The Management of Specialty Drugs: Opportunities and Challenges

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Innovations X
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“Is there a doctor who accepts Medicaid in the house?”
Specialty Drugs to be Half of Spend by 2018

Forecast PMPM Net Drug Spend, Pharmacy and Medical Benefit, for Commercial Plan Sponsors

Source: Artemetrx, “An Evaluation of Specialty Drug Pricing Under the Pharmacy and Medical Benefit,” March 2014
Projected Growth in National Health and Outpatient Prescription Drug Expenditures, 2012-2024


Published on Drug Channels (www.DrugChannels.net) on August 11, 2015.
Change in Net Spending for Outpatient Prescription Drugs, by Payer, 2013 vs. 2014

<table>
<thead>
<tr>
<th>Payer</th>
<th>2013 (%)</th>
<th>2014 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employer-Sponsored Private Insurance</td>
<td>9.1%</td>
<td>48.2%</td>
</tr>
<tr>
<td>Individually-Purchased Private Insurance</td>
<td>16.9%</td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>24.3%</td>
<td></td>
</tr>
<tr>
<td>Other public payers</td>
<td>3.9%</td>
<td></td>
</tr>
<tr>
<td>Out-of-Pocket</td>
<td>2.7%</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>12.2%</td>
<td></td>
</tr>
</tbody>
</table>

1. Includes workers' compensation and Pembroke Consulting estimates for employer share of private insurance.
2. Includes those with Medicare supplemental coverage and all individually purchased plans, including coverage purchased through the Marketplaces. Figure reflects Pembroke Consulting estimates for prescription drug spending for Individually Purchased Private Insurance.
3. Includes Children's Health Insurance Program (Titles XIX and XXI), Department of Defense, Department of Veterans Affairs, Indian Health Service, workers' compensation, general assistance, maternal and child health, and other federal, state, and local programs. Other federal programs include OEO, Federal General and Medical, Federal General and Medical NEC, and High Risk Pools under ACA. Other state and local programs include state and local Subsidies and TDI.

Sources: Pembroke Consulting analysis of National Health Expenditure Accounts, Office of the Actuary in the Centers for Medicare & Medicaid Services, December 2015. Totals may not sum due to rounding.

Published on Drug Channels (www.DrugChannels.net) on December 10, 2015.
What’s Driving Drug Spending?

- 59% Drug Composition Changes or Price Increases
- 23% Overall, Economy-wide Inflation
- 10% Increase in Prescriptions Per Person
- 8% Population Growth

Spotlight on Medicaid

- HIV and hepatitis C therapy classes lead Medicaid specialty drug trend\(^1\)
- Medicaid is estimated to be the largest source of coverage for HIV care, covering half of all HIV patients in the U.S.\(^2\)
- The approval of newer HIV therapies means that spending on HIV will maintain a large impact on overall specialty drug spending in Medicaid
- To control spending while maintaining access, Medicaid managed care plans, PBMs, and specialty pharmacies must continue to implement a diverse set of benefit design, utilization management, and formulary administration techniques

\(^1\) Express Scripts 2015 Drug Trend Report.
\(^2\) Ibid.
The Solution: PBM and Payer-aligned Specialty Pharmacies

• PBM tools that have been used for years in the small-molecule drug categories can be successfully leveraged for specialty drugs

• Harnessing these cost-saving tools will be critical to managing expenses and enabling access to innovative specialty drugs

$250 billion
Amount PBM and specialty pharmacies will save payers over the next decade1

1Visante, prepared for PCMA. February 2016.
## Basic Tools to Manage Specialty Spend

