Specialty Drug Management Solutions You Haven’t Heard Before

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Agenda

• How to use channel and site of care optimization
• Does carving out specialty really work?
• How to predict your future specialty drug spend based on drugs in the pipeline and your population demographic
How to use channel and site of care optimization

CHANNEL ANALYSIS
Do You Know Where Your Drug Spend Is Coming From?

For many employers, there is just as much specialty drug spend on the medical side as on the pharmacy side.
Comparing Specialty: Medical vs. Rx

**Medical Challenges**
- Administration costs are not measured
- Specialty rebates are not paid to plan sponsor or measured
- Little control over site of care and distribution channels
- Health plan may not assist with specialty Patient Assistance Programs

**Coordination Challenges**
- ASP pricing vs. AWP pricing (see chart below)
- Member cost sharing is often not coordinated across benefits
- Different vendors are often responsible for Rx vs. pharmacy, even if Rx is “carved-in”
- Systems may not integrate medical and pharmacy data well

<table>
<thead>
<tr>
<th></th>
<th>Pharmacy</th>
<th>Office, Clinic, Home Infusion</th>
<th>Outpatient Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claim Layout</td>
<td>National Council for Prescription Drug Programs (NCPDP)</td>
<td>HCFA 1500 Medicare standard</td>
<td>UB 92</td>
</tr>
<tr>
<td>Drug Code</td>
<td>National Drug Code (NDC-11) Unique to drug, manufacturer, form, strength, and size</td>
<td>HCPCs, J codes, Q codes Unique to drug or drug class J code is specific to generic ingredient and quantity</td>
<td>Revenue code 3-digit code indicates where and what type of service Does not identify drug level information</td>
</tr>
<tr>
<td>Pricing Benchmark</td>
<td>Average wholesale price (AWP)</td>
<td>Average sales price (ASP)</td>
<td>Percent of billed charges</td>
</tr>
<tr>
<td>Transparency</td>
<td>High</td>
<td>Medium</td>
<td>Low</td>
</tr>
</tbody>
</table>
Challenges with Blocking JCodes

• Typically we want professionally administered drugs to run through the medical plan (in Jcodes) and self-administered drugs to run through the Rx plan

• Even if we think we can source a drug less expensively through the Rx plan, there are challenges associated with blocking Jcodes and requiring medications to run through the Rx/PBM plan instead of the medical plan

• White bagging
  – The drug is purchased from the PBM through the Rx plan and sent directly to the physician at the site of care for administration
  – Physicians may have a problem with this because they did not purchase the drug from their source and they do not make any revenue off of the drug
  – The physician may charge an additional administration fee anyway

• Brown bagging
  – The drug is purchased from the PBM through the Rx plan and the patient brings the drug in to the site of care to have it professionally administered
  – Many physicians refuse to do this because of the liability associated with administering a drug the patient brings in themselves (they don’t know for sure if the drug is correct, how the drug has been stored, if it has been kept at the correct temperature, etc.)
Candidates for Site of Care Optimization

Benchmark Population: % Spend by Site of Care

Remicade is one example of a drug that can be administered in the outpatient hospital setting or the office setting. Significant savings can often be realized by moving to the office setting.
Top Medical Specialty Spend
Site of Care Optimization Details—Example

<table>
<thead>
<tr>
<th>Drug</th>
<th>J Code</th>
<th>Outpatient Hospital</th>
<th>Office</th>
<th>Feasibility of Moving Site of Care</th>
<th>Maximum Savings Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Total Allowed</td>
<td>Procedure Count</td>
<td>Avg Allowed/Procedure</td>
<td>Total Allowed</td>
</tr>
<tr>
<td>Remicade</td>
<td>J1745</td>
<td>$34,562</td>
<td>5</td>
<td>$6,912</td>
<td>$411,081</td>
</tr>
<tr>
<td>Orencia</td>
<td>J0129</td>
<td>$70,725</td>
<td>10</td>
<td>$7,072</td>
<td>$20,251</td>
</tr>
<tr>
<td>Velcade</td>
<td>J9041</td>
<td>$51,417</td>
<td>23</td>
<td>$2,236</td>
<td>$32,300</td>
</tr>
<tr>
<td>Botox</td>
<td>J0585</td>
<td>$30,597</td>
<td>9</td>
<td>$3,400</td>
<td>$20,886</td>
</tr>
</tbody>
</table>

