Disclosures

- Patrick Gleason declares he is employed by a pharmacy benefit manager, Prime Therapeutics.
- He has no other conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Learning Objectives

- State a working definition of the term “specialty drug.”
- Describe at least five factors that influence whether a drug product is considered a “specialty drug.”
- Explain differences in the coverage of specialty drugs in the pharmacy benefit versus the medical benefit of an insured or prepaid health program.
- List new channels of distribution emerging for specialty drugs.
- Identify the relative role of traditional drugs and specialty drugs in total spending by U.S. health insurance plans.

Prime Therapeutics

- 13 Blue Plan owners
- 19 Blue Plan clients
- 25.6 million members
- $22.5 billion drug spend managed
- 337 million annual claim volume (weighted)
- 67,000+ retail pharmacies in network
- 7.2 million prescriptions shipped via PrimeMail®
- $4.4 billion revenue in 2014
- 3,900 employees
Drugs now comprise more than 25 percent of all employer health insurance expenditures.

- True
- False

Specialty drugs are currently over 40 percent of all employer drug expenditures.

- True
- False

The specialty drug member cost share where there begins to be a statistically significant increase in new start abandonment was:

A. $50
B. $100
C. $150
D. $250
E. $500

The most common specialty benefit cost share is:

A. $50
B. $100
C. 20 percent coinsurance
D. 50 percent coinsurance
E. Co-insurance with minimum and maximum

The leading employer specialty management strategy is:

A. Narrow specialty network
B. Medical benefit drug coverage changes to influence site of care
C. Formulary exclusion with limited brand coverage across therapeutic categories
D. Utilization management (e.g., prior authorization, step-therapy, quantity limits)

Prescription drugs' sizable share of health spending

**THE WALL STREET JOURNAL**

- 19 percent of employer health care expenditures is retail (Rx benefit) drugs
- 23 percent of employer health care expenditures is hospital care
- Combined Rx benefit + medical benefit drug > 25 percent of total health care expenditures

Prime Therapeutics: Commercial book of business

Over 15 million members during 2014

Pharmacy benefit
- $24.78 per member per month (PMPM) specialty drug expenditures
- 31 percent of all drug expenditures was specialty drug expense

Medical benefit
- $18.06 PMPM spent on drugs

Medical + pharmacy benefit specialty drugs
- 43 percent of all drug expenditures in 2014

Medical + pharmacy benefit specialty drugs by category and benefit coverage

Total Medical

Total Pharmacy

Specialty drug spend by category and benefit coverage

The importance of a comprehensive picture: 15 million commercially insured members

Top Pharmacy benefit specialty drugs

<table>
<thead>
<tr>
<th>Class</th>
<th>% of Rx specialty spend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humira</td>
<td>13.1</td>
</tr>
<tr>
<td>Sovaldi</td>
<td>10.5</td>
</tr>
<tr>
<td>Enbrel</td>
<td>8.0</td>
</tr>
<tr>
<td>Copaxone</td>
<td>4.3</td>
</tr>
<tr>
<td>Rebif/Avonex</td>
<td>4.0</td>
</tr>
<tr>
<td>Tecfidera</td>
<td>3.2</td>
</tr>
<tr>
<td>Atripla</td>
<td>3.1</td>
</tr>
<tr>
<td>Somatropin</td>
<td>2.6</td>
</tr>
<tr>
<td>Oxalo</td>
<td>1.9</td>
</tr>
</tbody>
</table>

Top Medical benefit specialty drugs

<table>
<thead>
<tr>
<th>Class</th>
<th>% of Medical specialty spend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remicade</td>
<td>11.4</td>
</tr>
<tr>
<td>Neulasta</td>
<td>9.9</td>
</tr>
<tr>
<td>Avastin</td>
<td>7.0</td>
</tr>
<tr>
<td>Herceptin</td>
<td>5.9</td>
</tr>
<tr>
<td>Rituxan</td>
<td>5.5</td>
</tr>
<tr>
<td>Alimata</td>
<td>2.1</td>
</tr>
<tr>
<td>Gammunex-C</td>
<td>2.0</td>
</tr>
<tr>
<td>Doxetaxel</td>
<td>2.0</td>
</tr>
</tbody>
</table>

