

# Navigating the Specialty Medication Journey Between Pharmacy & Medical Benefits

Presented by:

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The information within this CME/CE activity is for continuing education purposes only, and is not intended to substitute for the medical judgment of the healthcare provider. Recommendations for use of any particular therapeutic agents or methods are based upon the best available scientific evidence and clinical guidelines. Reference in this activity to any specific commercial products, process, service, manufacturer, or company does not constitute its endorsement or recommendation.

- I do not intend to discuss non-FDA approved medications.
- I have not had any relevant financial relationships during the past 12 months to disclose that pertains to this presentation.

# Objectives

1. Define specialty medications, pharmacy drug benefit, and medical drug benefit.
2. Explain the process for specialty medication reimbursement on the pharmacy and medical benefit.
3. List examples of specialty medications that can be reimbursed on either pharmacy or medical benefit
4. Identify possible solutions to maximize cost management of specialty medications regardless of the drug benefit (i.e., pharmacy or medical drug benefit)

# Specialty pharmacy & medications – how defined?

- Lacking one accepted, industry-wide definition for the terms “specialty pharmacy” or “specialty medication”



# Specialty pharmacy: defined

“ ... the service created to manage the handling and service requirements of specialty pharmaceuticals, including dispensing, distribution, reimbursement, case-management and other services specific to patients with rare and/or chronic diseases.”

National Association of Chain Drug Stores

# Specialty pharmacy: defined

“Specialty pharmacies are distinct from traditional pharmacies in coordinating many aspects of patient care and disease management. They are designed to efficiently deliver medications with special handling, storage and distribution requirements with standardized processes that permit economies of scale. Specialty pharmacies are also designed to improved clinical and economic outcomes for patients with complex, often chronic and rare conditions, ...”

Academy of Managed Care Pharmacists (AMCP)

# Specialty medications

- Common characteristics

Treatment of complex, chronic, and/or rare conditions

High cost \$\$

Requires special storage and handling

Special administration: infusion, injectable, inhaled

Available through exclusive, restricted or limited distribution

Ongoing monitoring required for safety and/or efficacy

Hagerman J, Freed S, Rice G. Specialty pharmacy: a unique and growing industry. Pharmacy Today [Internet]. 2013 Jul 01 [cited 2014 Jan 14].

URAC. The Patient-Centered Outgrowth of Specialty Pharmacy. 2011. Available at: [https://www.urac.org/wp-content/uploads/2012/09/urac\\_pqm\\_specialty\\_white\\_paper.pdf](https://www.urac.org/wp-content/uploads/2012/09/urac_pqm_specialty_white_paper.pdf).



# Specialty drug dosage forms

- Specialty drugs come in different dosage forms
  - Oral medications
  - Inhaled medications
  - Self-administered injectables
  - Office-administered injectables, or
  - Infused medications

