



Specialty Pharmacy

Nicole Kloeppe, Pharm.D.
OptumRx High Touch Specialty Pharmacist



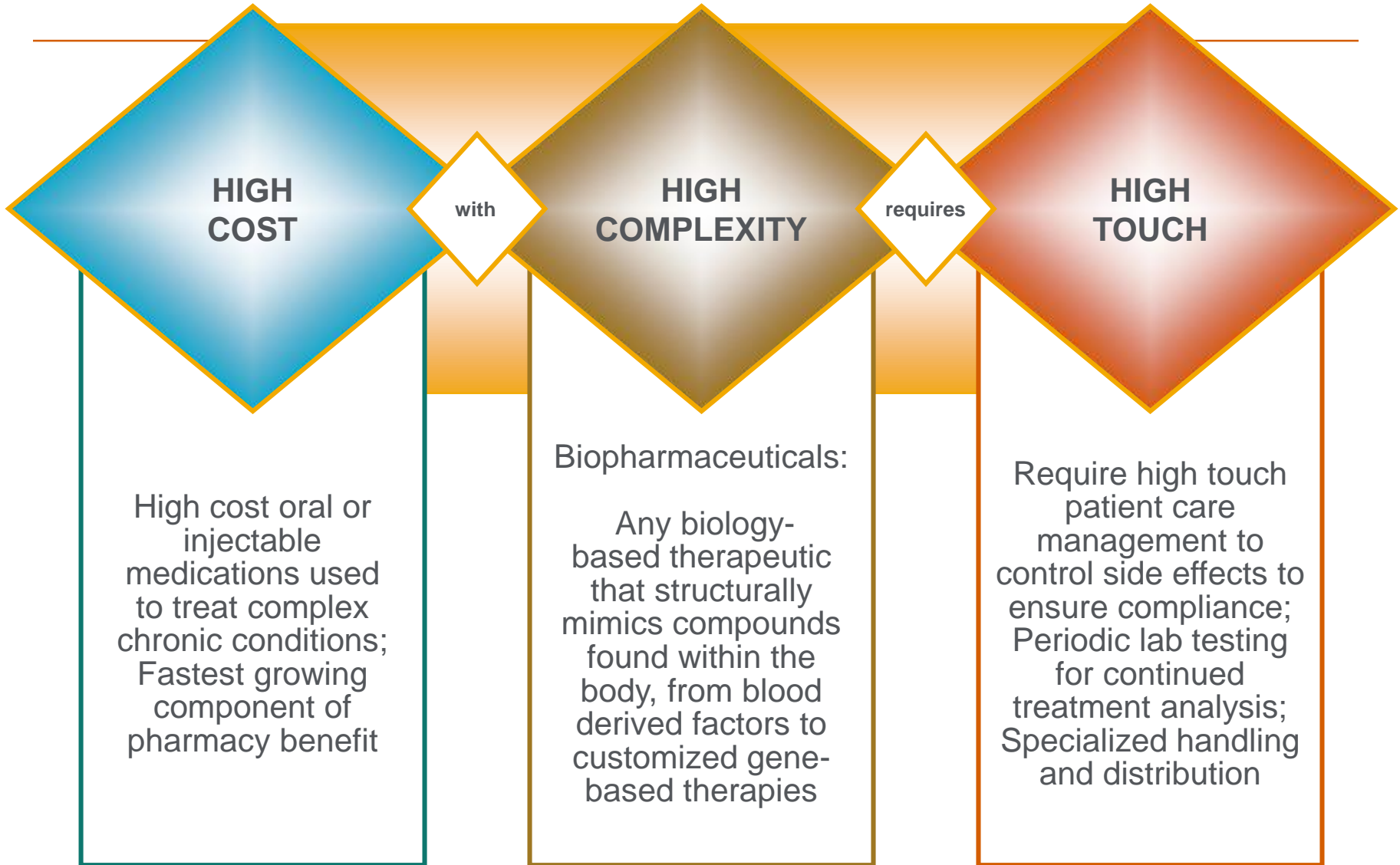
Presentation overview

- Specialty 101
- Clinical Management Program
- Future of Specialty Pharmacy



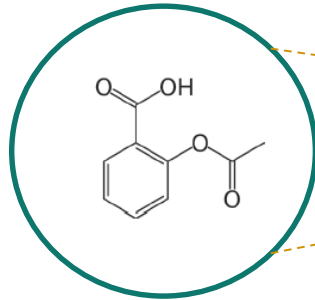
Specialty 101

What are Specialty Drugs?