Specialty drugs: Inflationary and utilization (2012-2014)

- 15 million commercially insured members
- Average age 35 years
- 50 percent women

Distribution of spending across medical and pharmacy benefits varies by drug class

Tools to manage specialty spend

Patient cost share & formulary (drug list) management

<table>
<thead>
<tr>
<th>Utilization management</th>
<th>Contracting management</th>
<th>Care management</th>
<th>Clinical management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior authorization</td>
<td>Rebate</td>
<td>Formulary</td>
<td>Pharmacy service</td>
</tr>
<tr>
<td>Step therapy</td>
<td>Fee schedules</td>
<td>Pharmacy service</td>
<td>Coordination of care</td>
</tr>
<tr>
<td>Quantity limit</td>
<td></td>
<td>Pharmacy service</td>
<td></td>
</tr>
</tbody>
</table>


| Table 10: Cost-sharing Structures and Amounts in the Pharmacy and Medical Benefits in 2015 and 2016 |
|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|
Multiple sclerosis (MS) specialty drug costs
• ~13 percent increase in MS drug cost year over year
• If 20 percent coinsurance, $960 monthly member contribution
  – Yearly member contribution $11,520

Prime health insurance marketplace: Enrollment and deductibles
Individual deductible by metallic level
2015 and 2016


Hepatitis C drugs utilization management impact
• In the first half of 2015, plans using Metavir score-based prior authorization had:
  • 36 percent lower utilization
  • 200 fewer new starts
• Cost neutrality of treating hepatitis C in people with Metavir score < 2 has not been demonstrated.1,2

Specialty pharmacy

Tools to manage specialty spend

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Pharmaceutical companies coupons

Program provides up to $8,000 of assistance per patient for each 12-month period to cover out of pocket costs for ENBREL®, including copayments, coinsurance and prescription deductibles. See more at: https://www.enbrel.com/support/financial-assistance/

Source: Health Affairs 2014;33(10):1761-1769

Specialty drug coupons patient pay impact at Prime Therapeutics Specialty Pharmacy™

117,330 prescriptions with a coupon

- Patient pay before coupon
- After coupon

Source: Health Affairs 2014;33(10):1761-1769

Cost share (patient pay) impact on primary non-adherence

Unadjusted abandonment rates of specialty drugs by 15,937 patients newly initiating or restarting use

Source: Health Affairs 2014;33(10):1761-1769; authors Catherine I. Starner, G. Caleb Alexander, Kevin Bowen, Yang Qiu, Peter J. Wickersham and Patrick P. Gleason

Prime Therapeutics Specialty Pharmacy™ prescriptions dispensed by condition/drug class

<table>
<thead>
<tr>
<th>Core Category Claims</th>
<th>Patients</th>
<th>Patient Paid</th>
<th>Plan Paid</th>
<th>Total Paid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologic Anti-Inflammatory</td>
<td>184,347</td>
<td>$28,692,572</td>
<td>$554,197,794</td>
<td>$582,890,366</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>99,842</td>
<td>$19,350,996</td>
<td>$464,245,066</td>
<td>$483,596,062</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>16,059</td>
<td>$3,873,329</td>
<td>$224,852,337</td>
<td>$228,725,666</td>
</tr>
<tr>
<td>Cancer – Oral drugs</td>
<td>24,575</td>
<td>$3,195,650</td>
<td>$154,771,380</td>
<td>$157,967,030</td>
</tr>
<tr>
<td>Growth Hormones</td>
<td>20,389</td>
<td>$3,257,027</td>
<td>$71,486,463</td>
<td>$74,743,490</td>
</tr>
<tr>
<td>Cystic Fibrosis</td>
<td>5,399</td>
<td>$577,770</td>
<td>$25,774,986</td>
<td>$26,352,757</td>
</tr>
<tr>
<td>Infertility</td>
<td>18,334</td>
<td>$1,814,340</td>
<td>$31,108,127</td>
<td>$32,922,467</td>
</tr>
<tr>
<td>Hemophilia</td>
<td>1,423</td>
<td>$188,499</td>
<td>$35,711,939</td>
<td>$35,900,438</td>
</tr>
<tr>
<td>Others*</td>
<td>26,498</td>
<td>$2,913,468</td>
<td>$69,544,976</td>
<td>$72,458,444</td>
</tr>
<tr>
<td>Overall</td>
<td>396,866</td>
<td>$63,863,651</td>
<td>$1,631,693,068</td>
<td>$1,695,556,719</td>
</tr>
</tbody>
</table>