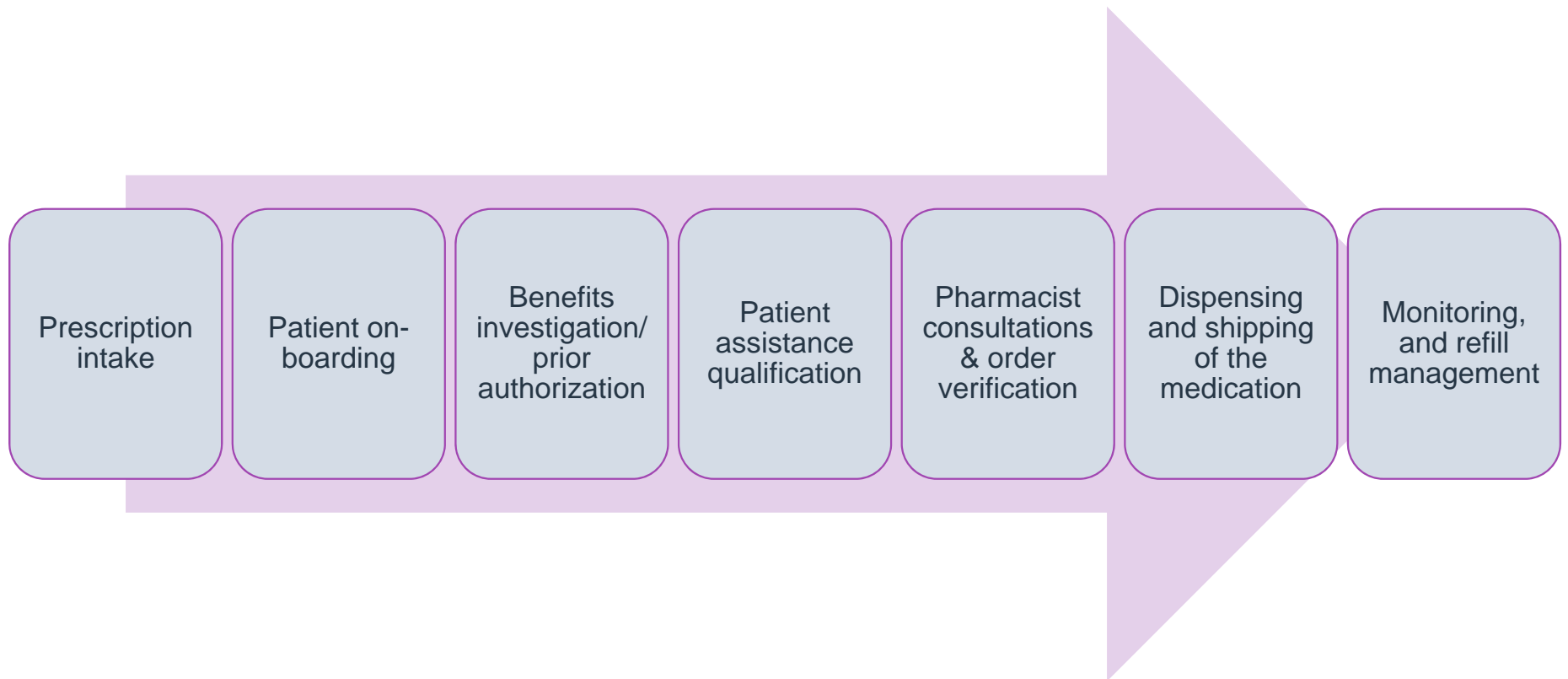
# Specialty medication definition

- Who defines which drugs are specialty drugs?
  - Government?
  - Payors?
  - Pharmaceutical Companies?
  - Others?
  
- Is the definition changing?

