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.
Disclosures

- 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”
“… 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

Steiber D, Erhardt DP. Specialty pharmacy in community pharmacy: The time is now – and how! November 2006.
“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**

<table>
<thead>
<tr>
<th>Treatment of complex, chronic, and/or rare conditions</th>
<th>High cost $$</th>
<th>Requires special storage and handling</th>
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<tbody>
<tr>
<td>Special administration: infusion, injectable, inhaled</td>
<td>Available through exclusive, restricted or limited distribution</td>
<td>Ongoing monitoring required for safety and/or efficacy</td>
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</tbody>
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Hagerman J, Freed S, Rice G. Specialty pharmacy: a unique and growing industry. Pharmacy Today [Internet]. 2013 Jul 01 [cited 2014 Jan 14].

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 intake
- Patient onboarding
- Benefits investigation/prior authorization
- Patient assistance qualification
- Pharmacist consultations & order verification
- Dispensing and shipping of the medication
- Monitoring, and refill management

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

- Electronic
- Faxed
- Verbal
- Written
Enrollment forms

- New or refill prescription
- Contains significant level of detail
  - Patient demographics
  - Injection training
  - Insurance information
  - Lab coordination
  - Medical assessment
  - Prescriber information
Drug spend is typically mixed between pharmacy and medical benefits, resulting in pharmaceutical costs hidden in medical benefit.
Key definitions

- **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.

http://www.drugs.com/ndc.html
Key definitions

- **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.
Key definitions

- **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)

http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html?redirect=/medhcpcsgeninfo/
Key definitions

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

http://www.drugchannels.net/2013/02/specialty-pharmacies-keep-gaining-on.html
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 to the patient
  - Patients to bring their drug to their medical appointment

http://www.drugchannels.net/2013/02/specialty-pharmacies-keep-gaining-on.html
Test claim

Test Claim Rejected

Prior Authorization Needed?

Pharmacist Verification

Prior Authorization Review

Benefits Investigation
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.
HCFA-1500

- 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
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