*Others include primarily pulmonary hypertension lung disorders, immune globulins, enzyme deficiencies, human immunodeficiency virus, cancer-injectable and anticoagulants.

† Members column does not sum due to some members using drugs in multiple core categories.

Prime Therapeutics research implications

- As patient cost shares go beyond $250 per month, more patients abandon their initial multiple sclerosis or biologic anti-inflammatory prescription
- A patient’s cost share for preferred tier specialty drugs on the formulary (drug list) should be $250 or less per month
- When coupons were applied, they reduced patient cost share to less than $250 and saved patients $6 of every $10 they are asked to pay out of pocket
- Unless used on preferred specialty drugs, coupons undermine insurer’s ability to manage costs, risking increases to premiums
- Laws banning specialty drug tiers and/or capping cost shares will likely increase costs and result in more limit drug access due to expanded formulary exclusion lists

Copay coupons/Patient assistance programs (PAP)

<table>
<thead>
<tr>
<th>Core Category</th>
<th>Copay/PAP Claims</th>
<th>Copay/PAP Members</th>
<th>Copay/PAP Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologic Anti-Inflammatory</td>
<td>120,466</td>
<td>21,856</td>
<td>$23,029,214</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>53,706</td>
<td>8,714</td>
<td>$12,669,452</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>6,290</td>
<td>1,547</td>
<td>$2,937,912</td>
</tr>
<tr>
<td>Cancer – Oral drugs</td>
<td>2,185</td>
<td>614</td>
<td>$1,245,836</td>
</tr>
<tr>
<td>Growth Hormones</td>
<td>5,139</td>
<td>1,024</td>
<td>$687,064</td>
</tr>
<tr>
<td>Cystic Fibrosis</td>
<td>1,252</td>
<td>315</td>
<td>$252,862</td>
</tr>
<tr>
<td>Infertility</td>
<td>149</td>
<td>77</td>
<td>$25,187</td>
</tr>
<tr>
<td>Hemophilia</td>
<td>86</td>
<td>18</td>
<td>$21,440</td>
</tr>
<tr>
<td>Others*</td>
<td>5,016</td>
<td>1,138</td>
<td>$880,328</td>
</tr>
<tr>
<td>Overall</td>
<td>194,289</td>
<td>35,230</td>
<td>$41,749,295</td>
</tr>
</tbody>
</table>

*Others include primarily pulmonary hypertension lung disorders, immune globulins, enzyme deficiencies, human immunodeficiency virus, cancer-injectable and anticoagulants.

† Members column does not sum due to some members using drugs in multiple core categories.

Source: Prime Therapeutics LLC, 2014 internal data

- Saved members more than $41.7 million in 2014
- 35,230 members (60 percent) received a copay offset
- $1,185 average savings per member who received any copay offset

Prime Therapeutics research implications

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Research needs

Key Points
- Specialty drug expenses will soon be half of all drug expenditures, with substantial expense through the medical benefit.
- Insurers are implementing more limited formularies, utilization management and cost sharing to address rising specialty expenditures.
- Pharmaceutical manufacturer coupons are frequently used to eliminate member cost sharing, negating the formulary cost share tiering.
- More research is needed to understand the pharmacy benefit management tools impact on practice, clinical outcomes and costs.