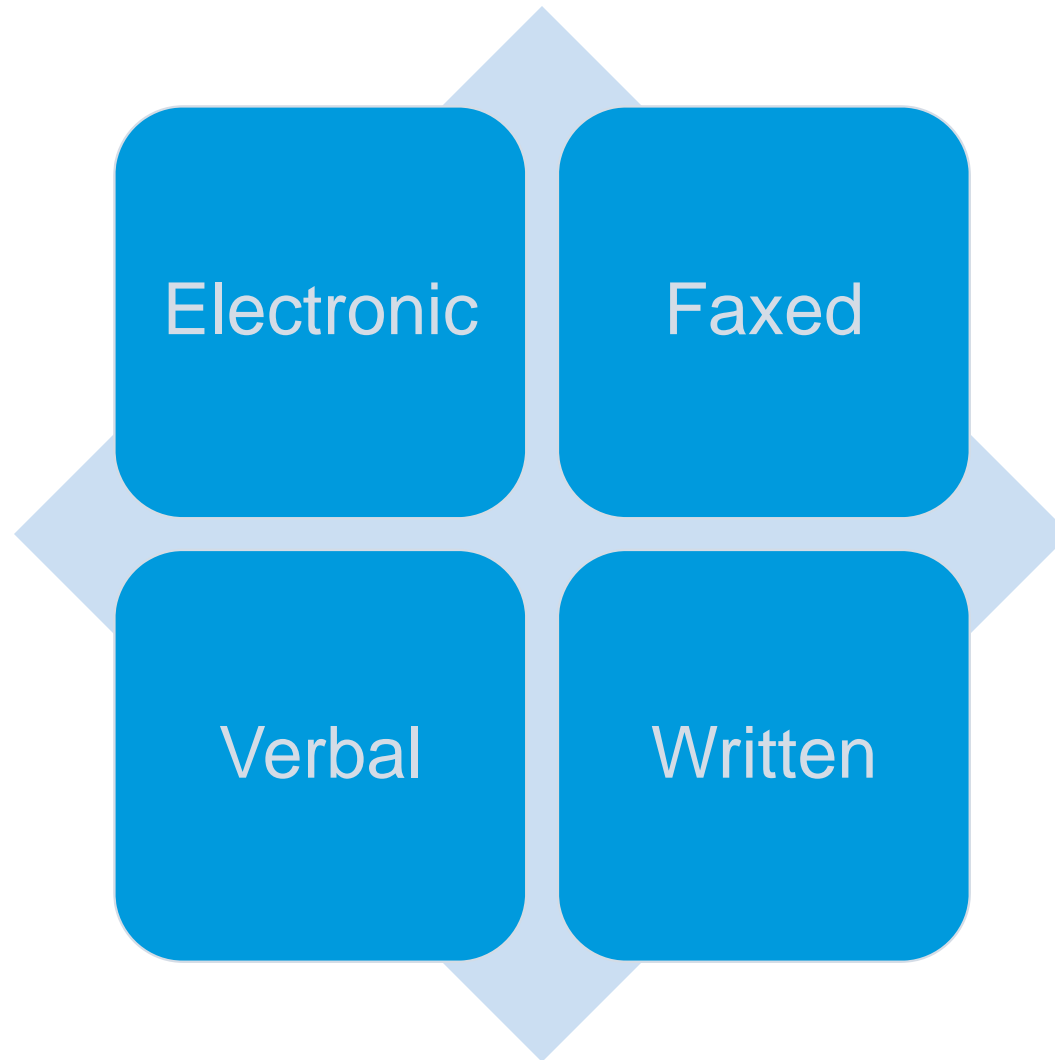
# Specialty drug delivery channels

- The drugs may be delivered at:
  - Physicians' offices
  - Infusion centers
  - Hospitals
  - Specialty pharmacy provider
  - Traditional retail or mail-order pharmacies, and
  - Patients' homes
- The delivery channel helps determine:
  - Whether drugs are covered under the medical or pharmacy benefit
  - The level of patient cost-sharing required, and
  - The degree of clinical and disease management available to the patient

# Specialty pharmacy process



# Prescription obtainment



# Enrollment forms



- New or refill prescription
- Contains significant level of detail
  - Patient demographics
  - Injection training
  - Insurance information
  - Lab coordination
  - Medical assessment
  - Prescriber information

**Single Point of Contact for Office:**  
877.575.SPOC (7762)  
\*\*FAX: 866.376.1448\*\*

**HEPATITIS C ENROLLMENT**

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**Patient Information**

Patient: \_\_\_\_\_ Caregiver: \_\_\_\_\_  
 SS#: \_\_\_\_\_ DOB: \_\_\_\_\_  Male  Female  
 Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_  
 Best Phone #: \_\_\_\_\_ Cell: \_\_\_\_\_ Alternate Phone #: \_\_\_\_\_ Cell: \_\_\_\_\_  
 Weight: \_\_\_\_\_ kgs or lbs (circle one) Recorded Date: \_\_\_\_\_ Allergies: \_\_\_\_\_  NKDA

**INSURANCE INFORMATION: PLEASE FAX COPY OF INSURANCE CARD (FRONT & BACK)**

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**Medical Assessment**

Please Complete This Entire Section

Diagnosis:  070.54 HCV (Chronic) Genotype: \_\_\_\_\_ Subtype: \_\_\_\_\_  
 For genotype 1a, is the Q80K polymorphism present?  Yes  No  
 Previously treated for HCV?  Yes  No # of weeks: \_\_\_\_\_  
 Relapsed  Partial Response  Null Response  
 Liver biopsy done?  Yes  No Date: \_\_\_\_\_ Result: \_\_\_\_\_  
 Is the patient interferon-intolerant?  Yes  No Is the patient awaiting liver transplantation for hepatocellular carcinoma?  Yes  No