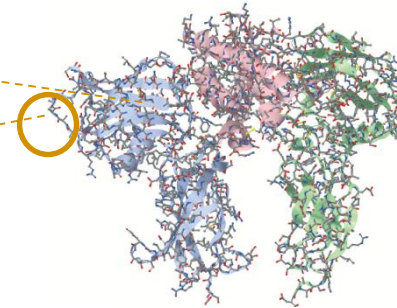


Biologic Medications

What makes biologics different?



example: aspirin¹



TRADITIONAL MEDICATIONS

These are your typical brand and generic medications.

Simple structure

Easy to reproduce and replicate with one patent

FDA approval requires ~50 simple tests²

Many generics available

Average 30-day cost: ~\$80

BIOLOGIC MEDICATIONS

Many specialty medications are considered “biologics”.

Extremely complex structure

Made in living cells = identical copies impossible with hundreds of patents

FDA approval requires ~250 complex tests²

Generics, or “biosimilars,” not yet available

Average 30-day cost: >\$2000

1. P&T. Biosimilars Part 1: Proposed Regulatory Criteria for FDA Approval. May 2013.

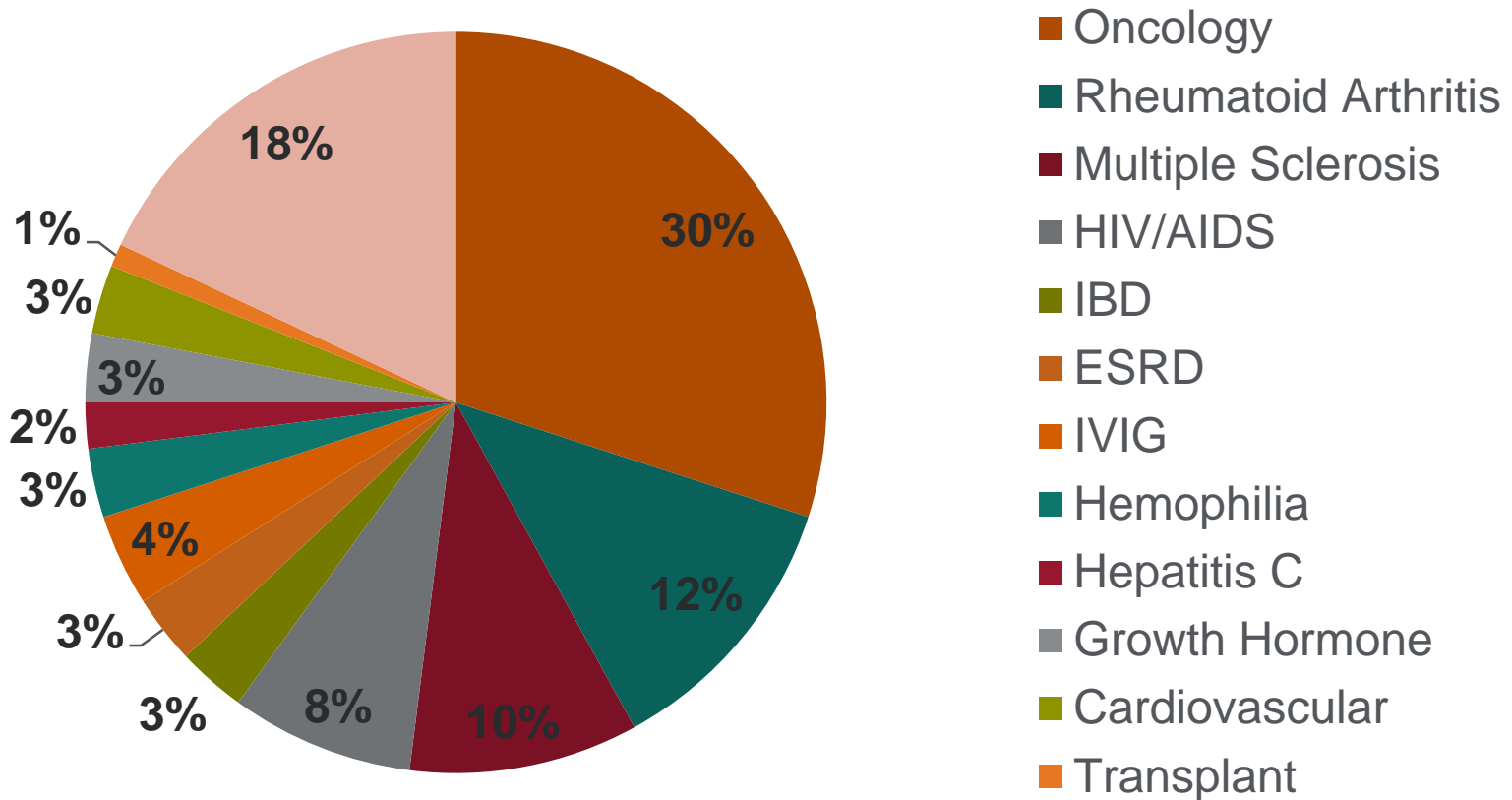
2. Buildingciologics.com. Manufacturing Matters with Biological Medicines: How Are Biological Medicines Different from Other Medications? 2013.

