The US Specialty Pharmaceuticals Marketplace, with Hepatitis C Case Study

July 13, 2014
Master of Science: Seminar in Healthcare Decision Analysis
USC School of Pharmacy & Schaeffer Center for Health Policy & Outcomes

Elan Rubinstein, Pharm.D., MPH
EB Rubinstein Associates
www.ebrubinsteinassociates.com
Introduction to EBRA

**Serving:**

**CHANNELS**
- Group purchasing organization
- Pharmacy chain
- Specialty pharmacy

**PAYERS**
- MidAtlantic Business Group
- CCIIO/CMS – ACA pharmacy policy
- Self-insured employer

**MANUFACTURERS**
- Category launch strategy
- Product positioning strategy

**ASSOCIATIONS**
- Academy of Managed Care Pharmacy
- National Renal Administers Association
- National Business Coalition on Health

**CONSULTANTS**
- 1798 Consultants
- Logistics Management Institute
- Tag & Associates

**STARTUPS**
- Castlight Health pharmacy program
- Psychiatric telemedicine

**Services provided:**

- Product positioning
- Claims analysis
- Market research/analysis
- Market modeling
- Pharmacy benefits
- Pharmacy coverage policy
- Advisory board facilitation
- Program development
Topics

1. Overview of specialty pharmaceuticals (SPRx)
2. Payer approaches to managing SPRx
3. Provider issues in managing SPRx
4. Insurance coverage issues related to managing SPRx
5. Patient role in managing SPRx
6. Case study: Hepatitis C
7. Breakouts
Topics

1. Overview of specialty pharmaceuticals (SPRx)
2. Payer approaches to managing SPRx
3. Provider issues in managing SPRx
4. Insurance coverage issues related to managing SPRx
5. Patient role in managing SPRx
6. Case study: Hepatitis C
7. Breakouts
Treatment for complex or life-threatening health conditions now includes the use of certain drugs broadly referred to as specialty drugs. These are typically made using advanced biotechnology methods and are referred to as “biologics” or “large molecules.” While no standard definition exists, specialty drugs generally are defined as having one or more of the following characteristics:

- Complex to manufacture, requiring special handling and administration
- Injectable or oral, self-administered or administered by a health care provider
- Costly, both in total and on a per-patient basis; taken by a relatively small share of the population who have complex medical conditions
- Difficult for patients to take without ongoing clinical support; also challenging for providers to manage
### SPRx different from other Rx

<table>
<thead>
<tr>
<th></th>
<th>Common</th>
<th>Specialty</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Condition</strong></td>
<td>Common Acute</td>
<td>Common Chronic</td>
</tr>
<tr>
<td><strong>U.S. Patient Population</strong></td>
<td>Millions</td>
<td>Affects &gt;50 million</td>
</tr>
<tr>
<td><strong>Duration of Therapy</strong></td>
<td>About 10 days/episode</td>
<td>Ongoing (maintenance)</td>
</tr>
<tr>
<td><strong>Cost of Therapy</strong></td>
<td>~ $100/episode</td>
<td>$1,000+/year</td>
</tr>
<tr>
<td><strong>Medication</strong></td>
<td>Anti-infective</td>
<td>Lipitor®</td>
</tr>
<tr>
<td><strong>Indication</strong></td>
<td>Acute bacterial infection</td>
<td>Cholesterol reduction</td>
</tr>
<tr>
<td><strong>Handling Requirements</strong></td>
<td>No special requirements</td>
<td>No special requirements</td>
</tr>
</tbody>
</table>

**U.S Pharmaceutical Market:**

Specialty Trends
Issues & Outlook
Prepared for Armada

By Doug Long
VP Industry Relations
dlong@us.imshealth.com
May 7, 2014

Elan Rubinstein, Pharm.D., MPH 060914
Drugs fall into three key categories

**GENERIC**
- $33
- Multiple manufacturers
- Same active ingredient as brand-name counterpart
- Cheaper than brand-name drugs once multiple generic compounds are in production
- Little to no marketing

**BRAND**
- $337
- Patent-protected
- Typically owned by a single manufacturer
- Heavy marketing often involved
  - Direct-to-consumer advertising and samples
  - Traditional physician marketing
- Drug copay coupons becoming popular

**SPECIALTY**
- $2,400
- Patent-protected
- Require extensive R&D and difficult to manufacture
- Usually treat specific chronic, genetic, or rare conditions (e.g., cancer, multiple sclerosis, rheumatoid arthritis)
- Biologics (e.g., injectables)
- May require special handling, monitoring, preparation and storage
- Could be generic or brand
- Steep growth in use expected

---

Based on year end 2012 allowed cost

**Mail and Retail**

---

Trends in Pharmacy

Joe Bojman, FSA, MAAA
SOA 2013 Annual Meeting
Session 79
October 22, 2013
Blue Cross Blue Shield of Michigan
SPRx annualized cost higher for diseases with small patient numbers (pg 1)
SPRx