Baseline Labs	Result	Date
Hgb		
ALT		
AST		
HCV RNA		

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**Interferon**

PEGASYS<sup>®</sup> Qty: 4 doses (28 days) Refill #: \_\_\_\_\_  
 ProClick™ 180 mcg Autoinjector, 180 mcg SubQ once weekly  
 ProClick™ 135 mcg Autoinjector, 135 mcg SubQ once weekly  
 Prefilled Syringe 180 mcg/0.5 mL, 180 mcg SubQ once weekly  
 Prefilled Syringe 180 mcg/0.5 mL, 135 mcg SubQ once weekly  
 Vial 180 mcg/mL, 180 mcg (1 mL) SubQ once weekly  
 Vial 180 mcg/mL, 135 mcg (0.75 mL) SubQ once weekly

PEG-INTRON<sup>®</sup>  REDDEN<sup>®</sup>  VIAL  
 SELECTDOSE™

Weight kg (lb) Dosing (based on 1.5 mcg/kg/week with Ribavirin)

<40 (<88)	<input type="checkbox"/> 50 mcg (0.5 mL) SubQ weekly
40-50 (88-111)	<input type="checkbox"/> 64 mcg (0.4 mL) SubQ weekly
51-60 (112-133)	<input type="checkbox"/> 80 mcg (0.5 mL) Sub-Q weekly
61-75 (134-166)	<input type="checkbox"/> 96 mcg (0.4 mL) SubQ weekly
76-85 (167-187)	<input type="checkbox"/> 120 mcg (0.5 mL) SubQ weekly
86-105 (188-231)	<input type="checkbox"/> 150 mcg (0.5 mL) SubQ weekly
> 105 (>231)	<input type="checkbox"/> 1.5 mcg/kg/week (may require multiple strengths)

Qty: 4 doses (28 days) Refill #: \_\_\_\_\_

**Ribavirin**

Ribasphere<sup>®</sup> Ribapak<sup>™</sup>  Moderiba<sup>™</sup> Dose Pack

To dispense Brand product only, DAW must be written here: \_\_\_\_\_

600 mg/day – 200 mg q AM and 400 mg q PM Qty: 28 x 200 mg + 28 x 400 mg tabs

800 mg/day – 400 mg q AM and 400 mg q PM Qty: 56 x 400 mg tabs

1000 mg/day – 400 mg q AM and 600 mg q PM Qty: 28 x 400 mg + 28 x 600 mg tabs

1200 mg/day – 600 mg q AM and 600 mg q PM Qty: 56 x 600 mg tabs

Refill #: \_\_\_\_\_

Ribasphere<sup>®</sup> 200 mg Tablet  Ribasphere<sup>®</sup> 200 mg Capsule  
 Moderiba<sup>™</sup> 200 mg Tablet

To dispense Brand product only, DAW must be written here: \_\_\_\_\_

200 mg q AM and 400 mg q PM Qty: 84 Ref: \_\_\_\_\_

400 mg q AM and 400 mg q PM Qty: 112 Ref: \_\_\_\_\_

400 mg q AM and 600 mg q PM Qty: 140 Ref: \_\_\_\_\_

600 mg q AM and 600 mg q PM Qty: 168 Ref: \_\_\_\_\_

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**Protease Inhibitor**

OLSYSIO™ (simeprevir) 150 mg  
 Directions: Take one capsule (150 mg) by mouth once daily with food for 12 weeks.  
 Quantity: 28 capsules (28 days) Refill #: 2

**Polymerase Inhibitor**

SOVALDI™ (sofosbuvir) 400 mg  
 Directions: Take one tablet (400 mg) by mouth once daily.  
 Quantity: 28 tablets (28 days) Refill #: \_\_\_\_\_

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**INJECTION TRAINING**

Diplomat to Coordinate  Office to Coordinate  
 RNE:FN to teach administration of injectable to caregiver/patient (in accordance with state laws)

