Today’s Discussion

- Rapidly rising Specialty drug costs affect *every* employer that sponsors pharmacy and medical benefit plans
- Today’s focus—
  - Specialty drug basics—Magnitude of the problem
  - Specialty drug costs
    - Pharmacy plan
    - Medical plan
  - Framework for managing Specialty drugs through pharmacy and medical benefit plans
Specialty Drugs—The Basics

• Produced with living organisms; some target specific gene
• Offer *first-time* management and sometimes *cure* of previously untreatable diseases and conditions, for example—
  – Hepatitis-C
  – MS
  – Rheumatoid Arthritis
  – Array of cancers
• Specialty drug administration—
  – Oral
  – Self-injectable
  – Infused
  – Inhaled
• Newer drugs—Majority oral or self-injectable
• Many require special storage/handling
Specialty Drugs—The Basics

• Virtually no Specialty generics because brand drugs cannot be duplicated exactly
• Emergence of “biosimilars”
  – Targeted to provide same efficacy as brand Specialty drug, but not duplicate brand drug
  – Potential savings—15% - 30% lower than brand drug after patent expiration
  – However, manufacturer of original drug may lower price to compete with biosimilars
• Until recently, Specialty drugs focused on relatively rare diseases
• Newly approved drugs and drugs in pipeline—treat common conditions—e.g., heart disease, diabetes and common cancers
• > 300 Specialty drugs in marketplace; > 900 in pipeline
• Typically, outpatient Specialty drug costs split roughly 50:50 between employer’s pharmacy and medical plans
Specialty Drugs—Pharmacy Plan

- Mostly orals and self-injectables
- Pricing clearly defined by 11-digit National Drug Codes (NDCs)
- Utilization typically ranges from 1% - 3% of plan members
- However, for many employers, currently represents ~ 25% - 35%+ of plan costs
- Average Specialty drug cost— > $3,000 per month
- On average, Specialty patient also uses 8 non-specialty drugs
- Annual Specialty trend—rate of increase in PMPM plan costs—20% - 30%+
- Utilization expected to increase 10% per year
- 8 of 10 drugs approved by FDA in next 5 years expected to be Specialty drugs
- By 2030, 9 of 10 top drugs by revenue will be Specialty drugs
Case Study—Employer A’s Specialty Rx costs projected to *quadruple* from 2012 to 2018

- **Actual 2012:** $6M; 23% of Employer’s Rx Costs
- **Actual 2014:** $9M; 31% of Employer’s Rx Costs
- **Projected 2018:** $24M; 45%+ of Employer’s Rx Costs
## Specialty Drugs—Sample Client’s Rx Experience

- Overall, Client’s Specialty drug plan experience consistent with rapidly rising cost of Specialty drugs experienced by other employers
- Specialty drugs are major driver of Client’s pharmacy plan costs and will continue to drive up costs going forward

<table>
<thead>
<tr>
<th>Metric</th>
<th>CY 2013 Experience</th>
<th>CY 2014 Experience</th>
<th>Change: 2013 to 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialty Total Cost</td>
<td>$2.3M</td>
<td>$3.7M</td>
<td>+60.3%</td>
</tr>
<tr>
<td>Specialty Utilizers as % of Members</td>
<td>0.9%</td>
<td>1.0%</td>
<td>+20.4%</td>
</tr>
<tr>
<td>Specialty Gross Cost PMPM</td>
<td>$161</td>
<td>$247</td>
<td>+53.4%</td>
</tr>
<tr>
<td>Specialty as % of Gross Cost</td>
<td>15.2%</td>
<td>20.3%</td>
<td>+32.9%</td>
</tr>
<tr>
<td>Specialty as % of Total Rxs</td>
<td>0.5%</td>
<td>0.6%</td>
<td>+25.1%</td>
</tr>
<tr>
<td>% Member Cost Share</td>
<td>4.2%</td>
<td>3.6%</td>
<td>-13.1%</td>
</tr>
</tbody>
</table>

Source: CVS Caremark 2014 Rx Insight Report on Client’s pharmacy plan experience.
Specialty Drugs—Sample Client’s Rx Experience

- Breakdown of Specialty trend

<table>
<thead>
<tr>
<th>Trend Component</th>
<th>% Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price Inflation</td>
<td>+13.4%</td>
</tr>
<tr>
<td>Utilization</td>
<td>+24.6%</td>
</tr>
<tr>
<td>Drug Mix</td>
<td>+8.5%</td>
</tr>
</tbody>
</table>

- Combination of these factors contributes to dramatic increase in Client’s Specialty drug costs
- Unless Client implements an effective strategy to manage these costs, expect Specialty drug costs to continue their dramatic upward spiral
Specialty Drugs—Medical Plan