- Professionally administered drugs may be difficult to move from one site of care to another, particularly if the doctor or oncologist is associated with a particular site.
- Further discussion with the medical carrier on each drug above would be necessary to understand the potential of changing site of care.
Medical Specialty Opportunities

Site of Care Optimization Clinical Considerations

• There are challenges associated with changing a current patient’s site of care
• In general, chemotherapy site of care should be left to the physician
• Many physician practices are now owned by hospital systems
  – These physicians may be incentivized to utilize their hospital outpatient facilities to administer a drug
• How do we change site of care?
  – Through prior authorization process
  – Recommend alternate site after the first infusion
  – Incent patients to use an alternative site with lower cost share
  – Communications to patients about more convenient and lower cost site of care without incentives
  – Health plan has to be on board
  – Physician has to be on board
Does carving out specialty pharmacy really work?

SPECIALTY PHARMACY CARVE-OUT
### Laundry List of Possible Solutions

- Specialty solutions are not “one size fits all”
- Specialized solutions for: Each patient, Each disease, Each employer

<table>
<thead>
<tr>
<th>Compliance monitoring &amp; reporting</th>
<th>Appropriate supply limits</th>
<th>Formulary exclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacogenomics and “precision medicine”</td>
<td>Split fills</td>
<td>Patient contracts</td>
</tr>
<tr>
<td>Control auto-ship</td>
<td>Clinical coaching</td>
<td>No first fill at retail</td>
</tr>
<tr>
<td>Exclude at launch</td>
<td>Peer-to-peer consultation with physician</td>
<td>Injections training</td>
</tr>
<tr>
<td>Manufacturer assistance tracking</td>
<td>New physician payment models</td>
<td>Channel optimization</td>
</tr>
<tr>
<td>Preferred products</td>
<td>Targeted step therapy</td>
<td>Site of care optimization</td>
</tr>
<tr>
<td>Biosimilars planning</td>
<td>Meaningful prior authorization process</td>
<td>Duration management</td>
</tr>
<tr>
<td>Evidence-based guidelines</td>
<td>Provider education coordination</td>
<td>Companion diagnostics</td>
</tr>
</tbody>
</table>

Retail vs. exclusive specialty arrangements
Pricing guarantees
Specialty rebate strategies
Contractual definitions
Technology tools for compliance monitoring
Required continuous lab tests
Evidence-based guidelines
3rd party prior authorization
Why Carve Out?

• Can your PBM/carrier do everything on the laundry list that you want them to do?
  – Are they good at it?
  – Are they incentivized to do it?
• As PBMs/carriers push clients towards exclusive specialty fulfillment, independent specialty pharmacies want to keep business and are willing to compete for it.
• When your PBM owns specialty drug fulfillment, are they the best entity to also perform utilization management and prior authorization?
• Some groups want another entity to perform the prior authorization and direct the PBM to fill the script.
• Do you do this for all specialty drugs or just certain disease states?
• Can a hospital system in your area provide specialty drug fulfillment services and care to your members?
• “Best in Class” specialty pharmacies
Why Not Carve Out?

• Adds another vendor
• Adds another data feed
• Might complicate the patient/provider experience
• Your PBM/carrier will likely increase costs somewhere else if they lose the specialty pharmacy business
• For carriers, synergies may exist in an integrated model as certain specialty drugs are filled on the medical side
• How is a specialty drug defined? You must be specific about which drugs are specialty and which are covered by the PBM and which are covered by the specialty vendor
• Your specialty vendor must have access to limited distribution drugs
Can Your PBM Track Manufacturer Assistance?