**LAB COORDINATION**

Diplomat to Coordinate  
 (please fill out lab request form)

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**Prescriber Information**

Anticipated Start Date: \_\_\_\_\_ Prescriber Specialty: \_\_\_\_\_  
 Ship to:  Patient  Physician  Clinic  Other: \_\_\_\_\_ NPI #: \_\_\_\_\_  
 Prescriber: \_\_\_\_\_  
 Phone #: \_\_\_\_\_ Fax #: \_\_\_\_\_ Contact Name: \_\_\_\_\_  
 Office Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_  
 Physician's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

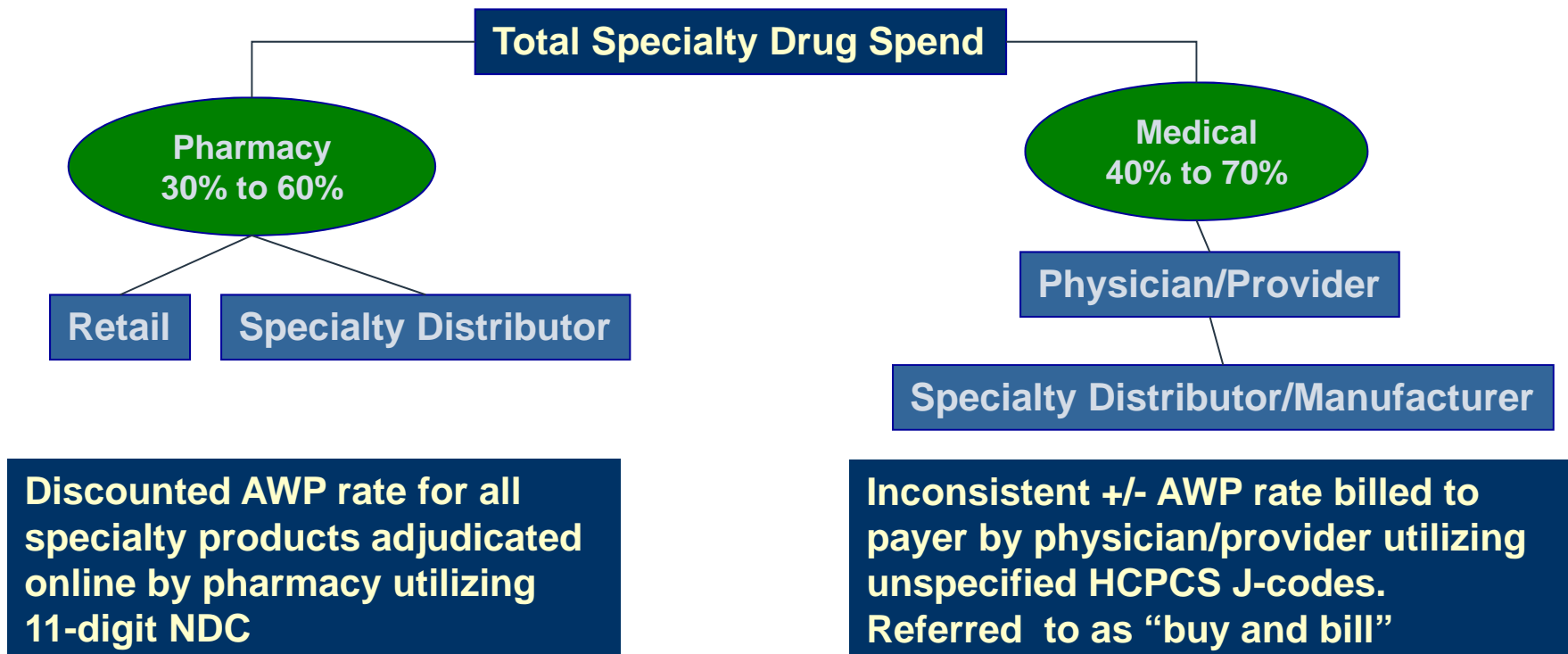
Authorizes Diplomat and its representatives to act as an agent to initiate/coordinate the insurance prior authorization process, coordinate and receive patient lab values, and coordinate injection training.