*annualized* cost higher for diseases with small patient numbers (pg 2)
Many SPRx in development, especially oncology.
SPRx split between pharmacy & medical benefit at about 50:50
Pharma focus shifting to SPRx
Genomic testing identifies patients most likely to respond to a particular Rx (aka ‘personalized medicine’).
High SPRx trend for commercial payers (stats for pharmacy benefit only)

<table>
<thead>
<tr>
<th></th>
<th>Express Scripts¹</th>
<th>CVS Caremark²</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total 2012 Trend</strong></td>
<td>2.7%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Total Utilization</td>
<td>0.6%</td>
<td>-0.5%</td>
</tr>
<tr>
<td>Total Cost / Mix</td>
<td>2.1%</td>
<td>0.8%</td>
</tr>
<tr>
<td><strong>Traditional 2012 Trend</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Traditional Utilization</td>
<td>0.6%</td>
<td>-0.6%</td>
</tr>
<tr>
<td>Traditional Cost / Mix</td>
<td>-2.2%</td>
<td>-3.0%</td>
</tr>
<tr>
<td><strong>Specialty 2012 Trend</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specialty Utilization</td>
<td>-0.4%</td>
<td>3.2%</td>
</tr>
<tr>
<td>Specialty Cost/Mix</td>
<td>18.7%</td>
<td>14.9%</td>
</tr>
</tbody>
</table>

Biosimilars will complicate SPRx management

<table>
<thead>
<tr>
<th>Type</th>
<th>Originals</th>
<th>Non Originals</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>True Innovator</strong></td>
<td>Disruptive technologies, big advances in efficacy</td>
<td>Affordable high quality</td>
</tr>
<tr>
<td><strong>Biobetters</strong></td>
<td>Efficacy/safety improvements</td>
<td>Less stringent comparability</td>
</tr>
<tr>
<td><strong>Biosimilars</strong></td>
<td>Clinically equivalence and comparability to originators</td>
<td>Drug aiming to copy innovator, Focus on patient access, EMs</td>
</tr>
<tr>
<td><strong>Non Original Biologics</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description</th>
<th>Target</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New drug against new target</strong></td>
<td>Same target but differentiated (e.g. Better efficacy, safety, administration)</td>
<td>Herceptin, Perjeta, Herzuma, Reditux</td>
</tr>
</tbody>
</table>
Brand replacement by small molecule generics

Exhibit 11: U.S. generic efficiency reached 95% in 2012

This won't happen with biosimilars

Source: IMS NPA, Dec 2012
Growth: Biosimilars ≠ small molecule generics

- Slow uptake in the US due to new legislation enabling innovators to delay the approval process of new biosimilars
- Uptake in Europe accelerates due to more mature framework
- Emerging countries (Asia specifically) ramping up

2015
1.7 - 2.7 Bn US$

2020
6 - 12 Bn US$

Share of Total Biologics Market - 2020

- Key upside drivers represented by the US market

May 2014
Innovation in cancer care and implications for health systems

IMS INSTITUTE
HEALTHCARE INFORMATICS

Source: IMS analysis on MIDAS data, Extrapolation of MIDAS data. Projected pre-expiry sales, modeled for expected volume erosion and price discounts based on analogues and evidence from marketed biosimilars.
Topics

1. Overview of specialty pharmaceuticals (SPRx)
2. Payer approaches to managing SPRx
3. Provider issues in managing SPRx
4. Insurance coverage issues related to managing SPRx
5. Patient role in managing SPRx
6. Case study: Hepatitis C
7. Breakouts
Payers with >200 workers → two-thirds of all covered workers

Distribution of Employers, Workers, and Workers Covered by Health Benefits, by Firm Size, 2013

NOTES: Data are based on a special data request to the U.S. Census Bureau for their most recent (2010) Statistics of U.S. Businesses data on private sector firms. State and local government data are from the Census Bureau’s 2007 Census of Governments.

Self-insured employers usually deliver care through ASOs

Percentage of Covered Workers in Partially or Completely Self-Funded Plans, by Firm Size, 1999-2013

- All Small Firms (3-199 Workers)
- All Large Firms (200 or more)

* Estimate is statistically different from estimate for the previous year shown (p<.05).

NOTE: Sixty-one percent of covered workers are in a partially or completely self-funded plan in 2013. Due to a change in the survey questionnaire, funding status was not asked of firms with conventional plans in 2006. Therefore, conventional plan funding status is not included in the averages in this exhibit for 2006. For definitions of Self-Funded and Fully Insured plans, see the introduction to Section 10.

Employers do not understand specialty pharmacy.

