New Approaches to Formulary Management

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Overview

I. Marketplace Overview: Stakeholder Roles & Functions
II. Dynamic Trends
III. Pipeline Principle
IV. Approach to Drug Evaluation & Formulary Management
V. Role of Data, Analytics, & Modeling
VI. Closing the Loop: Outcomes & Reporting
VII. Case Study
VIII. Looking Ahead: The Next Wave of Management Options
Stakeholders in the Pharmaceutical Marketplace:

**PhRMA**  **Manufacturers**

**Wholesalers**

**Distributors**
- Retail
- Mail
- Specialty Pharmacies

**Hospitals**

**Infusion Ctrs**

**Physician Offices**

**Payers**  **PBMs**

**Prescribers**

**Consumers**

**Advocacy Groups**

**Regulators**

**Legislators**
Dynamics of Pharmacy Trend

**Specialty Medications**
- Specialty pharmacy growth is the single greatest contributing factor to trend.
- Today, specialty spend accounts for about 1/3 of all Rx spend and projected to increase to 50% in just 3 years.\(^1\)

**Patent Expirations**
- The heavy wave of blockbuster patent expirations has passed, pushing generic fill rates to their peak – around 85% of all claims.\(^2\)
- $90-$100B in patent expirations over the next 2 years,\(^2\) but mostly tied to specialty medications.

**Direct to Consumer (DTC)**
- The pharmaceutical industry is estimated to increase social media spending to $1.86B in 2015.\(^3\)
- TV ads remain the primary form of DTC, accounting for over half of media spending and resulting in an average of 80 drugs ads per hour per day in the U.S.\(^4\)

**Drug Price Inflation**
- Manufacturers have sustained double-digit annual price increases for both brand and specialty categories over the last 3 years.\(^5\)
- Competitive dynamics differ between brands and specialty drugs, but is the underlying cause of inflation.

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Specialty Market
The shift from traditional

Over half of the medications launched in 2013 and 2014\(^1\) were specialty.

Reasons for the market shift:

- **Traditional medication pipeline waning**, no new blockbusters. For most traditional chronic conditions (high blood pressure, diabetes, high cholesterol, depression), effective medication options exist, most in a generic form.

- **Opportunities for lower side-effect profiles**, higher cure/success rates, and a push towards more oral therapies versus injections/infusions.

- **Orphan drugs** are used for conditions that affect less than 200,000 people nationwide\(^3\). In the US, about 25 million have a rare condition. 80% of rare diseases have been identified to genetic origins.\(^4\)

- **Personalized/targeted medicine** uses pharmacogenomic biomarkers so that doctors can identify which patients would benefit from a treatment, have an adverse response, or no response at all, prior to treatment.\(^5\)

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Top Spend Classes

- **hepatitis**: Sales were $10.5B in 2014 for Sovaldi / Harvoni
- **cancer**: By 2022, 18M Americans will be living with it
- **inflammatory conditions**: More than 46 million people in the U.S. have them
- **multiple sclerosis**: $1.2 million average lifetime treatment cost
- **HIV**: Infects 50,000 people in the U.S. each year

70% of total pharmacy drug spend represented by 5 classes

Cancer: The American Association for Cancer Research (AACR) / Inflammatory Conditions: National Institute of Arthritis and Musculoskeletal and Skin Diseases / Multiple Sclerosis: Scope, Stanford Medicine / Hep C: Gilead data / HIV: CDC
Pipeline Principle: Stay Ahead of the Curve
## Pipeline Forecast: Blockbuster Drugs

### New Drug Approvals and Applications

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Drug Class</th>
<th>Indication/Use</th>
<th>Route</th>
<th>Est. Change in PMPM</th>
<th>Launch Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Hepatitis C</td>
<td>Hepatitis C</td>
<td>PO</td>
<td></td>
<td>3Q2014-2015</td>
</tr>
<tr>
<td>Trulicity</td>
<td>dulaglutide</td>
<td>GLP-1 agonist</td>
<td>Type 2 diabetes</td>
<td>SC</td>
<td></td>
<td>11/2014</td>
</tr>
<tr>
<td>Cosentyx</td>
<td>secukinumab</td>
<td>IL-17 receptor antagonist</td>
<td>Plaque psoriasis</td>
<td>SC/IV</td>
<td></td>
<td>2/2015</td>
</tr>
<tr>
<td>Afrezza</td>
<td>insulin human</td>
<td>Insulin</td>
<td>Diabetes</td>
<td>INH</td>
<td></td>
<td>1Q2015</td>
</tr>
<tr>
<td>Ofev</td>
<td>nintedanib</td>
<td>Tyrosine kinase inhibitor</td>
<td>Idiopathic pulmonary fibrosis</td>
<td>PO</td>
<td></td>
<td>11/2014</td>
</tr>
<tr>
<td>Esbriet</td>
<td>pirfenidone</td>
<td>TGF-beta synthesis and TNG-alpha synthesis inhibitor</td>
<td>Idiopathic pulmonary fibrosis</td>
<td>PO</td>
<td></td>
<td>11/2014</td>
</tr>
<tr>
<td>TBD</td>
<td>evolocumab</td>
<td>PCSK-9 inhibitor</td>
<td>Hyperlipidemia</td>
<td>SC</td>
<td></td>
<td>8/28/2015</td>
</tr>
<tr>
<td>TBD</td>
<td>alirocumab</td>
<td>PCSK-9 inhibitor</td>
<td>Hyperlipidemia</td>
<td>SC</td>
<td></td>
<td>2Q2015-3Q2015</td>
</tr>
<tr>
<td>TBD</td>
<td>bococizumab</td>
<td>PCSK-9 inhibitor</td>
<td>Hyperlipidemia</td>
<td>SC</td>
<td></td>
<td>2H2016</td>
</tr>
<tr>
<td>TBD</td>
<td>ivacaftor / lumacaftor</td>
<td>Corrector ion channel modulator</td>
<td>Cystic fibrosis</td>
<td>PO</td>
<td></td>
<td>2Q2015-3Q2015</td>
</tr>
</tbody>
</table>