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# Specialty drug benefit designs

**Drug spend is typically mixed between pharmacy and medical benefits, resulting in pharmaceutical costs hidden in medical benefit**



## ■ NDC

- The National Drug Code is a unique 10-digit, 3-segment numeric identifier assigned to each medication listed under Section 510 of the US Federal Food, Drug, and Cosmetic Act
- The segments identify the labeler or vendor, product, and trade package
  - The first segment is 4 or 5 digits long and assigned by the Food and Drug Administration (FDA)
  - The second segment, the product code, is 3 or 4 digits long and identifies a specific strength, dosage form, and formulation
  - The third segment and identifies package forms and sizes



- HCFA form 1500
  - The official standard form used by physicians and other providers when submitting bills/claims for reimbursement to Medicare, Medicaid, and private insurers for health services
  - HCFA 1500 contains Pt demographics, diagnostic codes, CPT/HCPCS codes, diagnosis codes, units.

- HCPCS J-codes

- J Codes: permanent codes used to report injectable drugs that ordinarily cannot be self-administered; chemotherapy, immunosuppressive drugs and inhalation solutions as well as some orally administered drugs
- Example: J2323      Injection, natalizumab, 1 mg (administered as a 300-mg IV infusion once every 4 weeks over approximately 1 hour)

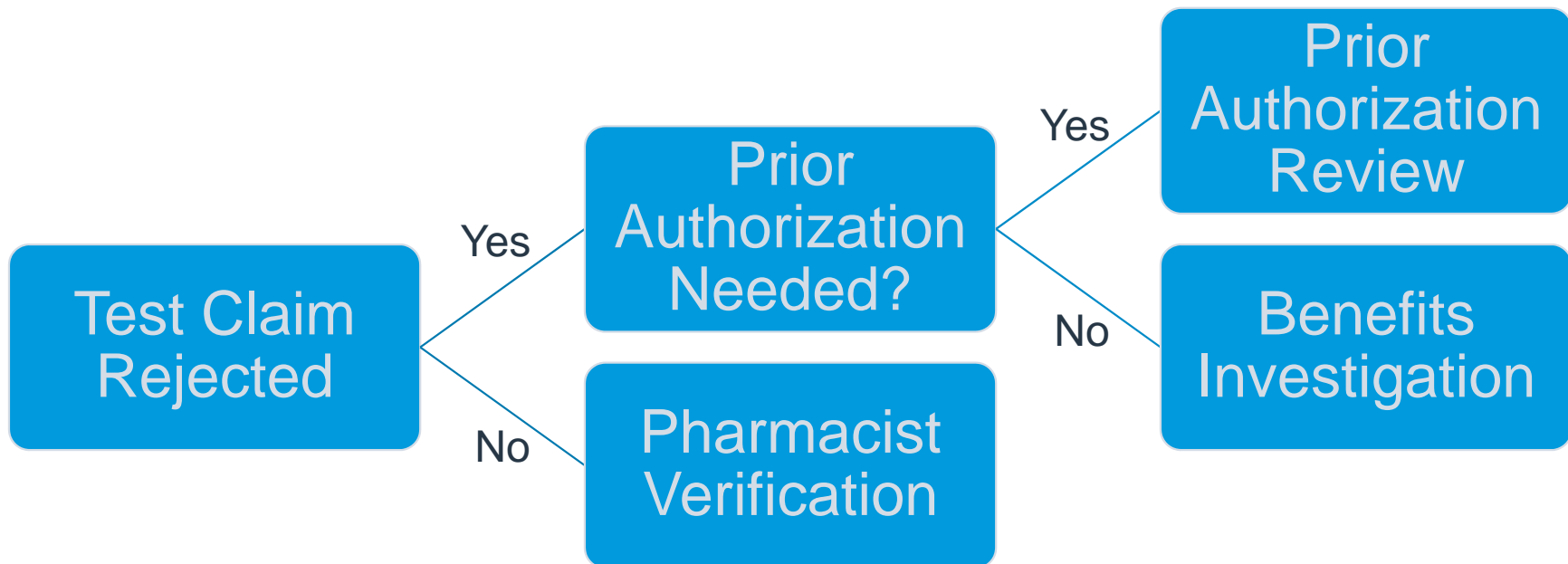
- Physician Buy & Bill
  - Purchase the drug
  - Manage the inventory the inventory
  - Administer the drug
  - Submit claims for reimbursement for both reimbursement for both the drug and professional services

