

Development of Outpatient Pharmacy Services for Specialty Medications

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Learning Objectives for Pharmacists and Technicians

- Interpret what is considered a specialty medication.
- Investigate the barriers that delay initiation of therapy and how they can be overcome.
- Choose financial assistance options for patients on specialty medications.

Presenters have no conflicts of interest to disclose.



How familiar are you with what is considered a specialty medication and how it differs from a typical prescription medication?

A. Very familiar

B. Somewhat familiar

C. Not familiar



What is a specialty medication?

- No standard industry definition
- High-cost
- Treats rare or orphan diseases
- Complex disease management
- Injectable, infused, inhaled, or oral therapies
- Has unique storage or shipment requirements
- May be defined by payers as a specialty



	Specialty	Non-Specialty
Type of Prescriber	Specialists	Generalists
Costs to Patient	High	Lower
Pharmacy Access	Restricted to specialty pharmacies	Widely available in most pharmacies
Insurance Restrictions	Prior authorization or step therapy required	May not require prior authorization
Disease Management	Additional patient education, adherence, and support	Traditional dispensing activities



Specialty Market

- Majority of new drugs currently being evaluated by the FDA
- Specialty medications will represent 50% of all US drug expenditures by 2020.*
- Large specialty pharmacies capture most of the market



*Pharmaceutical Executive. 2015 Pharm Science Strategic Outlook—An Industry in Flux: 2014–2015 Market Trends.

<https://www.ledluxor.com/image/data/news/led-lighting-market-share.jpg>



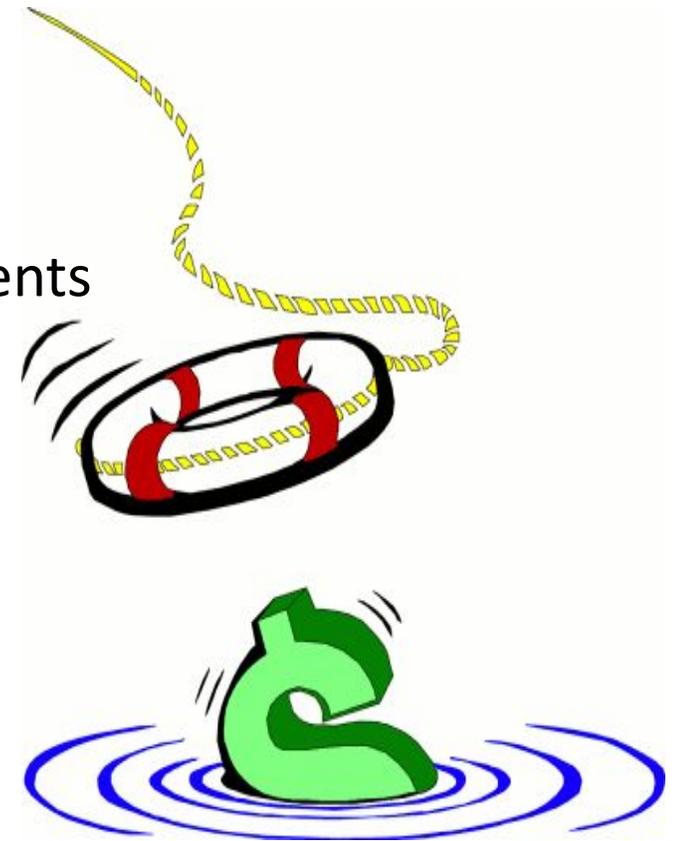
Loyola University Health System

- Regional, academic health system based in Chicago's western suburbs
 - Loyola University Medical Center (Maywood, IL)
 - Gottlieb Memorial Hospital (Melrose Park, IL)
 - MacNeal Hospital (Berwyn, IL)
- All clinicians are employees of the health system
- Shares the same Electronic Health Record
- 340B Entity



340B Drug Discount Program

- Requires drug manufacturers to provide significant discounts to eligible health care organizations and covered entities
 - High number of low-income Medicare and Medicaid patients
- Savings can be used to help fund clinic support programs
 - Pharmacy support programs
 - Additional patient financial assistance