Specialty Pharmacy Considerations

- Complex conditions
- Distribution limitations
- Administration considerations (e.g. home injectable/infusions, MD office administration)
- Require close supervision and monitoring to improve compliance and reduce waste
- Potential for significant waste due to high cost

Specialty Pharmacy Considerations: Complex Conditions

Share of specialty drug spending by disease state
for UnitedHealthcare fully insured commercial
plans, 2012



Specialty Pharmacy Considerations: Distribution

- OptumRx Mail order shipping procedures
- Storage requirements
- FDA and Manufacturer requirements
 - Limited distribution list
 - Manufacturer supplies product to contracted pharmacies only
 - Reporting requirements
 - Risk Evaluation and Mitigations Strategies (REMS)
 - Serial numbers for product tracking
 - Post-marketing studies

Shipping and Delivery



Medication Delivery
OptumRx Specialty Pharmacy will ship medication(s) with the accompanying materials



Tuesday through Friday
Saturday delivery is available if needed

Refrigerated Medications

1 business day

Non-refrigerated Medications

1-3 business days

Can ship to alternative addresses

Cannot deliver to P.O. Boxes

Signatures are required for over a certain dollar amount and/or doctor office deliveries

Free Supplies and Additional Information Included



- Welcome Letter
- Specialty Pharmacy Program Brochure
- Clinical Management Program Brochure
- Condition-Specific Information
- Refill Magnet



Specialty Pharmacy Considerations: Administration

- Injectable medication
 - Route of administration
 - Ancillary supplies
- Infusion therapy
 - Home use
 - Physician office administration
 - Ancillary supplies
- Oral medication
- Inhalable medication

Better Decisions are Critical for Complex Conditions

Medical Treatment

Knee Replacement

• \$50k

Coronary Bypass Surgery

• \$100k

Transplant

• \$250k+

One Time Expense

Pharmacy Treatment

Multiple Sclerosis

• \$50k

Pulmonary Hypertension

• \$100k

Hemophilia

• \$250k+

Annual Expense

To manage cost, everyone should be expected to make **Better Decisions.**

Progression of Treatment Options in Hepatitis C

TIMELINE	MEDICATIONS	TOTAL COST OF THERAPY	CURE RATE	
2001-2011	Dual therapy – <ul style="list-style-type: none"> • Peg-interferon (injection) • ribavirin (oral) 	\$20-40k	44%	
2011-2013	Incivek or Victrelis Added to dual therapy	\$50-70k	72%	
2013 (Q4)	NEW! Sovaldi or Olysio Replaces Incivek + Victrelis Added to dual therapy	\$108-168k	80-100%	Most successful treatment to date

Total cost per therapy depends on length of therapy and regimen.

Pharmacy Benefit vs Medical Benefit

1. How is the drug administered?
2. Which benefit supports better care?
3. What is the total cost impact?

Pharmacy Benefit

- Self-injected by member at home
- Distributed by retail, mail or specialty pharmacy

Medical Benefit

- Administration/handling by physician or nurse
- Careful physician oversight and support needed
- Faster access and less disruptive to members/physicians



Clinical Management Program

A holistic care management approach

TOTAL CARE COORDINATION

Personal Care Team

- Dedicated to specific conditions
- Direct access to clinicians
- On-going support
- Scheduled appointments
- Comprehensive assessments

Interventions

- Multi-disciplinary Collaboration
 - Non-Compliance
 - Adjustments in Therapy or Dose
- Support Program Referrals
- Side effect Management