# Key definitions

- White bagging
  - Drug is dispensed to the patient by a specialty pharmacy but drop-shipped directly to the physician office
- Brown bagging
  - Drug is dispensed to the patient by a specialty pharmacy and drop-shipped directly patient
  - patients to bring their drug to their medical appointment



# Test claim



# Medical vs. pharmacy benefit coverage

- **Medical**
  - Typically not self administered
  - Typically billed post service directly to health plan by provider via CMS1500 claim
  - Utilization management/step therapy not commonplace (but increasing)
- **Pharmacy**
  - Typically are self administered
  - Billed by the dispensing pharmacy via a real time adjudication
  - Subject to PBM/Payor rules - Utilization management/step therapy commonplace.

- Not adjudicated in real time
  - Limits drug utilization reviews
  - Appropriate dosing
  - Formulary controls
  - Difficult to assess appropriate costs
- Incorrect data can be submitted
- Preauthorization may be necessary/recommended

# Dispensing and Site of Care

- **Site of Care options can have a direct impact on costs**
  - **Physician's office (\$\$\$)**
  - **Hospital outpatient dept. (\$\$\$\$)**
  - **Freestanding infusion center/clinic (\$\$ - \$\$\$)**
  - **Worksite medical center (\$ - \$\$)**
  - **Home – mobile infusion therapy provider (\$ - \$\$)**
  - **Retail Clinic (\$ - \$\$)**



# Challenges of reimbursing through medical vs. pharmacy benefit

- Medical benefit reimbursements are difficult to track and manage costs
- PBMs often do not have access to medical reimbursement data on costs running through the medical plan
- Differences in drug classes and condition groupings and route of administration determines which benefit covers the drug
  - Pharmacy – Typically covers self-administered oral, injectable and inhaled
  - Medical – Typically covers injected or infused by doctor's office, hospital out patient center, free-standing infusion center or mobile infusion at home

# Examples of specialty medications billed pharmacy/medical benefit

- Ustekinumab (Stelara)
- Abatacept (Orencia)
- Golimumab (Simponi, Aria)

# Key tactics for managing specialty pharmacy & medical benefits

1. Therapeutic coverage coordination for pharmacy & medical benefits
2. Drug utilization strategies
3. Step therapy
4. Prior authorization for pharmacy benefit
5. Quantity limits
6. Site of care options
7. Prior authorization & drug utilization strategies for the medical benefit
8. Combining medical & pharmacy data
9. Case management
10. Practice & therapy guidelines



# Post CE Questions

1. Which of the following is not a common characteristic of specialty medications?
  - a. High cost
  - b. Treatment of complex, chronic, and/or rare conditions
  - c. Oral therapies only
  - d. Ongoing monitoring required for safety and/or efficacy
2. Which of the following information is not included in the enrollment form?
  - a. Patient demographics
  - b. Insurance information
  - c. Prescriber information
  - d. Patient social security number
3. Which of the following medications could be on either the pharmacy or medical benefit?
  - a. Ustekinumab (Stelara)
  - b. Abiraterone (Zytiga)
  - c. Abatacept (Orencia)
  - d. Both A & C are correct
4. A test claim is used to determine whether reimbursement is on the pharmacy or medical benefit.
  - a. True
  - b. False
5. Which of the following are key tactics for managing specialty pharmacy & medical benefits?
  - a. Therapeutic coverage coordination for pharmacy & medical benefits
  - b. Prior authorization & drug utilization strategies for the medical benefit
  - c. Site of care options
  - d. All of the above

**Thank you.**

Questions

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