Specialty Drugs: The Challenges and Opportunities

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Learning Objectives

- Describe changes in the pharmacy marketplace which are contributing to the importance of the specialty pharmacy category
- Identify the top 5 specialty drug categories and the fastest growing specialty categories
- Discuss the challenges and benefits of specialty pharmacy distribution models for physician-administered drugs
- Review the current reimbursement structure for specialty drugs and discuss potential alternative reimbursement mechanisms
- Discuss the role of medication therapy management and other pharmacy cognitive services in the provision of specialty drugs

What is a specialty drug, and why is it special?

- MN Statute 256B.0625:
  Specialty pharmacy products are defined as those used by a small number of recipients or recipients with complex and chronic diseases that require expensive and challenging drug regimens. Examples of these conditions include, but are not limited to: multiple sclerosis, HIV/AIDS, transplantation, hepatitis C, growth hormone deficiency, Crohn’s Disease, rheumatoid arthritis, and certain forms of cancer. Specialty pharmaceutical products include injectable and infusion therapies, biotechnology drugs, antihemophilic factor products, high-cost therapies, and therapies that require complex care.
What makes a specialty drug special?

- High Cost
- Complicated Disease
- Complicated Regimen
- Complicated administration

You know it when you see it!

Topics for Discussion

- Specialty Drugs: increasing role in prescription drug marketplace
- Specialty Drug Reimbursement Structure
- Specialty Drugs in Clinic/Outpatient Settings
- Role of Pharmacist Services in Specialty Drug Management
Specialty drugs accounting for a higher portion of drug spending

Source: MHCP FFS claims data, all major programs

Traditional brand name drugs on the decline

Source: MHCP FFS claims data, all major programs
Are we losing the Middle Class (of drugs)?

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average $ per Rx</td>
<td>$68.64</td>
<td>$67.19</td>
</tr>
<tr>
<td>Average $ per Brand name Rx</td>
<td>$149.93</td>
<td>$255.96</td>
</tr>
<tr>
<td>Average $ per Generic Rx</td>
<td>$23.50</td>
<td>$25.28</td>
</tr>
<tr>
<td>Generic Utilization Rate</td>
<td>67.9%</td>
<td>86.4%</td>
</tr>
</tbody>
</table>

Specialty drug cost under the medical and pharmacy benefits is expected to exceed 50% of all drug costs by 2018.

Source: EMD Serono 2014 Specialty Drug Digest
Payer Challenges in the new world of specialty

- Traditional contracting strategies ineffective
- Lack of competition in many specialty disease states
- Limited manufacturer distribution for some specialty drugs
- Balancing cost sharing and patient access
- New high cost specialty drugs approved for higher prevalence diseases

Top specialty drug categories

<table>
<thead>
<tr>
<th>COMPONENTS OF TREND FOR THE TOP 10 SPECIALTY THERAPY CLASSES</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>20.0%</td>
<td>18.0%</td>
<td>15.0%</td>
<td>12.0%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>30.0%</td>
<td>28.0%</td>
<td>24.0%</td>
<td>21.0%</td>
</tr>
<tr>
<td>HIV</td>
<td>4.0%</td>
<td>3.5%</td>
<td>3.0%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>10.0%</td>
<td>9.0%</td>
<td>8.0%</td>
<td>7.0%</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>2.0%</td>
<td>1.5%</td>
<td>1.0%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Mental Health</td>
<td>1.0%</td>
<td>0.8%</td>
<td>0.6%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Blood Disorders</td>
<td>0.5%</td>
<td>0.4%</td>
<td>0.3%</td>
<td>0.2%</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Other</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td><strong>THERAPIST Dosen</strong></td>
<td>25%</td>
<td>23%</td>
<td>21%</td>
<td>19%</td>
</tr>
</tbody>
</table>

Source: Express Scripts 2014 Drug Trend Report

Reimbursement Structure

- Reimbursement rates based on AWP or WAC still common
  - AWP-18% plus $1.22 reported as average¹
  - MN fee-for-service MA uses MAC + $3.65
- Many payers using a specialty MAC
- Some payers directly contract with an exclusive specialty mail-order pharmacy

¹PBMi 2014 Prescription Drug Benefit Cost and Plan Design Report
Future Reimbursement Challenges

- CMS movement to AAC-based methodology
  - NADAC does not include specialty drugs
  - Few sources of specialty cost data
  - Invoice pricing for specialty drugs might not be accurate due to volume purchasing or other incentives
- Unclear how to best structure specialty pharmacy dispensing fee under AAC methodology
- Payment rates for clinic-administered specialty drugs
  - ASP and unintended consequences
  - MAC, variable fee schedule, and other methodologies

Additional Challenge: Pharmacy vs. Medical Benefit

- Market is mixed between pharmacy and medical benefit for specialty drugs

Specialty Pharmacy vs. Buy-and-Bill

- Billing of outpatient pharmacy claim in medical vs. pharmacy benefit

Source: EMD Serono Specialty Digest 10th edition

Source: Pharmaceutical Strategies Group
Potential Advantages of Specialty Pharmacy Model

- Streamlined Prior Authorization Processes
- Improved utilization management and Drug Utilization Review (DUR)
- Less financial risk to the prescriber
- Eliminates mark-up revenue for prescriber (may reduce incentive to prescribe high-margin items)

Disadvantages to Specialty Pharmacy Model

- Significant potential for waste
  - Recent report found 20% of drugs shipped to physicians office are ultimately not used\(^1\)
- Additional administrative burden on providers
  - Patient-specific drugs require special storage and handling
- Drug ingredient cost may be higher
  - More discounts available to clinics/outpatient hospitals

\(^1\)ICORE 2012 Medical Pharmacy and Oncology Trend Report

Pharmacists and Payers can work together to optimize specialty drug value

- Patient assessment and readiness-to-treat
- Medication Therapy Management
- Adherence counseling
- Therapeutic monitoring
- Disease Management/Case Management
So…what’s special about specialty drugs and specialty pharmacies?

- New opportunities for undertreated disease states
  - Potential for significant improvement in morbidity and mortality
- With great opportunity comes great responsibility
  - Less margin for error
  - Small amount of waste is a huge financial loss for the payer and the system
  - Patient education is key!
- Dispensing specialty drugs is not what makes a pharmacy special
  - A true specialty pharmacy must coordinate with the patient and the payer to ensure optimal care