Benefits of 340B Contract Pharmacy

- 340B savings come back to entity
- Single point-of-contact at pharmacy
- Access to limited distribution drugs
- Supplement with existing patient management programs that received accreditation



Downsides of 340B Contract Pharmacy

- Professional or administrative fee per claim
- Inability to control quality of service
- Reliance on third-party software to filter 340B-eligible claims
- Patient compliance



Specialty Medication Services (SMS) at Loyola

- Outsourced dispensing of specialty medications
 - Reduced upfront capital investment
 - Labor
 - Space
 - Technology
 - Drug inventory
 - Reduced risk
 - Restricted access to drugs by manufacturer
 - Patients locked to specific network pharmacy



Baseline Assessment



- Each clinic managed their own patients
- No standardized workflow in place
- Extended delays in initiation of therapy
- Unknown adherence rates
- No pharmacist involvement
 - Clinical appropriateness
 - Dosing verification
 - Drug-drug interactions
 - Medication or administration education

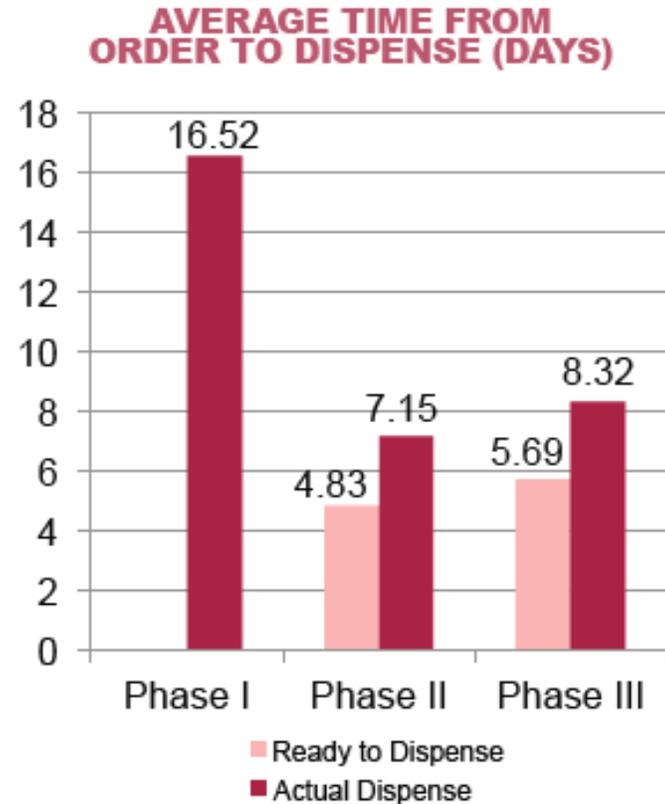


Initiation of Service

- 1 PharmD FTE managing oral oncolytic medications
- 26 oncologists
- Referral volume in oncology
 - 2015: ~33 referrals/month
 - 2016: ~37 referrals/month
 - 2017: ~33 referrals/month



SMS Impact on Oral Oncolytics



- Retrospective study
 - Phase I: Prior to SMS
 - Phase II: After SMS
 - Phase III: One year after SMS
- Decreased time to actual dispense by 57%
- Decreased time to ready to dispense by 71%



Expansion of Service

- May 2017
 - 2 PharmD FTE
 - 2 CPhT FTE
 - Rheumatology, Hepatology, Cardiology
- December 2017
 - 2 PharmD FTE
 - 1 CPhT FTE
 - Neurology, ID/HIV

