Specialty Pharmacy 101
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Manager, Diplomat Education & Training and Residency Program Coordinator

- Target audience: Pharmacists & technicians
- ACPE#: 0202-0000-17-035-L04-P/T
- Activity type: Knowledge-based

Learning Objectives
1. Identify key characteristics that indicate a medication requires specialty management
2. List common diseases treated with specialty pharmaceuticals
3. Discuss the services offered by specialty pharmacies that are more complex than those offered as part of the standard of care at community pharmacies

Different Areas of Pharmacy Practice
- Academia
- Ambulatory Care
- Compounding
- Consulting
- Governmental
- Hospital
- Long-term Care
- Nuclear
- Otorhology
- Research
- Retail
- Specialty Pharmacy

How familiar are you with the term “specialty pharmacy”?

- Very familiar: 500494
- Somewhat familiar: 500495
- Not at all familiar: 500496
- Not applicable: 500497
**Definition**

**Specialty Pharmacy:**
Defined by the National Association of Chain Drug Stores (NACDS) as “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.”

**Definition**

**National Association of Specialty Pharmacy (NASP)**
- A state-licensed pharmacy that solely or largely provides only medications for people with serious health conditions requiring complex therapies.
- Should be accredited by independent third parties to ensure consistent quality of care.
- The specialty pharmacy’s patient-centric model is designed to provide a comprehensive and coordinated model of care for patients with chronic illnesses and complex medical conditions, achieve superior clinical and economic outcomes, and expedite patient access to care.

**Accreditation**

- Accreditation Commission for Health Care (ACHC)
- Center for Pharmacy Practice Accreditation (CPPA)
- The Joint Commission
- URAC

**Accreditation**

- Requirement for many networks provides a competitive advantage.
- Requires evaluation of current processes.
- Identifies areas for improvement.
- Helps ensure compliance with internal policies.
- Provides a stamp of approval.

- Time-consuming.
- Extensive documentation and reporting required.
- Associated cost.
- Need to figure out which is the best fit for your organization based on your needs and the anticipated return on investment.

**Types of Specialty Pharmacies**

- Chain-based
- Hospital systems
- Independents
- Pharmacy benefit manager-owned (PBM)
- Plan-owned
- Others

**Traditional vs. Specialty**

<table>
<thead>
<tr>
<th>Traditional</th>
<th>Specialty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration: Oral, topical</td>
<td>Administration: Oral, injectable, infused</td>
</tr>
<tr>
<td>Some education regarding administration and medication storage</td>
<td>Robust counseling regarding administration and medication storage</td>
</tr>
<tr>
<td>Counseling occurs at baseline and as needed throughout therapy</td>
<td>High-touch and frequent counseling sessions supported by adherence and disease-specific surveys</td>
</tr>
</tbody>
</table>
Definition

Specialty Pharmaceuticals

May be defined as “high-cost injectable, infused, oral, or inhaled drugs that generally require close supervision and monitoring of the patient’s drug therapy.”

High-Cost
High-Complexity
High-Touch

Specialty Designation

To be considered a “specialty” pharmaceutical, a medication may have some or all of the following characteristics:

- Treatment of complex, chronic, and/or rare conditions
- High cost, often exceeding $10,000, with some costing more than $100,000 annually
- Availability through exclusive, restricted or limited distribution
- Special storage, handling
- Ongoing monitoring for safety and/or efficacy
- Risk Evaluation and Mitigation Strategy (REMS) requirements

To be considered a “specialty” pharmaceutical, a medication may have some or all of the following characteristics:


All specialty pharmaceuticals are able to be dispensed from any pharmacy?

True
500494
False
500495
500496
500497

Drug Development Trends

- New drug approval totals were down in 2016, compared to 2015.
  - 22 novel new drug approvals in 2016
  - 45 novel new drug approvals in 2015
  - 2015: highest yearly total since 1996
  - 28 new drug approvals per year on average from 2006 to 2014

- Additionally in 2016, there were approximately 17 expanded indications and new formulations for previously approved specialty drugs.

- Oral oncology and rare diseases have the most upcoming expected approvals in the next year.

* Ranked by 2016 per member per year spend.

Top 10 Specialty Drugs, 2016*

- Humira® Pen® (adalimumab)
- Enbrel® (etanercept)
- Tecfidera® (dimethyl fumarate)
- Copaxone® (glatiramer)
- Harvoni® (ledipasvir/sofosbuvir)
- Revlimid® (lenalidomide)
- Gilenya® (fingolimod)
- Truvada® (emtricitabine/tenofovir disoproxil fumarate)
- Humira® (adalimumab)
- Stelara® (ustekinumab)

*Based on sales per year per person

Distribution Channels

Open
Both specialty and retail pharmacies have access to a product.

Limited/Restricted
Manufacturer chooses a small network of pharmacies to handle a product.