Drugs now comprise more than 25 percent of all employer health insurance expenditures.
- True
- False

Specialty drugs are currently over 40 percent of all employer drug expenditures.
- True
- False

The specialty drug member cost share where there begins to be a statistically significant increase in new start abandonment was:
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B. Medical benefit drug coverage changes to influence site of care  
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Specialty Drugs: How Did That Iceberg Get Here?  
New Channels & Framework for Drugs

Stephen W. Schondelmeyer, PharmD, PhD, FAPhA  
CMC Endowed Chair in Pharmaceutical Management & Economics  
Professor & Director, PRIME Institute  
College of Pharmacy, University of Minnesota

Disclosures
Stephen W. Schondelmeyer declares that:
- He is employed by the University of Minnesota and conducts drug benefit management for the University’s health benefit program (UPlan).  
- He has grants from the Minnesota Department of Health and the AARP Public Policy Institute.  
- He serves on the Editorial Advisory Board of Drug Topics and First Report Managed Care.  
- He has no other grants, employment, gifts, stock holdings, and honoraria.

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Learning Objectives
- State a working definition of the term “specialty drug.”  
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- Explain differences in the coverage of specialty drugs in the pharmacy benefit versus the medical benefit of an insured or prepaid health program.  
- List new channels of distribution emerging for specialty drugs.  
- Identify the relative role of traditional drugs and specialty drugs in total spending by U.S. health insurance plans.

Which of the following is NOT a common factor used to define specialty drugs?
A. Complex, chronic conditions  
B. Administration by injection or inhalation  
C. High cost drug  
D. Oral route of administration
What percent of total healthcare spending by commercial insurers in the U.S. in 2016 is expected to be spent on drug therapy?

A. 7% to 8%
B. 9% to 10%
C. 12% to 15%
D. 29% to 34%

Which of the following channels of distribution is showing the least growth due to specialty drugs?

A. Hospital Outpatient
B. Mail Order Pharmacies
C. Limited Distribution Pharmacies
D. Physician’s Offices

Which of the following is NOT true regarding drug expenditures for a commercially insured population in 2016?

A. Drug spending is a small part of health expenditures at about 10%.
B. Drug spending exceeds spending on physicians.
C. Drug spending exceeds total hospital inpatient spending.
D. Specialty drug spending in all settings accounts for about 40% of total drug spending.

Factors Considered in Defining a Specialty Drug

- Special or complex handling & distribution requirements, or
- Route of administration such as injection, infusion, inhalation, implantation, or instillation (“the 5 I’s”), or
- Patient management, monitoring or disease support system before, or after, drug administration, or
- Special patient training & education needed for safe & effective use or for self-administration, or
- FDA approval by a BLA versus an NDA, or
- FDA designation as an Orphan Indication for the drug, or
- FDA approved Risk Evaluation & Mitigation (REMS) program, or
- Chronic or high risk disease or certain therapeutic categories, or
- Drugs with Limited Distribution (voluntary or required), and

Specialty Drugs: Overview

- Defining a “Specialty Drug”
- Channels of Distribution for Specialty Drugs
- Coverage of Specialty Drugs
- Monitoring Specialty Drug Spend & Trend
- Impact of Specialty Drug Patterns on Pharmacy Practice
- Impact of Specialty Drug Patterns on Research

Does High Cost Define Specialty Drugs?

- High cost is the most common element listed.\(^{(1)}\)
- High cost is “always noted” but not always included in the formal definition.\(^{(2)}\)
- Level for “high cost” varies
  - Ranges from costs that exceed $500 to $2,500 per month\(^{(3)}\).
- High cost alone is not sufficient to define a specialty drug since this factor alone would place many high cost, traditional brand name drugs on the specialty list.\(^{(1)}\)

Impact of High Cost Limit for Specialty Drugs

<table>
<thead>
<tr>
<th>% of Claims</th>
<th>% of Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>$600: 3.5% of claims &amp; 49.0% of spend</td>
<td>$600: 3.5% of claims &amp; 49.0% of spend</td>
</tr>
<tr>
<td>$1,000: 2.2% of claims &amp; 41.8% of spend</td>
<td>$1,000: 2.2% of claims &amp; 41.8% of spend</td>
</tr>
<tr>
<td>$2,500: 1.3% of claims &amp; 32.8% of spend</td>
<td>$2,500: 1.3% of claims &amp; 32.8% of spend</td>
</tr>
<tr>
<td>$5,000: 0.7% of claims &amp; 20.8% of spend</td>
<td>$5,000: 0.7% of claims &amp; 20.8% of spend</td>
</tr>
</tbody>
</table>

* Prescription claims & dollars from self-insured population for calendar year 2015, compiled by PRIME Institute, University of Minnesota.