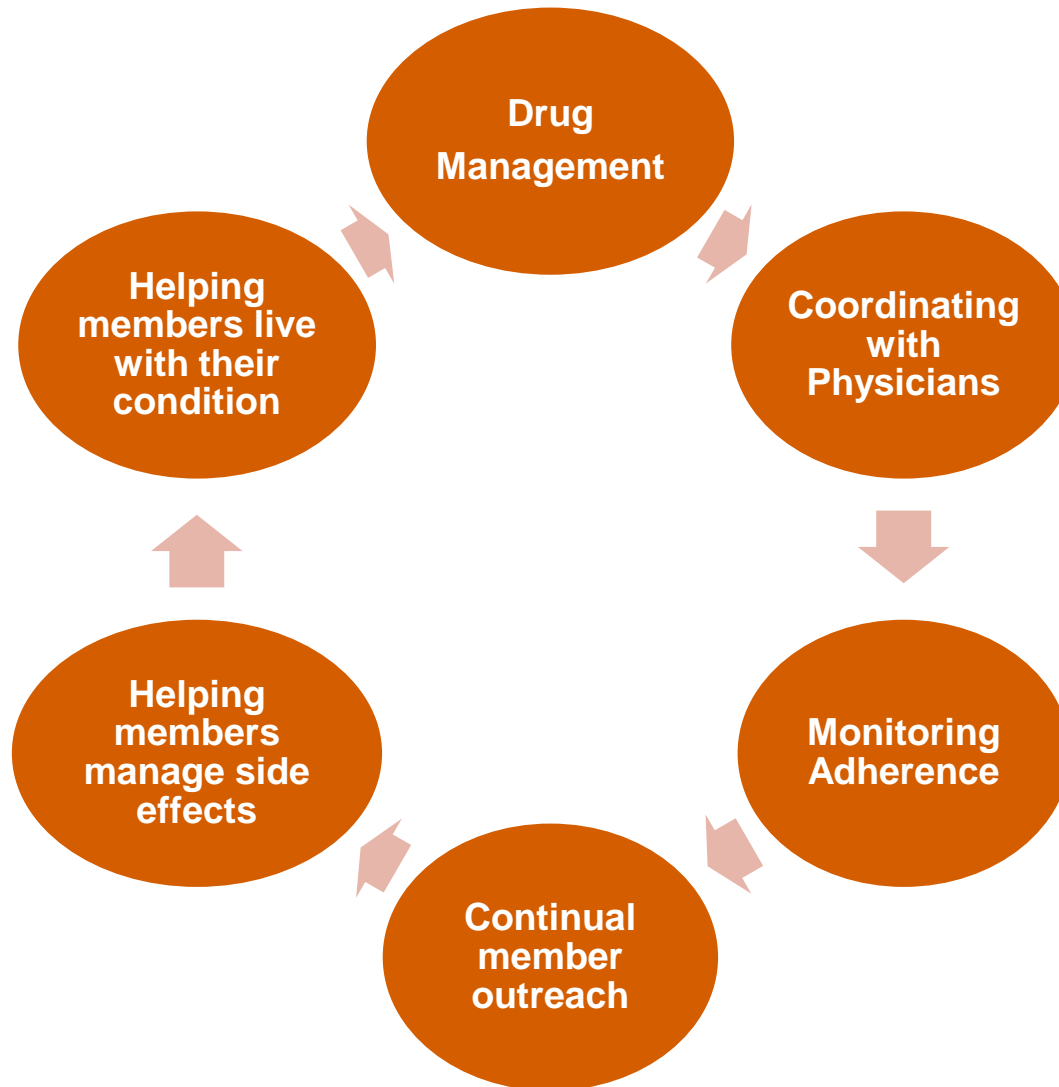
Member-Specific Care Plan

- Education Resources
 - Care Plan Topics
 - Booklets
 - Pamphlets
 - Internet resources

Financial Assistance

- Assistance Program Referrals
 - Support for costs
- Payment Plans
 - Aid with managing costs

Complete Care Management



Complete Care Management

Drug Management

- Review utilization and distribution so members get the right drug at the right price at the right time
- Reduce waste
- Financial assistance

Complete Care Management

Coordinating with Physicians

- Communicate issues related to patient's side effects
- Provide care plans from clinical management program
- Pharmacists and nurses have a one-on-one relationships with patients, and are subsequently better prepared to act as a patient advocate
- Communicate with physicians on compliance with REMS and manufacturer requirements

Complete Care Management

Monitoring Adherence

- Screen for adherence during refills
- Check for lab tests
- Review side effects and barriers to adherence
- Assess for complications that may prohibit members from managing their condition

Complete Care Management

Continual Member Outreach

- Support patients with a phone call every month to schedule deliveries
- Assist patient adhere to treatment and helps prevent setbacks
- Motivational Interviewing for continued adherence
- Scheduled Clinical Management Program appointments

Complete Care Management

Helping members manage side effects

- Referrals to other services
 - Optum Behavioral Health Services
 - Home nursing
- We are positioned to quickly contact providers to better support the member and help manage side effects

Complete Care Management

Helping members live with their condition

- Patients receive on-going phone calls from a pharmacist or nurse to discuss test results and changes in condition
- Provided a care plan after a Clinical Management Program consult
- Monthly education about their condition, medications, and managing side effects

Clinical Management Program (CMP)



ENROLLMENT

Promoted to eligible member during first call as well as subsequent refills, if they have not already enrolled.