<table>
<thead>
<tr>
<th>Utilization Management</th>
<th>Contracting Management</th>
<th>Care / Case Management</th>
<th>Channel Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Prior authorization</td>
<td>• Rebates</td>
<td>• Patient counseling to ensure safe &amp; effective drug use</td>
<td>• Use of specialty pharmacies</td>
</tr>
<tr>
<td>• Step therapy</td>
<td>• Fee schedules</td>
<td>• Patient services to ensure use of preferred care network and specialists</td>
<td>• Specialty pharmacy network</td>
</tr>
<tr>
<td>• Quantity limit maximums per prescription fill</td>
<td></td>
<td>• Coordination of care</td>
<td>• Drug purchasing discounts</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Adherence programs</td>
<td>• Site of care optimization</td>
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<tr>
<td></td>
<td></td>
<td>• Clinical outcomes measures</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Drug utilization review</td>
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</tr>
</tbody>
</table>

## Specialty Pharmacy Best Practices: Credentialing Criteria

<table>
<thead>
<tr>
<th>Standards</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accreditation</td>
<td>Accredited by independent specialty pharmacy accreditation org(s)</td>
</tr>
<tr>
<td>Organizational structure</td>
<td>Organizational structure in place to support all necessary operations</td>
</tr>
<tr>
<td>Pharmacy accessibility</td>
<td>Clinical staff are available to speak with patients 24/7 regarding treatment</td>
</tr>
<tr>
<td>Appropriate therapy</td>
<td>Specialized pharmacists verify the correct medication is being prescribed at the correct dose and frequency</td>
</tr>
<tr>
<td>Care coordination</td>
<td>Specialty pharmacy staff provide patients with all necessary supplies, specialty drug administration training, and support</td>
</tr>
<tr>
<td>Adherence management</td>
<td>Specialty pharmacy staff contact patients before each scheduled fill to arrange the dispensing of their next dose, identify potential adherence barriers, and manage treatment effects</td>
</tr>
<tr>
<td>Ancillary supplies</td>
<td>Patients are provided with all necessary supplies needed to administer their medications</td>
</tr>
</tbody>
</table>

1 Criteria may include, but are not limited to this compilation of best practices.  
# Specialty Pharmacy Best Practices: Credentialing Criteria

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<tr>
<td>Counseling</td>
<td>Pharmacists provide patients with relevant information regarding their specialty drug and disease state.</td>
</tr>
<tr>
<td>Specialty medication fulfillment</td>
<td>Specialty pharmacies ensure that specialty medications are stocked and readily accessible for patient dispensing as soon as requested.</td>
</tr>
<tr>
<td>Cold chain management</td>
<td>Specialty pharmacies have detailed cold chain management procedures that include thorough tracking requirements.</td>
</tr>
<tr>
<td>Specialty clinical protocols</td>
<td>Pharmacists closely follow all disease state and drug-specific clinical protocols for dispensing, monitoring, and patient follow-up processes.</td>
</tr>
<tr>
<td>Patient assistance programs</td>
<td>Patients have access to financial assistance programs provided through drug manufacturers, foundations, and other organizations</td>
</tr>
<tr>
<td>Patient education</td>
<td>Specialty pharmacies ensure multiple languages and methods of education are available to patients</td>
</tr>
</tbody>
</table>

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Other Ways to Bring Drug Costs Down

- Speed competition among therapies
  - Hepatitis C: head-to-head competition lowers costs
  - Need FDA to approve me-too brands faster

- More selective formularies (i.e., exclusions)—complicated in Medicaid

- Creative contracting with manufacturers
  - Shared risk
  - Outcomes-based contracts
  - Indication-based contracts

- Proposals to annuitize drug costs invite discussion of who should capture value
Head to Head Competition Reduced the Cost of an Average Hepatitis C Drug by More than 40%

Source: Visante, prepared for PCMA. February 2016.
Risk Sharing Agreements: Works in Progress

- Payers may reduce risk through risk-sharing with manufacturers

<table>
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<tr>
<th>Performance-Based Schemes</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Schemes tied to specific performance metrics such as biomarkers, clinical outcomes, or other metrics (e.g., hospitalizations)</td>
</tr>
<tr>
<td>- Indications-based schemes</td>
</tr>
<tr>
<td>- Schemes tied to adherence, where known to improve outcomes (e.g., for diabetics)</td>
</tr>
<tr>
<td>- Includes coverage with evidence development and “guarantee” type schemes</td>
</tr>
<tr>
<td>- Patient-targeting-based schemes</td>
</tr>
</tbody>
</table>

- U.S. accounts for only 12% of global risk sharing agreements
- But strong interest in outcomes-based agreements – part of pay for performance
- Substantial barriers remain to widespread adoption – how will Medicaid programs adopt?