† Absolute PMPM provided for hepatitis C drug class
* PMPM provided for the class of PCSK-9 inhibitors

Note: Expected launch dates are subject to change. Budget impact analyses are based on assumptions and estimates with available information at the time of pipeline drug evaluations. PMPM calculations are not plan specific and various factors may alter these analyses (e.g., contracting strategy, benefit design, etc.). Actual pricing and budget impacts may vary. OptumRx® is not responsible for any decision or outcome that may result from use of this report.
Approach to Drug Evaluation and Formulary Placement

We take a comprehensive approach to determine a drug’s value, including impact to overall healthcare costs and outcomes, to determine its tier placement and management requirements.
Pipeline Data, Analytics, & Modeling

Drivers for Formulary Decisions
<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Therapeutic Use</strong></td>
<td>• Indication</td>
</tr>
<tr>
<td></td>
<td>• Target population</td>
</tr>
<tr>
<td></td>
<td>• Clinical efficacy</td>
</tr>
<tr>
<td><strong>Clinical Profile</strong></td>
<td>• Therapeutic class</td>
</tr>
<tr>
<td></td>
<td>• Formulation and administration</td>
</tr>
<tr>
<td></td>
<td>• Safety profile</td>
</tr>
<tr>
<td><strong>Competitive Environment</strong></td>
<td>• Market analysis</td>
</tr>
<tr>
<td></td>
<td>• Projected sales and/or utilization</td>
</tr>
<tr>
<td><strong>Regulatory Status</strong></td>
<td>• Drug development status</td>
</tr>
<tr>
<td></td>
<td>• FDA status</td>
</tr>
</tbody>
</table>
OptumRx utilizes two interdependent committees to determine clinical recommendations and financial impact of drug placement, ultimately building the core formulary to maximize clinical quality with a focus on lowest net cost.
Utilization Management: Strategy Drivers

Pipeline Forecasting

Factors that contribute to plan benefit design

Pharmacy & Medical Data

• Rates (prevalence, adherence, utilization)
• Membership size
• Cost of Comparator Drugs
• Current Trend of Drug Class
• % of Subset of Membership with Certain Condition(s)
• % New Starts, % Switches

Pipeline Forecast

Modeling

UM Strategy P&T Review

Factors that contribute to plan benefit design:

• Prior authorization algorithm
• Contracting strategies
• Clinical data
• Consultant input
• Treatment guidelines
Monitoring of Drug *Post Launch*

Clinical Programs

Post-Launch Outcomes
  – Drug Cost Savings
  – Medical Cost Savings

Continued Evaluation of Clinical Literature
  – Alternative Treatment Options
  – Outcomes Data

Pharmacovigilance Monitoring / Patient Registry

*Reevaluation of Utilization Management Strategies*

Formulary Review
Using Data and Clinical Modeling to Drive Better Decisions that Impact Patient Quality of Care

New Drug Pipeline Impact on PMPM Case Study: Kalydeco® (used to treat Cystic Fibrosis)
A new class of hyperlipidemia drugs (PCSK9-Inhibitors) are expected in mid 2015.

71 Million
Americans have high cholesterol

11 Million
Americans uncontrolled on cholesterol therapy may be targeted

$10K
In projected annual treatment costs

Expected 2015/2016+ launch:
• Repatha™ (evolocumab)
• Praluent™ (alirocumab)
• bococizumab

Drug Characteristics:
• Injectable (1-2x month)
• Biologic
• About 40 times more costly than current drugs

Biosimilar Approvals

Regulatory approval is key to widespread acceptance.

- Chemical generics are FDA Interchangeable.
  - Conventional drugs benefit from a well-established approval process.¹

- Biosimilars are struggling with the FDA approval process. Many questions remain concerning what the FDA will require to approve biosimilars.¹
  - FDA marketing approval process?
  - FDA biosimilar standard for interchangeability?
  - Post-approval data required?
  - Safety and efficacy studies required?

Annual U.S. Sales

- $9 billion
  - Humira

- $4 billion
  - Enbrel

Biggest potential biologics coming in 2016:

Humira® and Enbrel®, two of the largest-selling drugs in the world, are scheduled to lose their patent protection in 2016.

High annual sales make these lucrative targets for biosimilar competition.

Nearly a dozen pharmaceutical manufacturers have versions of RA biologics in development.

Looking Forward / Staying Ahead

**Future Advances**

<table>
<thead>
<tr>
<th>Medical Necessity Expansion</th>
<th>Implementation of new drug policies with prior authorization and medical necessity – expansion of genetic testing and lab value requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sites of Service</td>
<td>Directing to lower-cost sites of service – requiring infusion of drug in the home or ambulatory infusion suite setting when clinically appropriate</td>
</tr>
<tr>
<td>Price &amp; Contract Innovations</td>
<td>Accountable care organizations, physician NDC contracting preferred providers, and Center of Excellence</td>
</tr>
<tr>
<td>Preferred Products</td>
<td>Negotiate preferred products across both pharmacy and medical benefits to leverage lower cost alternatives and rebates</td>
</tr>
<tr>
<td>Utilization Management</td>
<td>Expanding and innovating new utilization management programs</td>
</tr>
<tr>
<td>Next Level Physician &amp; Consumer Engagement</td>
<td>Innovative Ways to Engage at the Point of Care</td>
</tr>
</tbody>
</table>
Questions?