DEDICATED CMP CALL CENTER

Comprised of:

- Customer Service Advocates –
 - Schedules appointments
 - Confirms medication + diagnosis
 - Answers questions about program
- Pharmacists and Nurses –
 - Provides individualized member consultations

PROGRAM OVERVIEW

Designated nurse or pharmacist **contacts the member on a regular schedule** based on their needs –

- Are you new to this medication?
- Are they having trouble taking their medication?
- Do they need help managing their side effects?

Concierge Services

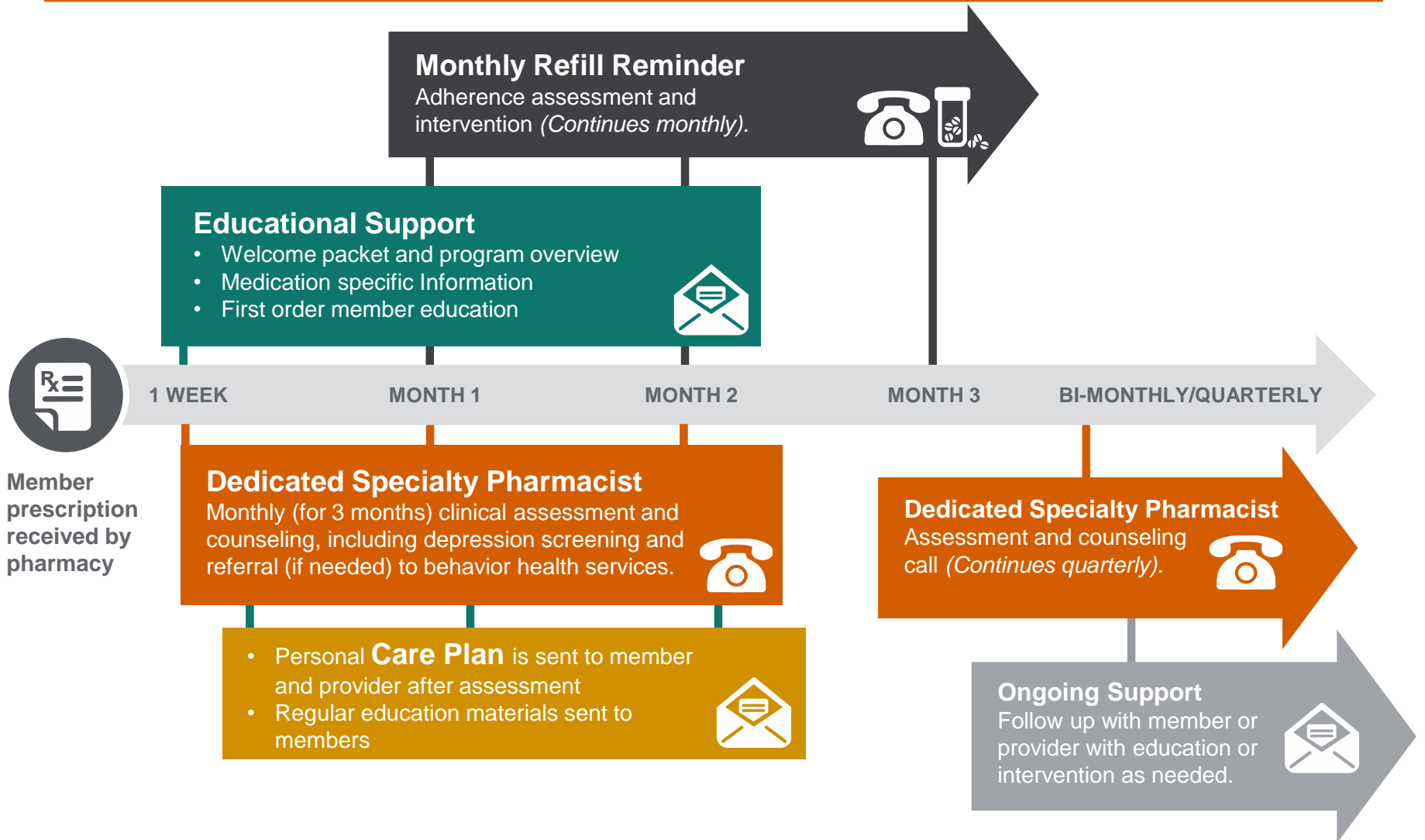
- Provider outreach
- Financial resources
- 24/7 pharmacist support

