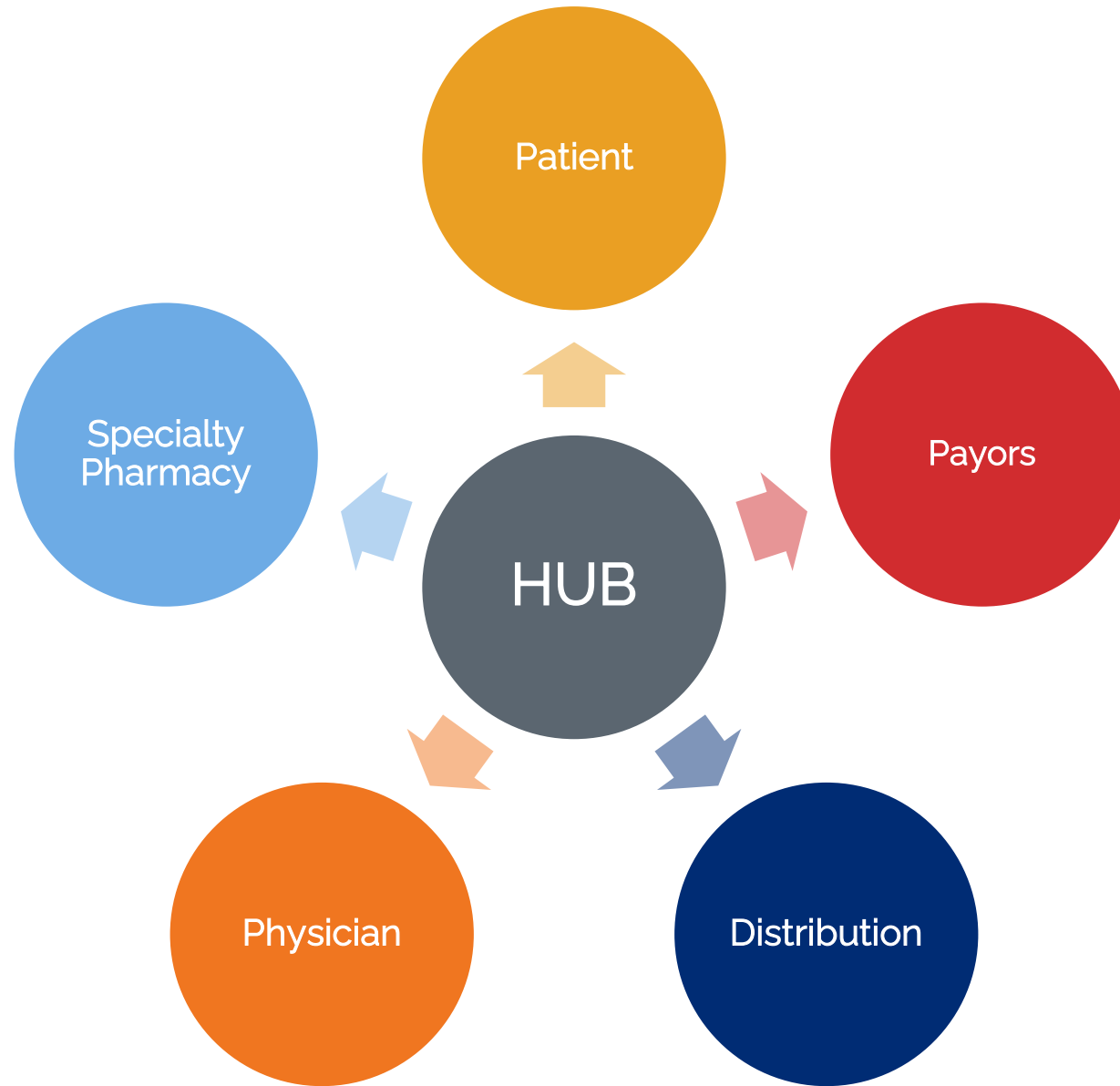




## Hub Services

# 7. Hub Services

- Hub: organization (typically hired by a drug manufacturer) offering a suite of patient support services to aid with medication processing and fulfillment
- Goal: standardize patient and provider support across networks on behalf of a pharmaceutical manufacturer
- Example hub services:
  - Benefits investigation
  - Prior authorization processing
  - Bridge supplies or Rx triaging
  - Data reporting
  - Financial & co-pay assistance
  - Patient education
  - Compliance with REMS



Clark J. Kaddis A. PharmacyToday. (2017, January 1). Continuing evolution of hub services. Retrieved September 9, 2022 from <https://www.pharmacytoday.org/article/S1042-0991%2816%2931650-4/fulltext>





# Patient Financial Assistance

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# Types of Patient Financial Assistance Programs

Resources available for the uninsured or those not able to afford their medications.