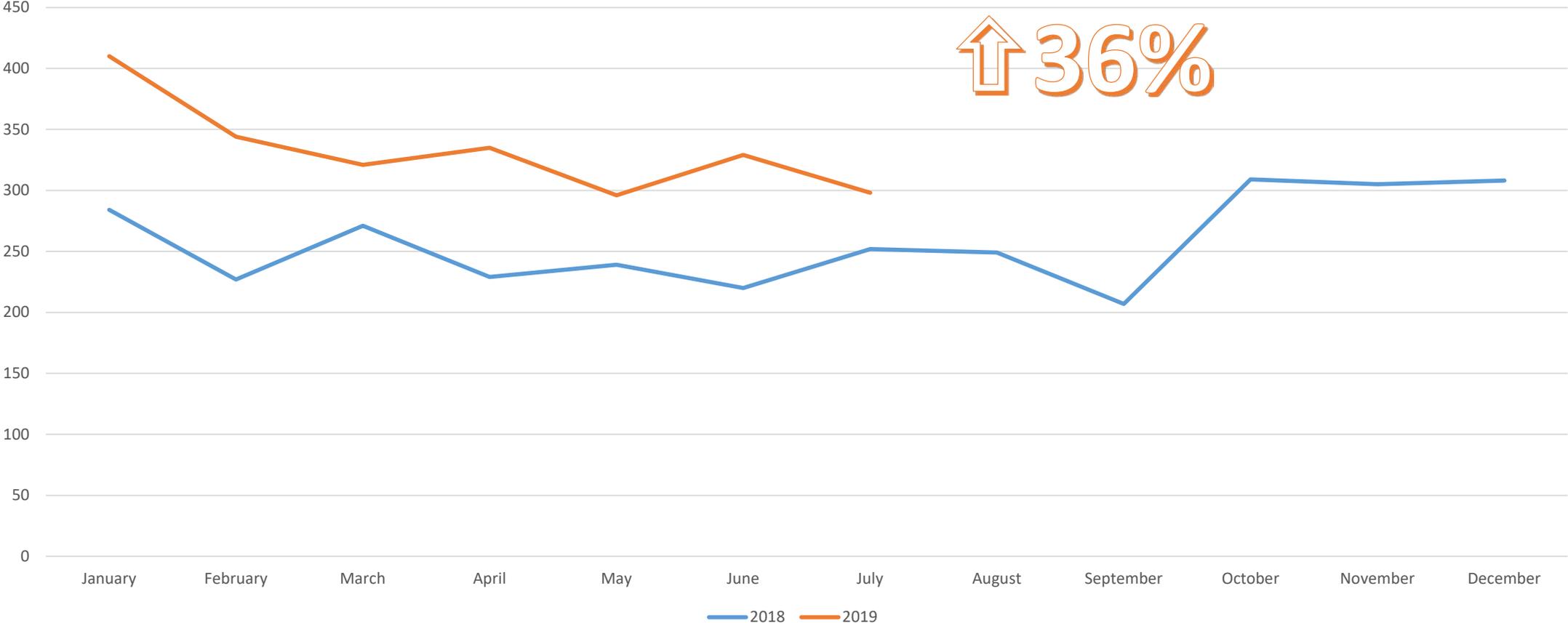


Discussion with Key Stakeholders

- Evaluation of volume for each specialty
- Understand the key players
 - Prescribers
 - Nurse or coordinator
 - Clinic manager
- Emphasize the benefits of change
- Anticipate pushback



Total Referral Volume (2018 vs 2019)