Programs cover > 95% of Specialty Claimants

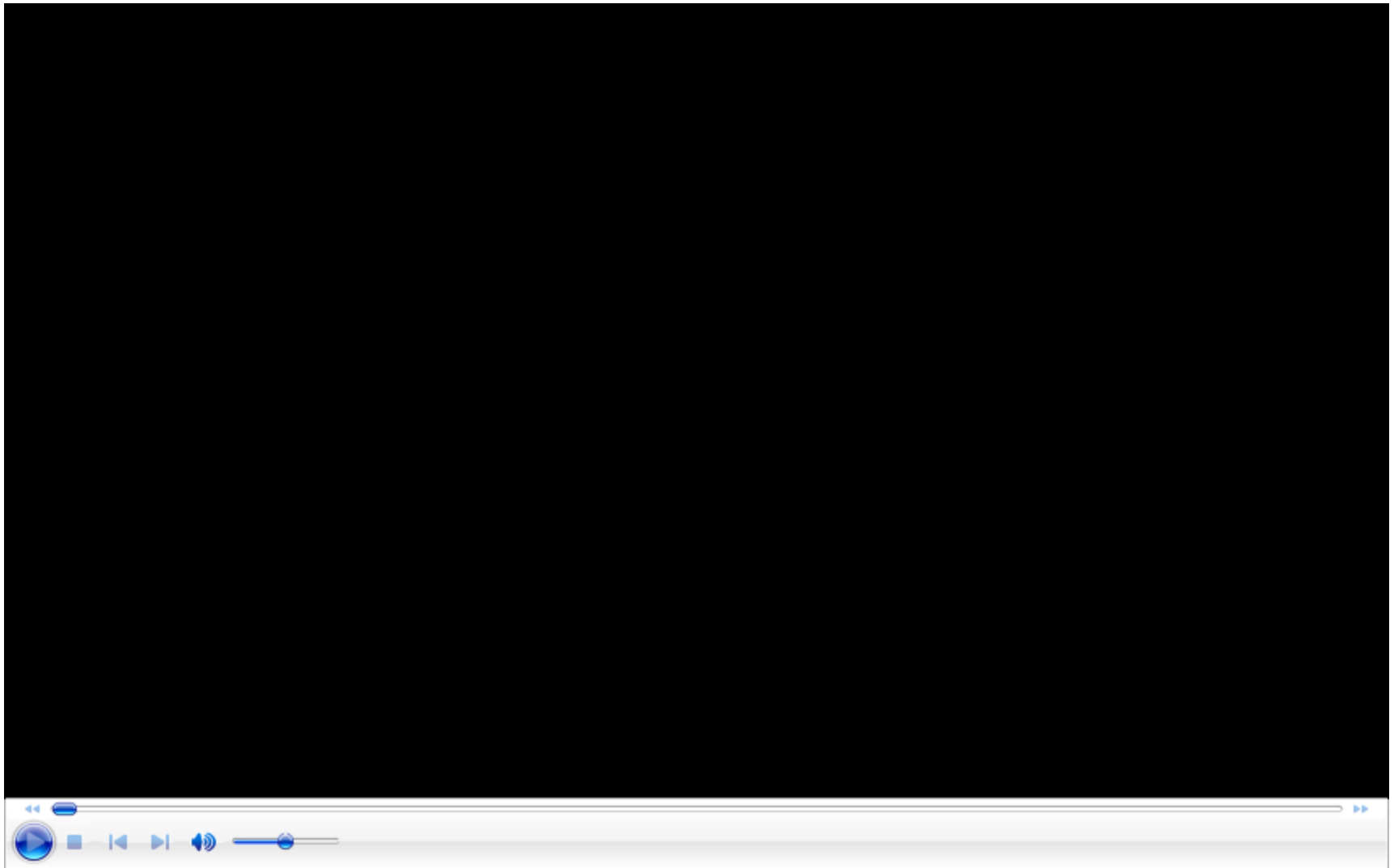
- Crohn's Disease
- Hemophilia
- Hepatitis C
- HIV/AIDS
- Inflammatory Rheumatic Conditions
 - Ankylosing Spondylitis
 - Juvenile Rheumatoid Arthritis
 - Psoriatic Arthritis
 - Rheumatoid Arthritis
- Multiple Sclerosis
- Oncology
- Psoriasis
- Pulmonary Arterial Hypertension
- Transplant

Specialty Pharmacy Program

Proactive Monitoring and Support



OptumRx Storytellers – meet Ginny



High Touch Pharmacy

- FDA Risk Evaluation and Mitigation Strategy (REMS) in place with required training, certifications, or other requirements
 - Patient Consultations
 - Detailed reporting requirements
 - Drug Utilization Review (DUR) with required interventions
- Manufacturer safety requirements
- Hemophilia Clinical Management
- High level of patient and provider interaction

Let's Take a Walk with John

We're providing oversight and care every step of the way in the most cost effective manner.

JOHN'S
EXPERIENCE
WITH
OPTUMRx
SPECIALTY
PHARMACY

- John's specialty pharmacist **regularly assesses John's needs:**
 - Supplies
 - Factor Dose
 - Upcoming doctor or dentist visits
- We also make sure John has **the right amount of factor** on-hand and **adjust how much is dispensed** to align with his dose and limit waste.