A Working Definition for a Specialty Drug

- A drug that “requires a difficult or unusual process of delivery to the patient (preparation, handling, storage, inventory, distribution, Risk Evaluation & Mitigation (REMS) program, data collection, or administration)”(1) or
- “Patient management prior to, or following, administration (monitoring, disease or therapeutic support systems).”(1)
- High cost (always noted, but may vary by plan).

Who Determines Specialty Drug Definition?

- Medicare Part D - $600 per claim (unchanged since 2006)
- Medicare Part A & B – Drugs given in physician’s office
- Medicaid - State determines list & cost limit
- Self-Insured Employer (or Union) – determines list & cost limit
- Managed Care Plan – determines list & cost limit
- PBM – determines list & cost limit
- Specialty Pharmacy – determines list & cost limit

Coverage of Specialty Drugs

- Manufacturer gets FDA Approval for drug
- Medicare & Medicaid have to cover the drug
- Private & Commercial have pressure to cover the drug
  - Civil lawsuit for inadequate treatment if not covered
- FDA approval without utilization management tools is like writing a Blank Check to the manufacturer.

Coverage under:
- Medical benefit (Commercial Medical or Medicare Parts A & B)
- Pharmacy benefit (Commercial Pharmacy or Medicare Part D)

Specialty Drugs: Coverage

<table>
<thead>
<tr>
<th>Coverage Issue</th>
<th>Pharmacy Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescriptions束</td>
<td>Not always written</td>
</tr>
<tr>
<td>Transaction Record</td>
<td>Bundled in office visit claims</td>
</tr>
<tr>
<td>Drugs Identified</td>
<td>HCPCS (J Codes) used</td>
</tr>
<tr>
<td>Drug Cost</td>
<td>Drug cost part of total visit</td>
</tr>
<tr>
<td>Drug volume</td>
<td>Drug mg &amp; dose uncertain</td>
</tr>
<tr>
<td>Hidden incentives</td>
<td>Provider discount unknown</td>
</tr>
<tr>
<td>Timely Claims</td>
<td>Claims processed (less than 30 days)</td>
</tr>
<tr>
<td>Utilization mgnt</td>
<td>Retrospective DUR (at least)</td>
</tr>
<tr>
<td>Case Management</td>
<td>Poor info., access, not easy</td>
</tr>
<tr>
<td>Drug Use Data</td>
<td>Not available, not included</td>
</tr>
<tr>
<td>Drug Cost</td>
<td>20%-100% &gt; Pharmacy benefit</td>
</tr>
</tbody>
</table>

Based on prescriptions
- Claim for each prescription
- NDC # for each drug
- Drug cost is known
- Drug mg & dose known
- Pharmacy price known
- Claims processed (less than 30 days)
- Concurrent DUR, PA
- Good info., easily done
- Readily available
- Costs less than medical benefit

Specialty Drug Distribution Channels

- How and where specialty drugs are distributed is a choice and is influenced by:
  - Drug Manufacturer
  - FDA
  - Wholesalers & Specialty Wholesalers
  - Plan Sponsors (private & public)
  - PBMs
  - Specialty pharmacies & limited distribution pharmacies
- “Specialty pharmaceuticals may also be dispensed by retail, hospital, or infusion pharmacies, which may provide some (or all) of the services that specialty pharmacies provide.”(1)

Specialty Drug Channels

- Growth in new drug $'s is in specialty drugs
- Growth in Pharmacy Benefit is in:
  - Specialty pharmacies (PBM-owned or stand alone)
  - Limited distribution pharmacies (manufacturer chosen)
- Growth in Medical Benefit is in:
  - Physician’s offices & clinics (manufacturer & provider driven)
  - Hospital outpatient (manufacturer & hospital driven)
  - Home infusion providers (provider & patient driven)

Source: Prepared by PRIME Institute, University of Minnesota.