Source: “Private Sector RSAs in the United States,” September 2015 issue of American Journal of Managed Care, Vols. 21, No. 9
Some Examples of Risk-Sharing Agreements

• **Actonel** (osteoporosis) – manufacturer rebates to health plan if fractures while on the drug
  – (Warner Chilcott and Health Alliance, 2008)

• **Januvia/Janumet** (diabetes) – blood glucose control plus adherence
  – (Merck and Cigna, 2009)

• **Repatha** (cholesterol) – replication of clinical trial results for cholesterol lowering
  – (Harvard-Pilgrim and Amgen, 2015)

• **Entresto** (heart failure) – replication of clinical trial results/reduced hospitalization
  – (Novartis and Aetna, Cigna, 2016)

Sources: Public reports/press accounts
Potential Barriers to Risk Sharing Agreements

Public Policy Impediments
1. Implications for Medicaid Best Price
2. Medicare Part D protected classes
3. Anti-kickback statutes
4. Limits on pharma manufacturer discussions with payers ahead of drug approval

Operational Barriers
1. Significant additional contracting effort (compared to traditional rebates / discounts)
2. Challenges in identifying, defining, and measuring meaningful real-world outcomes
3. Data infrastructure inadequate for measuring / monitoring relevant outcomes
4. Difficulty in reaching contractual agreement (e.g., on the selection of outcomes, patients, data collection methods)
5. Payer concerns about adverse patient selection
6. Fragmented multi-payer insurance market with significant switching among plans
7. Challenges in assessing risk upfront due to uncertainties in real-world performance
8. Lack of control over product use
9. Significant resources and costs associated with ongoing adjudication

Sources: PCMA, Brian Solow, Optum Rx, and “Private Sector RSAs in the United States,” American Journal of Managed Care, Vol. 21, No. 9 (September 2015).
Who Captures a Drug’s Value?

- What is value? How much should cost be considered?

- Say a drug prevents hospitalizations or is a therapeutic breakthrough:
  - Does the manufacturer capture most of that value?
  - How much should the payer capture?
  - What about the patient?

- At one extreme, price just below otherwise expected medical and societal costs
  - E.g., drug for blindness priced at roughly cost of SSI

- At other extreme, price just above marginal cost
  - Proponents want transparency of R&D costs
  - Some propose medical-loss-ratio-like limits for pharma

- ICER* and similar groups hugely helpful in assessing value

*Institute for Clinical and Economic Review
One View of Fair Drug Pricing

Clinical Assessment + Value Assessment = Drug Price

Indication Level Pricing – Drug with Multiple Indications

<table>
<thead>
<tr>
<th>Effectiveness</th>
<th>Current Cost</th>
<th>Assessed Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication A</td>
<td>+++</td>
<td>$$$</td>
</tr>
<tr>
<td>Indication B</td>
<td>+</td>
<td>$$$</td>
</tr>
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Indication Level Pricing – Multiple Drugs per Indication

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<tr>
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<tr>
<td>Drug A</td>
<td>++</td>
<td>$$$</td>
</tr>
<tr>
<td>Drug B</td>
<td>++</td>
<td>$$$</td>
</tr>
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What Policy Levers Could Drive Value-based Pricing?

- Formulary inclusion/placement
- Extending/shortening FDA exclusivity periods
- Exercise of prior authorization, step therapy, etc.
- Rethinking Medicaid Drug Rebate Program
- Narrowing application of Medicaid Best Price
For More Information

Visit spcma.org

Download the sPCMA white paper:
The Management of Specialty Drugs