- Typically, ~50% of outpatient Specialty drug costs through medical plan—

<table>
<thead>
<tr>
<th>Site of Care</th>
<th>~ % Distribution of Specialty Costs</th>
<th>~ Relative Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient Hospital</td>
<td>45%</td>
<td>1.50+</td>
</tr>
<tr>
<td>Physician’s Office</td>
<td>35%</td>
<td>1.00</td>
</tr>
<tr>
<td>Home Infusion</td>
<td>13%</td>
<td>Not available</td>
</tr>
<tr>
<td>Other</td>
<td>7%</td>
<td>N/A</td>
</tr>
<tr>
<td>Drug Administration and Professional Fees</td>
<td>N/A</td>
<td>Outpatient hospital: 2 – 4X Physician’s office</td>
</tr>
</tbody>
</table>
## Specialty Drugs—Medical Plan

<table>
<thead>
<tr>
<th>Pricing Source</th>
<th>Pharmacy</th>
<th>Physician's Office, Infusion Centers, Home</th>
<th>Outpatient Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pricing Transparency</td>
<td>Highest</td>
<td>Less</td>
<td>Least</td>
</tr>
<tr>
<td>Average Wholesale Price (AWP)</td>
<td>Average Sales Price (ASP)</td>
<td>Percent of billed charges</td>
<td></td>
</tr>
</tbody>
</table>
Specialty Drugs—Medical Plan

- **Site of care** determines cost *without* necessarily improving outcomes
  - Physician office vs. outpatient hospital setting
- Site-of-Care Management—
  - Cost and utilization management varies, based on site of care and vendor clinical programs
  - Outpatient hospital setting *most costly*
  - Utilization tending to move toward more expensive sites of care
  - Pricing transparency *decreases* along continuum from pharmacy to outpatient hospital setting
Specialty Drugs—Future Outlook

- Specialty drug costs will continue their rapid rise as—
  - Utilization increases
  - Population ages
  - New drugs approved by the FDA, particularly for common conditions—e.g., heart disease and diabetes
  - FDA approves current Specialty drugs for broader indications
  - Specialty drug price inflation continues its upward spiral
- Presents significant hurdles for employers to effectively manage Specialty drug costs and utilization
- Clearly, many factors outside employer’s control
- Others within employer’s control and present savings opportunities
Framework for Managing Specialty Costs

• Understand *key drivers* of Specialty drug costs through medical *and* pharmacy plans

• Manage *both* Specialty drug costs and utilization
  – Ensure Client receiving *optimal* pricing through *both* the medical and pharmacy plans

• Ensure appropriate use
Framework for Managing Specialty Costs

- **Potential Savings—Pharmacy Plan**
  - **PBM Pricing**
    - *Benchmark* current Specialty drug pricing (and other pricing terms) to ensure pricing is marketplace competitive
    - If *Market Check* provision in PBM contract, use it to determine whether all pricing terms are marketplace competitive
    - If in last year of PBM contract, *leverage intensely competitive PBM marketplace* to achieve *optimal* PBM pricing through competitive bidding
    - Today’s PBM marketplace is a “*buyer’s market*” for plan sponsors, mainly because of PBM consolidation over past 8 years
    - As a result, *virtually all terms*—financial and non-financial—are *negotiable*
Framework for Managing Specialty Costs

• Potential Savings—Pharmacy Plan (continued)
  – Specialty Formulary
    • Implement preferred brand formulary if not done so already
  – Specialty Clinical Programs
    • Focused on ensuring right drug dispensed, at right time, at right dose for appropriate condition
      – Are these programs working effectively?
      – Are current PBM metrics valid measure of program success?
    • Ensure utilization management strategy in place for emerging Specialty drugs to prevent skyrocketing costs
      – Recent Example—PCSK-9 cholesterol-lowering drugs
        • First drug approved by FDA in July 2015
        • Reduce cholesterol in patients with genetic condition that cannot be treated with statin drugs or for members with side effects from statin drugs
        • Non-discounted Price: $14,500 per year
        • Self-injectable therapy requiring lifetime use
Framework for Managing Specialty Costs

- **Potential Savings—Medical Plan**
  - Pricing
    - Evaluate Specialty drug pricing by *site of care*—outpatient hospital, physician’s office, infusion center, and home infusion
    - Compare with pharmacy plan pricing
    - Determine *savings opportunity* if certain self-injectable and oral Specialty drugs covered only through pharmacy plan
    - Negotiate available Specialty drug *rebates* with medical vendor
  - Plan Design
    - Consider *copay/coinsurance incentives* to steer members to less costly settings for infused drugs
    - Lock out drugs more appropriately covered through pharmacy plan
    - Take advantage of patient assistance programs by manufacturers
Framework for Managing Specialty Costs

- **Recommended Next Step—Specialty Drug Analysis**
  - Specialty Drug Spending Assessment
    - Examine current program performance with benchmarking—both on the medical *and* pharmacy sides
    - Conduct *opportunity analysis* with financial assessment
      - Clinical management
      - Site-of-care management
      - Vendor reimbursement management
    - Provide strategic recommendations with *quantified* savings opportunities