Co-Pay Cards	Pharmaceutical Assistance Programs	Patient Assistance Foundations
Manufacturers help insured patients afford expensive prescription drugs by covering a portion or all of a member's deductible and copay for certain medications	Manufacturers provide financial assistance or drug free product to lower-income individuals	Charitable foundations Provide access to medications and financial support to underinsured patients who may be experiencing financial hardships.
Typically offered to commercial plans members only	Typically offered to commercial plans members only	Typically, open to all patients meeting funding requirements, which will vary by grant.



# Accumulator and Maximizer Programs

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# 9. Accumulator and Maximizer Programs

- Accumulator and maximizer programs are strategies developed by PBMs and insurers to influence how manufacturer copay cards pay for medications
- Copay accumulator programs
  - Prevent manufacturer copay cards from applying to or “accumulating toward” a patient’s deductible
  - May increase patient responsibility for healthcare costs
- Copay maximizer programs
  - Has an advantage over an accumulator because it reduces or eliminates the patient’s out-of-pocket obligations

# Maximizer vs. Accumulator

## Maximizer vs. Accumulator



Access Answered.

<b>ASSUME:</b>	Annual cost of medication: \$24,000	Patient coinsurance: 25% (\$500/month)	Copay assistance: Pay \$0 monthly copay	Copay assistance annual max: \$16,000	Patient annual max OOP: \$6,000	Patient Deductible: \$2,000
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	No Accum. Nor Max	With Accumulator	With Maximizer
<b>Copay Assistance Pays</b>	\$6,000	\$6,000	\$16,000
<b>Patient Pays</b>	\$0	\$2,000	\$2,000
<b>Payer Cost Share†</b>	\$18,000	\$16,000	\$6,000





# Accreditation

# 10. Specialty Pharmacy Accreditation

- Quality standards to differentiate specialty pharmacies providing specified services, clinical management, and outcomes
- Oftentimes required by payers to establish in-network status
- Extensive and costly process with reaccreditation cycles



# Accreditation Bodies

<u>URAC</u> The Utilization Review Accreditation Commission	<u>ACHC</u> The Accreditation Commission for Health Care	<u>TJC</u> The Joint Commission
Establishes quality standards for the entire healthcare industry, including health plans, pharmacies, and provider organizations. This body has become the gold standard for specialty. Renewed every 3 years.	Looks for the organization's dedication and best practices to better serve the patients. These pharmacies are committed to providing patient care at the highest level of standards. Renewed every 3 years.	Accredits more than 22,000 health care organizations and programs in the United States and evaluates the quality achievement in patient care and safety. Not specialty specific.



## Sample Accreditation Requirements



**Your Patient Management program includes patient education and protocols that are disease state and/or drug specific.**

**ENSURE** clinical protocols are based on specific clinical guidelines and are not generalized for all patients.



**Initial clinical assessments and periodic reassessments are performed and documented.**

**AUDIT** a random sample of patient files to confirm documentation of clinical assessments that evaluate appropriateness of therapy.



**All clinical assessments and interventions are performed by a pharmacist or other qualified health professional.**

**CHECK** a random sample of patient files to confirm clinical documentation has sign off by an appropriate clinician.



**The effectiveness of your Patient Management program is evaluated at least annually.**

**CONFIRM** the program evaluation uses sound methodology to consider clinical, financial, and quality of life benefits of the program.



**Dispensing procedures comply with all regulatory and best practice guidelines.**

**WALK** through your dispensing operations to ensure proper clinical oversight and processes for prescription processing, intake, utilization review, verification, preparation, and dispensing functions.



**Processes to maintain medication temperature and integrity during shipping have been implemented and tested.**

**VERIFY** your packing products and shipping methods have been tested for all temperature ranges in all seasons and you have a plan to periodically monitor these processes.



**Performance metrics for dispensing accuracy, distribution accuracy, and adherence are tracked.**

**REVIEW** Quality Management Committee meeting minutes to ensure documentation of monitoring these performance metrics and implementation of quality improvement when needed.



**Telephone performance metrics are monitored.**

**CHECK** your monthly and quarterly telephone metric reports to make sure you are meeting URAC's Average Abandonment Rate (5% or less) and Average Speed of Answer (80% of calls within 30 seconds) thresholds.



**Verification of licensure or certification for clinical staff is documented.**

**REVIEW** personnel records to ensure all staff whose job description requires a licensure or certification have evidence of primary source verification of the required credential.



**Your organization's Business Continuity Plan is in place and tested at least every two years.**

**ENSURE** you have a documented plan to address all systems and processes to minimize patient impact in an emergency.

# Summary

## Why Choose Specialty?

- Specialty will increase share of national pharmaceutical expenditures
- Many career options in business and clinical practice.
- Impact patient outcomes through providing comprehensive treatment through the utilization of high-touch medications
- Continual Change



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# Thank You

[Einodshofer.Rx@gmail.com](mailto:Einodshofer.Rx@gmail.com)