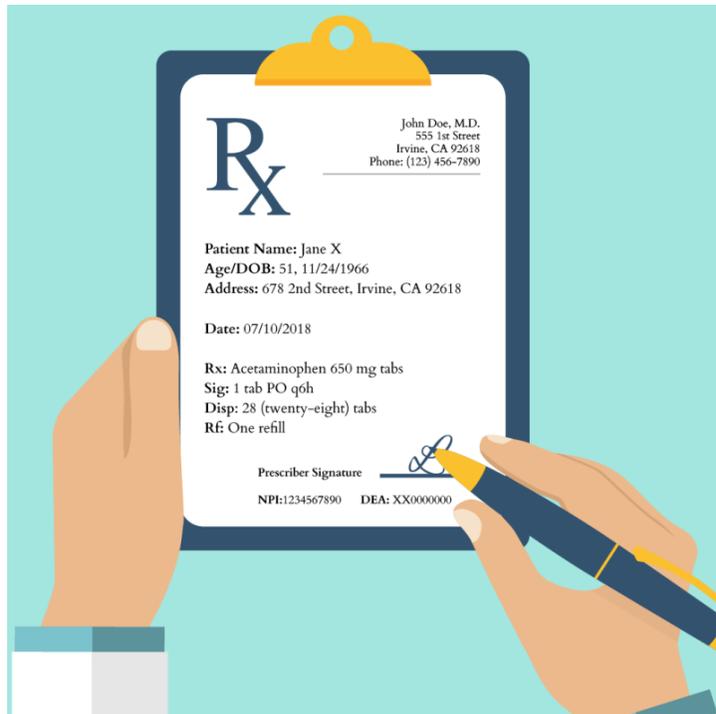


Average Monthly Referral Volume by Specialty

	2018	2019	% Change
CARDIOLOGY	13.3	10.3	-29%
HEPATOLOGY	24.4	23.3	-5%
INFECTIOUS DISEASE	10.1	6.9	-47%
NEUROLOGY	26.0	69.1	62%
ONCOLOGY	81.8	93.0	12%
RHEUMATOLOGY	92.8	101.9	9%
GASTROENTEROLOGY	16.7	12.7	-31%
TRANSPLANT	5.7	12.7	55%
PULMONOLOGY	3.0	14.4	79%



Specialty Areas Covered by SMS



- Oncology
- Rheumatology
- Hepatology
- Gastroenterology
- Transplant
- HIV / Infectious Disease
- Cardiology
- Multiple Sclerosis / Neurology
- Pulmonology