- John is **connected with a nearby Hemophilia Treatment Center (HTC)** which provides **comprehensive care** on all aspects of John's treatment including connecting John to a summer camp for kids with hemophilia.
- John's specialty pharmacist continues with **monthly check-in calls** with John's parents.

- Specialty pharmacy **monitors John's medication inventory**, checks his **weight for dosing**, and avoids **over-dispensing**. They even provide information for at home care when bumps and bruises occur.
- We connect John and his family with support services so they can **self-manage his symptoms** and are **less likely to go to a hospital** which helps to manage costs.

VS.

Proactive
Treatments

Continuous
Care

Hospital
Avoidance

JOHN'S
EXPERIENCE
WITHOUT A
SPECIALTY
PHARMACY

- Without our Specialty Pharmacy Program, there may be **no comprehensive assessment or oversight** of John's needs.

- John and his parents may **not be connected** to the right disease specialists to provide hemophilia focused care and **costs may be higher**.

- John's parents may be missing out on **preventive or self management measures** and may end up going to the hospital to control his bleeds.

Specialty Pharmacy Goals and Objectives

EMPOWER

Through education and support, enabling self-management of the medication regimen and any symptoms that may be present

MAXIMIZE

Therapeutic outcomes by promoting medication adherence and persistence and reducing the risk of side effects