• If they cannot, this alone may be sufficient reason to carve out specialty pharmacy

• All Rx member cost share now counts toward either a combined medical/Rx out-of-pocket maximum or a stand-alone Rx out-of-pocket maximum

• If a drug manufacturer pays $495 of a member’s $500 copay, you want $5 to count towards their OOP max, not $500!

• Some progressive PBMs are making changes to clients’ plan designs to maximize the manufacturer assistance on a drug-specific level
How to use your medical data to predict specialty drug spend in the future

PREDICTIVE MODELING
Why Predictive Modeling?

• Looking at historical Rx claims data and assuming that pattern will continue doesn’t make sense given the pipeline of specialty drugs
  – Remember hepatitis C?

• Industry benchmarks are little help to a small or mid-size self-funded plan because specialty spend and utilization are highly variable
  – The smaller your enrollment, the more important this is

• Predictive modeling can help determine what level of stop loss coverage makes the most sense
What Is Predictive Modeling?

The use of claims data to estimate the impact of future specialty drug claims based on the plan’s existing disease state and demographic profile.

- Estimated cost per year per patient
- Number of eligible patients
  - Info from FDA and PBM pipeline reports
  - Your medical claims data and ICD9 codes
- Percentage of eligible patients expected to seek treatment
  - Info from FDA and prescribing information
- Cost of medication for these patients to be replaced by new drug
  - Your Rx claims data

TOTAL ANNUAL COST OF NEW DRUG
Lumacaftor (Vertex) was approved in July 2015
Treats cystic fibrosis in patients with two copies of the F508del mutation, ages 12 and over
  - Breakthrough therapy → New type of treatment, not a “me too” drug
  - Orphan drug → Treats a very small population (often results in drug being more expensive in order to recoup costs)
  - Pharmacogenetic test → Not necessarily everyone with the disease will benefit from the drug, testing needed
Probabilities:
  - 30,000 people in the U.S. have CF
  - Globally, nearly half of people with CF have two copies of the F508del mutation
  - Study will be conducted in those ages 6-11, so could be approved for younger patients
Cost estimate: $300,000/year
What current treatment would this replace? Is anyone currently taking Kalydeco?
  - Kalydeco is only effective for approximately 7% of CF patients
  - Kalydeco costs $300,000/year
Cystic Fibrosis (CF) Example

- Assume according to your medical claims data, four members over age 12 have been diagnosed with cystic fibrosis
- Cost estimate: $300,000/year per person
- What current treatment would this replace? Are people currently taking Kalydeco alone now?
  - No one in your population has been taking Kalydeco
- Because the new medication is expected to work for 50% of CF patients, the expected annual cost once the new medication is available is:

\[
\text{Cost} = \text{Cost per year} \times \text{Number of patients} \times \text{Percentage eligible} - \text{Cost that would be replaced}
\]

\[
\begin{align*}
\text{Cost} & = 300,000 \, \text{per year} \times 4 \, \text{patients} \times 50\% \, \text{eligible} - 0 \, \text{in Kalydeco that would be replaced} \\
& = 600,000 \, \text{Additional Cost Per Year}
\end{align*}
\]

*Assumes everyone eligible for the drug will take it
High Cholesterol

- Traditionally treated by fairly low-cost statins
- In July, a new injectable treatment for cholesterol (PCSK9 inhibitors) is expected to hit the market
- Two manufacturers expected to release PCSK9 inhibitors within a month of each other
  - Could spur price competition
  - Pricing is expected to be $4,000-$12,000/year per patient for the new drug
- Doctors are being educated now
- [www.cholesterolneversleeps.com](http://www.cholesterolneversleeps.com) by Amgen
  - Out of the 212 million American adults, 71 million have high LDL-C
  - 37 million untreated
  - 23 million treated and at goal
  - 11 million treated and not at goal
- [www.cholesterolmatters.com](http://www.cholesterolmatters.com) by Sanofi and Regeneron
Who Could Be Eligible for PCSK9 Inhibitors?