Drug Claims by Distribution Channel: 2014
(Traditional Pharmacy & Medical Channels)

<table>
<thead>
<tr>
<th>Channel</th>
<th>% of Total Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional Pharmacy</td>
<td>58.6%</td>
</tr>
<tr>
<td>Specialty Pharmacy &amp; Med</td>
<td>41.4%</td>
</tr>
<tr>
<td>Brand Rx $</td>
<td>54.6%</td>
</tr>
<tr>
<td>Generic Rx $</td>
<td>19.0%</td>
</tr>
<tr>
<td>OTC as Rx $</td>
<td>1.2%</td>
</tr>
<tr>
<td>Pharmacy Specialty</td>
<td>18.9%</td>
</tr>
<tr>
<td>Medical Specialty</td>
<td>13.7%</td>
</tr>
<tr>
<td>Medical Benefit Other</td>
<td>13.0%</td>
</tr>
</tbody>
</table>

% Annual Growth Rate:
- Specialty Pharmacy & Medical: ~10% to +25%
- Traditional Pharmacy: ~2% to +5%

Source: U of M UPlan Health Benefit, 2014 (with estimates for Medical Drug Expenditures).
**Specialty Drugs Distribution**

- Pharmacy Network
- Physician or Clinic
- Specialty Pharmacy
- Manufacturer
- Wholesaler
- Specialty Wholesaler
- Mail Order Pharmacy
- Specialty Pharmacy
- Mail Order Pharmacy
- Specialty Pharmacy
- Patient

**New Specialty Drugs: 2009-2014**

- New Molecular Entities: 145
- Specialty Drugs: 96
- Traditional Drugs: 49
- 2/3 of New Approvals Were Specialty Drugs

**What is the Spend & Trend of Pharmaceuticals & Specialty Drugs?**

Are drugs a small part of the health care dollar?

**The Nation’s Health Dollar: 2015**

- Where Did It Go?
- What Role Did Drugs Play?
- Are Drugs Used in Other Sectors?
  - YES!

**Projected Healthcare Expenditures for Commercial Insured Population: 2016**

- Non-Drug Service
- Traditional Drugs
- Specialty Drugs
- All Drugs
- 20.5% Non-Drug Service
- 14.2% Traditional Drugs
- 34.7% Specialty Drugs
- $421
- $120
- $303
- $111
- $77
- Specialty Drugs
- Traditional Drugs
- Non-Drug Service

**Projected Healthcare Expenditures for Commercial Insured Population: 2016**

- Non-Drug Service
- Drugs Only
- Non-Drug Service
- $119
- $10
- $11
- $42
- $120
- $31
- $10
- $10
- $42

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$ PMPM

- Specialty Drugs
- Drugs Only
- Non-Drug Service

Non-Drug Service

Drugs Only

- Pharmacy Benefit Spending = Hospital Inpatient Spending - Drugs
- Pharmacy Benefit Spending > Physician Office Spending

Specialty Drugs

Specialty to Generic 100 : 1
Specialty to Brand 10 : 1
Brand to Generic 11 : 1


Where is the Spending Growth & Trend for Pharmaceuticals & Specialty Drugs?

Are drugs growing slower than the U.S. economy?

Avg Cost per Drug Claim in Self-Insured Employer Plan (UPlan): 2004-2015 (Feb.)

- Average Drug Claim $125
- Patented Brand $474
- Generic (Gen-Rx) $41

Brand Prices Increased > 13% in 2014

Source: Based on data from Univ. of Minnesota self-insured drug benefit (UPlan) 2004 to 2015 & compiled by PRIME Institute, University of Minnesota.

Specialty Drugs & Costs

What is the cost of specialty drugs?