ENHANCE

Quality of life

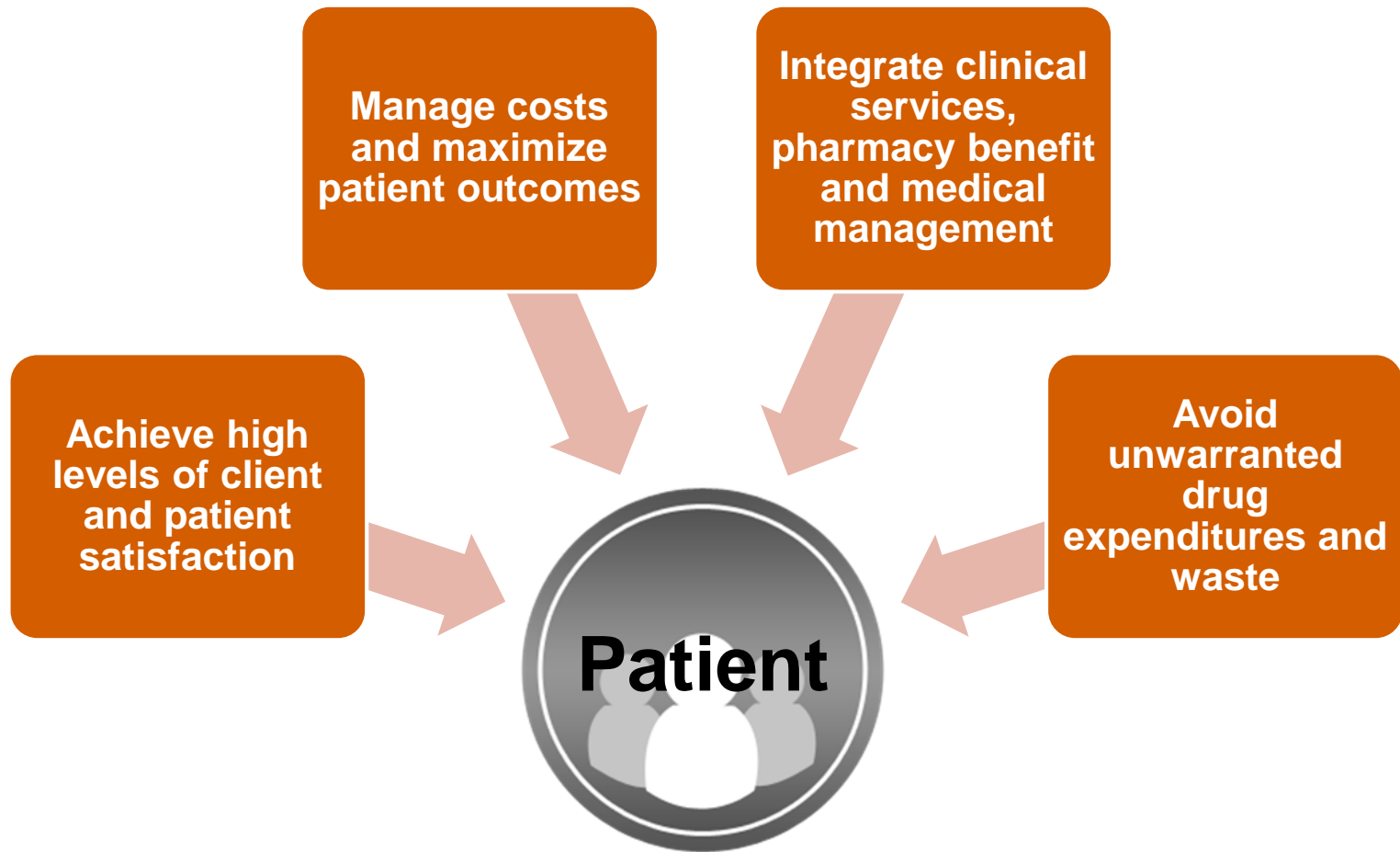
INCREASE

Knowledge of a patient's medical condition, treatment options, and overall management of their health

PROMOTE

Multi-disciplinary practice and interagency collaboration to achieve continuity of care

Specialty Care Management Philosophy

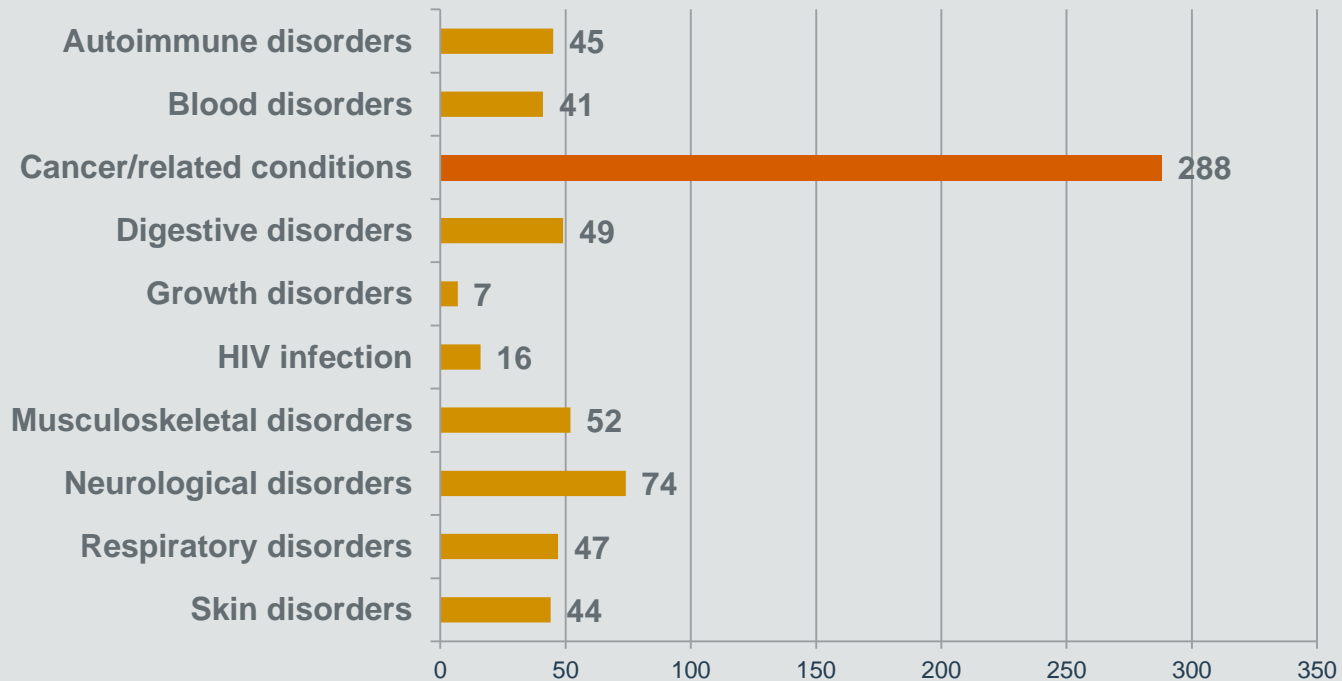




Future of Specialty Pharmacy

Specialty Drugs in Development

50% of drugs in the pipeline are specialty drugs. Of these, one-third are indicated for treating cancer.



Pipeline source: PHRMA 2013 Report – Innovation in the Biopharmaceutical Pipeline: A Multidimensional View. Jan. 2013.

The future of Specialty Pharmacy

- Specialty Pharmacy Practice
 - Specialty certification through Specialty Pharmacy Certification Board (SPCB)
 - Opportunities to specialize in specific disease states
 - Impact on other models of pharmacy practice
 - Traditional retail, home infusion, MD office infusion, hospital use
- Cost containment
 - Increased utilization of Specialty Pharmacy
- Biosimilars
 - Patient Protection and Affordable Care Act of 2010 (PPACA)



Thank You