**Familial hypercholesterolemia = genetically inherited high cholesterol**
- Many believe this will be the first category of patients treated
- Genetic form of high cholesterol impacting 620,000* Americans

**Beyond familial hypercholesterolemia, others may be eligible**
- Patients who can’t tolerate statins
- Severe cases where statins are ineffective
- History of coronary artery disease

**15-18 million Americans could eventually be candidates for PCSK9 inhibitors, and they aren’t all taking statins**
- Looking at statin utilization alone is not sufficient—patients who can’t tolerate statins aren’t going to be taking them. You must look at diagnosis codes in the medical data to identify others with hypercholesterolemia

*CVS Health Raises Concerns about the Potential Impact of New Class of Cholesterol Drugs on the Health Care System, February 17, 2015, www.cvshealth.com
Oncology Is Different

- Predictive modeling is difficult
- The oncology pipeline is exciting, but almost impossible to model for individual employers
  - Low frequency
  - High cost
  - High variability
- Contrast with PCSK9 inhibitors
  - Relatively high frequency as compared to oncology
  - Relatively low cost ($12K vs. $500K)
  - Relatively low variability (cost per patient should be consistent throughout the year and year over year because high cholesterol is a chronic condition)
## Specialty Drug Predictive Model Sample Results

<table>
<thead>
<tr>
<th>AVERAGE AGE</th>
<th>55.2</th>
<th>28.9</th>
<th>45.5</th>
<th>52.1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PERCENT SEEKING TREATMENT</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>HEPATITIS C</strong></td>
<td><strong>CLASS TOTAL</strong></td>
<td><strong>CYSTIC FIBROSIS</strong></td>
<td><strong>CLASS TOTAL</strong></td>
<td><strong>IDIOPATHIC PULMONARY FIBROSIS (BROAD)</strong></td>
</tr>
<tr>
<td>100%</td>
<td>22</td>
<td>$1,980,000</td>
<td>1</td>
<td>$225,000</td>
</tr>
<tr>
<td>90%</td>
<td>20</td>
<td>$1,800,000</td>
<td>1</td>
<td>$225,000</td>
</tr>
<tr>
<td>80%</td>
<td>18</td>
<td>$1,620,000</td>
<td>1</td>
<td>$225,000</td>
</tr>
<tr>
<td>70%</td>
<td>16</td>
<td>$1,440,000</td>
<td>1</td>
<td>$223,000</td>
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<tr>
<td>60%</td>
<td>14</td>
<td>$1,260,000</td>
<td>1</td>
<td>$225,000</td>
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<tr>
<td>50%</td>
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<td>$990,000</td>
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<td>40%</td>
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<td>30%</td>
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<td>20%</td>
<td>5</td>
<td>$450,000</td>
<td>1</td>
<td>$225,000</td>
</tr>
<tr>
<td>10%</td>
<td>3</td>
<td>$270,000</td>
<td>1</td>
<td>$225,000</td>
</tr>
<tr>
<td><strong>ESTIMATED COST</strong></td>
<td><strong>PER COURSE OF THERAPY</strong></td>
<td><strong>PER COURSE OF THERAPY</strong></td>
<td><strong>PER COURSE OF THERAPY</strong></td>
<td><strong>PER COURSE OF THERAPY</strong></td>
</tr>
</tbody>
</table>
Recommendations

• Use medical and pharmacy data to compare channel costs (medical benefit vs. pharmacy benefit) and site of care costs (outpatient hospital vs. home vs. physician office)

• Find out what your PBM can do to manage specialty spend and if carving out specialty has advantages

• Keep an eye on the specialty drug pipeline and use predictive modeling to budget for future expense and select appropriate stop loss protection