Exclusive
A single specialty pharmacy is selected to dispense and provide specific services for a product.
Disease States Typically Managed by Specialty Pharmacies

Which of the following disease states is typically managed by a specialty pharmacy?

- COPD 500494
- Diabetes 500495
- Hepatitis C Virus 500496
- Hyperuricemia 500497

Top 10 Therapy Classes, 2015

- INFLAMMATORY CONDITIONS
  - Adalimumab, etanercept
  - GlaxoSmithKline, dexamethasone
  - AbbVie Inc., tocilizumab
  - Celgene Corp., lenalidomide
- MULTIPLE SCLEROSIS
  - Glatiramer acetate, dimethyl fumarate
  - Teva Pharmaceuticals, natalizumab
  - Biogen, teriflunomide
  - Sanofi, fingolimod
- CANCER
  - Imatinib, lenalidomide
  - Novartis, nilotinib
  - Merck & Co., pembrolizumab
  - Gilead Sciences, entecavir
- HEPATITIS C
  - Ledipasvir/sofosbuvir, sofosbuvir
  - Merck & Co., elacridar
  - Pfizer Inc., paritaprevir
- HUMAN IMMUNODEFICIENCY VIRUS
  - Efavirenz/emtricitabine/tenofovir, ritonavir
  - Gilead Sciences, adefovir
  - Abbott Laboratories, abacavir
- GROWTH DEFICIENCY
  - Somatropin
  - Pfizer Inc., rhGH
  - Genentech, rhGH
- PULMONARY HYPERTENSION
  - Tadalafil, macitentan
  - Actelion Pharmaceuticals, bosentan
  - Partners HealthCare, sildenafil
- CYSTIC FIBROSIS
  - Lumacaftor/ivacaftor, nintedanib
  - Vertex Pharmaceuticals, ivacaftor
  - Novartis, nintedanib
- SLEEP DISORDERS
  - Sodium oxybate, tasimelteon
  - Jazz Pharmaceuticals, adenosine A2a receptor agonist
  - Supernus Pharmaceuticals, brivaracetam
- HEMOPHILIA
  - Desmopressin, antihemophilic factor [recombinant]
  - Baxter International, recombinant factor VIIa

Specialty Pharmacy Services

- 24-HOUR ACCESS TO PHARMACISTS
- ADHERENCE MANAGEMENT
- BENEFITS INVESTIGATION
- COMMUNICATION AND FOLLOW-UP WITH THE PHYSICIAN
- ENROLLMENT IN PATIENT ASSISTANCE PROGRAMS
Specialty Pharmacy Operations

Specialty Pharmacy Interactions

Specialty Pharmacy Process

Prescription Intake

Enrollment forms
Contains significant level of detail
- Allergies
- Diagnosis code
- Insurance information
- Patient demographics
- Previous therapies
- Reasoning for therapy discontinuation

Example

Intake Process
Overcoming Access Barriers

Four major processes dedicated to assisting patients and prescribers in gaining access to needed therapies

- Benefits Investigation
- Prior Authorization
- Access
- Appeals
- Copay Assistance

Disease State–Specific Departments

Department consisting of patient care coordinators, order entry technicians, pharmacists and/or nurses focusing on the care of patients with a specific disease/illness.

**RESPONSIBLE FOR:**
- Copay collection
- Delivery coordination
- Refill reminders
- Adherence assessments
- Side-effect assessments

Care Management

- Adherence
- Adverse Effects
- Disease Status
- Dosing/Prescribing
- Education

**AT EVERY REFILL**

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Clinical Support

- Specially pharmacies may have pharmacists, nurses, and pharmacy technicians supporting patient clinical needs
- Available 24/7 to clients, patients, physicians, and other clients
- May perform both clinical assessments and interventions

Key Clinical Responsibilities

- Assessment of clinical data to determine safety
- Drug-drug interactions
- Drug-disease interactions
- Duplication therapy
- Appropriateness based on indications
- Dosing

- Verify clinical appropriateness
- Route of administration
- Strength/lable
- Frequency/duration of therapy
- Adverse effects

- Patient education/adherence strategies
- Information and education on medication adherence
- Half-life, duration of therapy
- Appropriate use based on indication
- Appropriate dosage

- Monitoring
- Adverse effects
- Therapy adherence
- Reinstitution of clinical support programs
- Identify adverse events
- Manage therapy resistance
- Adjust non-adherence

Patient Distribution
Many specialty pharmaceuticals require special storage and handling?