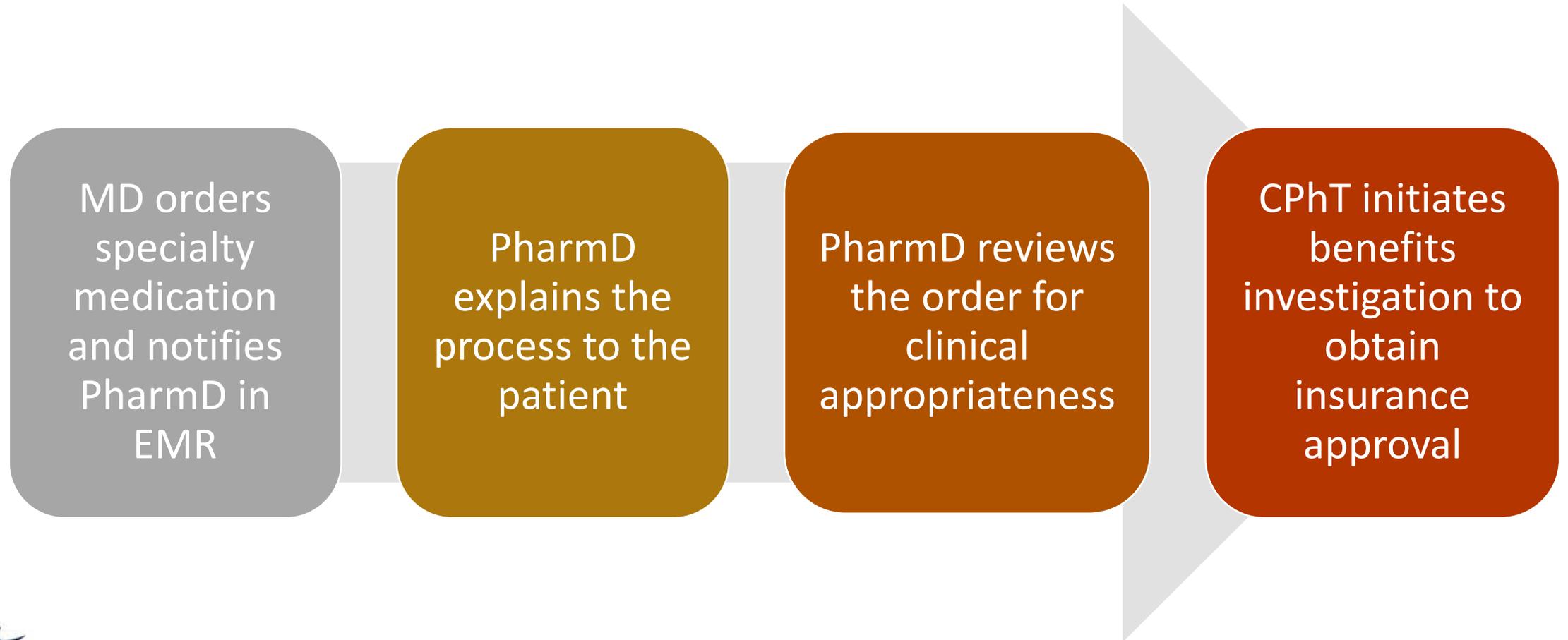
Learning Assessment Question

Which of the following characteristics are NOT commonly associated with specialty medications?

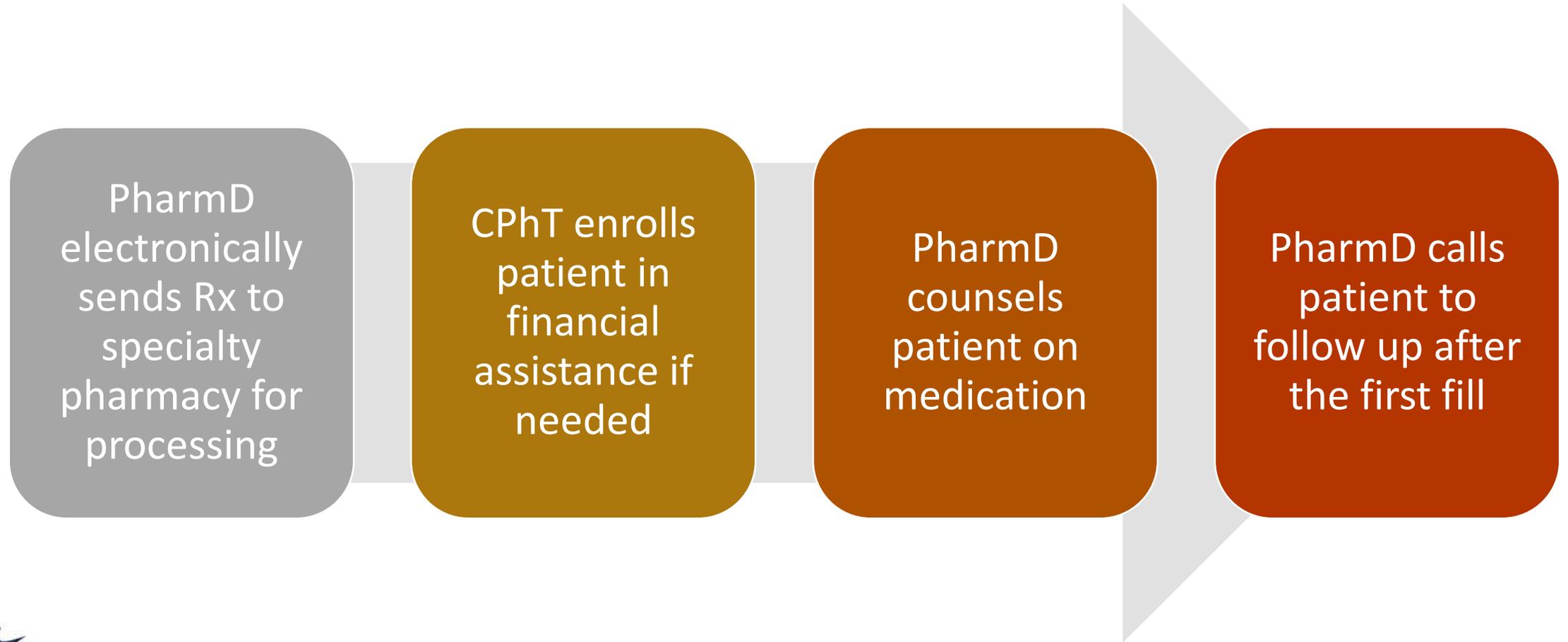
- A. High-cost
- B. Complex disease management
- C. Injectable, infused, inhaled, or oral therapies
- D. Does not require a prior authorization



Specialty Medication Services (SMS) Workflow



Workflow (cont.)