- Oncology: Xeloda, Afinitor, Gleevec, Tarceva, Nexavar
- Hepatitis C: Sofosbuvir, Olysio, Harvoni, Intron A
- Growth Hormone: Norditropin, somatropin, Genotropin, Motan
- Transplant Drugs: Cellcept, Rapamune, Prograf, Myfortic
- Arthritis Drugs: Enbrel, Humira, Remicade, Kineret
- Hemophilia Drugs: Kogenate FS, Bene (Bene), Recombinate
- Antiretrovirals (HIV): Truvada, Atripla, Kaletra, Emtriva
- Multiple Sclerosis: Avonex, Copaxone, Rebif, Tysabri
- Coagulation Drugs: Lovenox, Arixtra, Innohep, Fragmin
- Gaucher’s Disease: Cerezyme, Cerdelga
- Anemia Drugs: Procrit, Neupogen, Eprex, Neulasta, Aranesp
- Other Specialty

2013 Median Annual Household Income in U.S. ~ $ 53,657


- Income per Person
- Income per Household
- Specialty $53,364

Are Specialty Drugs Affordable — Even at the Societal Level?

- Brand $ 2,960
- Generic $ 283


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Specialty Drugs: Utilization

Covered Population of 40,093

- 40 with MS Will Seek Treatment (47%)
- 60 persons With Multiple Sclerosis (0.18%)

Annual Plan Cost $2.08 million

Cost of Drug Therapy $52,000 Per Person

Annual Plan Cost of Drug Therapy $51.88 PMPM

5.4% of Total PMPM

Specialty Drugs: Utilization

Covered Population of 40,093

- 15 with Hep C Will Seek Treatment (1.5%)
- 1,000 persons With Hepatitis C (2.5%)

Annual Plan Cost $1.53 million

Cost of Drug Therapy $102,000 Per Person

Annual Plan Cost of Drug Therapy $38.16 PMPM

4.0% of Total PMPM

Humulin U-500: Average $/Month for Commercial Insurance: 2005-2013

- $187
- $247
- $431
- $864

$5,172/Year

461% Increase In 8 Years

$2,248/Year

13% Increase In 4 Years: 2006 to 2010

$2,954/Year

100% Increase In 2 Years: 2010 to 2012

$43

$5,177/Year

$10,375/Year

75% Increase In 2 Years: 2012 to 2014

Based on data from self-insured drug benefit 2004 to 2013 & compiled by PRIME Institute, University of Minnesota.

When insulin has a 200% increase in price does the patient’s diabetes get 200% better?

NO !!!

Are We Getting Our Money’s Worth When Drug Prices Go Up 200%?

When a Drug Price Goes Up 200%? What Happens to the Cost-Effectiveness?

What Does the Future Hold?

• Drug spend is shifting to non-retail channels!
• The money is in care management not drug distribution.
• Pharmacists must become familiar with how to assess affordability of drug therapy.
• Pharmacists will be needed in unique practice settings.
• Pharmacists will be needed to manage biosimilars.
• Pharmacists have a role in pharmacogenomics.
• Pharmacists need to know the “value” of drugs.

What Is the Impact of Specialty Drugs Trends for Pharmacy Practice?
What Is the Impact of Specialty Drug Trends for Research?

- Pharmacists need to know the “value” of drugs.
- Price changes must be taken into account in applying economic analyses.
- Cost and price changes need to be taken into account in prescribing & formulary decisions.
- Need to understand and study the issue of affordability of drug therapy.
- Need to re-evaluate the threshold level for QALYs.
- Need to develop means to express price feedback without blocking access to needed drug therapy.

Need for More R & D

We need more R & D?

Increased R & D Will Result in Improved Health Value

Which of the following is NOT a common factor used to define specialty drugs?

A. Complex, chronic conditions
B. Administration by injection or inhalation
C. High cost drug
D. Oral route of administration

What percent of total healthcare spending by commercial insurers in the U.S. in 2016 is expected to be spent on drug therapy?

A. 7% to 8%
B. 9% to 10%
C. 12% to 15%
D. 29% to 34%

Which of the following channels of distribution is showing the least growth due to specialty drugs?

A. Hospital Outpatient
B. Mail Order Pharmacies
C. Limited Distribution Pharmacies
D. Physician’s Offices
Which of the following is NOT true regarding drug expenditures for a commercially insured population in 2016?

A. Drug spending is a small part of health expenditures at about 10%.
B. Drug spending exceeds spending on physicians.
C. Drug spending exceeds total hospital inpatient spending.
D. Specialty drug spending in all settings accounts for about 40% of total drug spending.