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Distribution

- Distribution center consisting of pharmacy technicians, pharmacists, inventory technicians, shipping technicians, and delivery drivers
- Prepares patient package(s) and ensures all required medications, educational materials, and supplies are included
- Ensures patient receives package on scheduled delivery day

Distribution Center

- Medication Delivery/Shipping
  - Freezer/refrigerator temperature and humidity are monitored and recorded daily
  - During business hours, the area is monitored by a licensed pharmacist and is locked and alarmed during nonbusiness hours
  - Stock is rotated and inspected for expiration dates

Specialty Packaging

Storage and Handling Considerations

- Auxiliary Supplies
- Billing Quantities
- Emergency Preparedness
- Original Packaging Requirements
- Product Sensitivities
Specialty Pharmacy Opportunities: Adherence

Patient Adherence

- Patient adherence should be a key focus area for specialty pharmacy providers
- Complex disease states + complex medications = challenges
- Many reasons for nonadherence
- 32 million Americans use ≥ three medications daily
- 75% of adults are nonadherent in one or more ways
- The economic impact of nonadherence is estimated to cost $100 billion annually

Factors Affecting Adherence

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<th>Interaction with health care system</th>
<th>Personal factors</th>
<th>Treatment factors</th>
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<td>Poor communication</td>
<td>Emotional state</td>
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Factors Affecting Adherence

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- Inadequate social support
- Regimen complexity
- Requirement for an alteration in behavior
- Cost
- Adverse events

Adherence Tools used in Specialty Pharmacy

- Compliance Packaging
- Prophylactic Starter Kits
- Technology
- Patient Training + Education
- Proactive Adherence Calls

Base Services
- Monthly adherence calls
- Side-effect management
- Patient education
- Prescriber outreach
- Nursing support
- Professional warm transfers

Enhanced Services
- Supports specific needs based on therapy regimen
- Addresses non-adherence issues
- Enhances patient education and communication
- Customizable and consistent with current adherence program
**Specialty Pharmacy Opportunities: Unique Pharmacist Roles**

**Manager, Education + Training**
- Overseeing internal and external training initiatives (e.g., annual, clinical, electives, orientation)
- Providing oversight to ASHP PGY-1 residency program as coordinator
- Acting as a preceptor for students on advanced pharmacy practice experiences

**Manager, Utilization Review + Outcomes Research**
- Managing a utilization review service for contracted payer groups
- Providing formulary strategy recommendations
- Working with industry on innovative, collaborative outcomes-based initiatives

**Manager, HIV/HCV Center of Excellence**
- Subject matter expert in hepatitis and HIV
- Managing a group of order-entry technicians
- Maintaining HCV clinical documents for specific managed care clients
- Responding to escalated patient care situations

**Senior Manager, Clinical Oncology**
- Developing and implementing oncology protocols
- Aligning clinical policies and procedures
- Clinical strategy, education, and cost-savings evaluation
- Providing support for oncology initiatives

**Additional Specialty Pharmacy Opportunities**
Future Pharmacist Opportunities

- Elective courses within college of pharmacy
- Pharmacy student clerkships [e.g., introductory/advanced pharmacy practice experientials]
- Shadowing/touring programs
- Summer internship programs
- Residency training with specialty focus

Residency Program

- Required Concentrated
  - Clinical Services
  - Community
  - Managed Care
  - Patient Care
  - Prior Authorization

- Required Longitudinal
  - Professional Development
  - Project Management
  - Staffing

- Electives
  - Advanced Community
  - Ambulatory Care
  - Clinical Education
  - Industry Relations
  - Oncology
  - Quality Management
  - Specialty infusion

Keeping Current with Specialty Pharmacy

- Associations
  - Academy of Managed Care Pharmacy (AMCP)
  - National Association of Specialty Pharmacy (NASP)

- Journals
  - Pharmacy Today
  - Specialty Pharmacy Journal
  - Specialty Pharmacy Times

- Reports/White Papers
  - Drug Trend Reports
  - EMCO Senior Annual Specialty Digest
  - URAC Specialty Pharmacy White Paper

- Pipeline Monitoring
  - External sources
  - Internal strategies

Summary

- Specialty practice requires a high-touch, patient-centric model along with close collaboration with multiple partners
- Patient monitoring parameters in specialty pharmacy include adherence, adverse events, disease symptoms, and improving quality of life
- Need to recognize common challenges associated with the practice of specialty pharmacy and identify solutions early to help ensure success

Assessment Questions

1. To be considered a specialty pharmaceutical, a medication may have which of the following characteristics:
   A. Treats acute, common conditions
   B. Low cost
   C. Infrequent monitoring throughout therapy
   D. Special storage, handling, and/or administration requirements
2. Which of the following are disease states typically managed by a specialty pharmacy?
   A. Cancer
   B. Inflammatory bowel disease
   C. Psoriasis
   D. All of the above

3. Which of the following specialty pharmacy services describes an individual assisting the patient and prescriber in determining what insurance coverage is available for a prescribed therapy?
   A. Appeal
   B. Benefits investigation
   C. Copay assistance
   D. Prior authorization

4. Specialty pharmacies may work on behalf of a patient and prescriber to obtain an approval on a required prior authorization.
   A. True
   B. False

Audience Questions?

Thank you!