Discussion Question

What are some barriers that delay initiation of therapy with a specialty medication?



What is the Added Benefit of SMS Involvement?



- Experience in ambulatory and retail setting
 - Board certification
 - Knowledge of insurance navigation
- Efficient communication
 - Staff access to EMR
 - Pharmacists work directly with providers
 - SMS coordinates and informs patient
- Clean prescriptions to contract pharmacies
 - Prior authorization approved
 - Financial assistance obtained



Patient Case

QE is a 29 year old female prescribed fingolimod to treat multiple sclerosis. She was previously treated with glatiramer and teriflunomide.

No significant drug-drug interactions were found with the current list of medications.

The patient is insured through Molina Medicaid and the initial prior authorization was denied.



Patient Case (cont.)

- Fingolimod baseline requirements:
 - CBC, CMP, Varicella Zoster Virus Antibody (VZV), pregnancy test
 - Completed after initial MD visit, except pregnancy test
 - Eye exam (macular edema screening)
 - ECG
 - First dose observation (FDO) appointment



There are several potential barriers for this patient to start therapy. Which of the following is NOT a barrier that has been identified?

- A. Outstanding labs
- B. Insurance coverage
- C. Drug-drug interaction
- D. Eye exam screening



Return to Patient Case - QE

- Eye exam completed
- PharmD notified clinic to schedule testing
- SMS notified drug manufacturer of new start
- Prior authorization resubmitted and approved
- FDO completed and prescription was sent to pharmacy, copay \$0
- PharmD counseled and provided pharmacy information to patient



Barriers to Start for Patient QE

- Patient going for eye exam
- SMS obtaining eye exam records
- Patient unsure whether she wanted to start new medication
- Waiting for available FDO date

Time to start for QE = 3 months



Cost Issues for Specialty Medications

- Prior authorization denials
 - Non-formulary or incomplete step therapy
 - Off-label use
- High copays
 - Medicare coverage gap
 - Generic or biosimilar drugs may not be affordable
- Assistance is based off of financial need
 - If household income is high, options are limited



Financial Assistance Options

Manufacturer Copay Cards

- Free trial cards for new patients
- Reduced monthly copay for commercially insured patients

Foundation or Charity Assistance

- Based on diagnosis and Federal Poverty Level
- Limited funds
- Medication must be covered by insurance



Financial Assistance Options (cont.)

Manufacturer Patient Assistance Program

- Insurance denial, or lack of foundation assistance
- Based Federal Poverty Level

Institution Assistance Fund

- Used as a last resort for patients that do not qualify for any other type of assistance.
- Funded by 340B savings



Resources for Finding Assistance

- Pharmaceutical companies website
 - Copay card enrollment
 - Patient Assistance Program (PAP) enrollment application
- NeedyMeds (www.needymeds.org)
 - Non-profit information site with links for assistance based on drug



Resources for Finding Assistance (cont.)

- Fund Finder (www.fundfinder.panfoundation.org)
 - Patient Access Network (PAN) Foundation created free site
 - Tracks several charitable foundations to determine what is available
- Good Rx (www.goodrx.com)
 - Free site for discount coupons
 - May be an option if coverage is denied or deductible is high



Patient Case

RA is a 76 yo M diagnosed with urothelial carcinoma with FGFR mutation. His oncologist prescribed erdafitinib. The prior authorization was approved, however the patients copay was over \$2000 for a one month supply.

Foundations are currently closed for assistance. An application was submitted to the patient assistance program (PAP) but it was denied since the household income was over the programs limit.

What is the next step to take?



Patient Case (cont.)

We contacted the PAP and were able to submit an appeal. The patient had to draft a letter showing expenses and how income was inflated on the tax statement due to a one time withdrawal.

The patient paid the first month to get started since the appeal review took several weeks.

The patient was finally approved and will be able to receive free drug through the end of the calendar year.



What
questions do
you have?