50% said Medical benefit/all SPRx ≤6%
Ratio of MB/all SPRx is actuarially about 54%
Employers’ top SPRx concerns

• Utilization
• Cost
• Compliance
Employers’ top SPRx management strategies

- PA
- DM
- SPRx network
- Formulary
- Steps
- Quantity limit
- Move MB ⇒ PB

Abbreviations:
- PA = prior authorization
- DM = disease management
- Steps = must-use-first therapy
- MB = Medical benefit
- PB = Pharmacy benefit
Most large employers find DM effective - Expect more evidence-based SPRx management

<table>
<thead>
<tr>
<th>Exhibit 14.1</th>
<th>Among Firms Offering Health Benefits, Distribution of Firms’ Opinions on the Effectiveness of the Following Strategies to Contain Health Insurance Costs, by Firm Size, 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wellness Programs</strong></td>
<td><strong>Very Effective</strong></td>
</tr>
<tr>
<td>All Small Firms (3-199 Workers)</td>
<td>35%</td>
</tr>
<tr>
<td>All Large Firms (200 or More Workers)</td>
<td>36</td>
</tr>
<tr>
<td>ALL FIRMS</td>
<td>35%</td>
</tr>
<tr>
<td><strong>Tighter Managed Care Restrictions</strong></td>
<td><strong>Very Effective</strong></td>
</tr>
<tr>
<td>All Small Firms (3-199 Workers)</td>
<td>7%</td>
</tr>
<tr>
<td>All Large Firms (200 or More Workers)</td>
<td>15</td>
</tr>
<tr>
<td>ALL FIRMS</td>
<td>8%</td>
</tr>
<tr>
<td><strong>Consumer-Driven Health Plans</strong></td>
<td><strong>Very Effective</strong></td>
</tr>
<tr>
<td>(Ex: High-Deductible Plan Combined with a Health Savings Account)</td>
<td></td>
</tr>
<tr>
<td>All Small Firms (3-199 Workers)</td>
<td>20%</td>
</tr>
<tr>
<td>All Large Firms (200 or More Workers)</td>
<td>31</td>
</tr>
<tr>
<td>ALL FIRMS</td>
<td>26%</td>
</tr>
<tr>
<td><strong>Higher Employee Cost Sharing</strong></td>
<td><strong>Very Effective</strong></td>
</tr>
<tr>
<td>All Small Firms (3-199 Workers)</td>
<td>17%</td>
</tr>
<tr>
<td>All Large Firms (200 or More Workers)</td>
<td>16</td>
</tr>
<tr>
<td>ALL FIRMS</td>
<td>17%</td>
</tr>
<tr>
<td><strong>Disease Management Programs</strong></td>
<td></td>
</tr>
<tr>
<td>All Small Firms (3-199 Workers)</td>
<td>22%</td>
</tr>
<tr>
<td>All Large Firms (200 or More Workers)</td>
<td>36</td>
</tr>
<tr>
<td>ALL FIRMS</td>
<td>22%</td>
</tr>
</tbody>
</table>

* Distributions are statistically different between All Small Firms and All Large Firms within category (p<.05).

Topics

1. Overview of specialty pharmaceuticals (SPRx)
2. Payer approaches to managing SPRx
3. Provider issues in managing SPRx
4. Insurance coverage issues related to managing SPRx
5. Patient role in managing SPRx
6. Case study: Hepatitis C
7. Breakouts
Specialty pharmacy SOC share varies with therapeutic category

Source: UnitedHealth Group, 2014
Notes: Includes therapy categories which represent more than 10 percent of spending on total specialty drugs; IBD = inflammatory bowel disease, ESRD = end-stage renal disease, IVIG = intravenous immunoglobulin
Community pharmacy as SPRx provider?

- Walgreens, CVSCaremark and others have local pharmacy programs supported by owned/contract SP systems, purchasing contracts, personnel and expertise

- J Visaria, SG Frazee, AJMC, 2/7/13. Express Scripts owns no retail pharmacies
  - “Primary objective of this study was to determine whether there are differences in hepatitis C regimen adherence between specialty & retail pharmacy patients.”
  - “…after adjusting for a number of known confounders, patients who used a single SP exclusively had on average 8.6% higher regimen adherence and 15 fewer gap days than patients who used retail pharmacy exclusively.”
  - “…patients using SP had nearly 60% higher odds of achieving SVR than patients using retail pharmacy.”  
    (Abbreviation: SVR = Sustained Virologic Response)
Physician practices are being purchased by hospitals

As professional service reimbursement flattens or falls and uncertainty over reform continues, physicians are increasingly becoming employed by hospitals and health systems.

Growing Trend

- Newly trained physicians see health systems as a “safe haven” from uncertainty.
- Health systems see primary care as a necessary investment to lock in future business.
- Smaller multispecialty groups are dissolving as select specialties pursue hospital employment to improve compensation levels.

"More than half of practicing U.S. physicians are now employed by hospitals or integrated delivery systems, a trend fueled by the intended creation of accountable care organizations and the prospect of more risk-based payment approaches."

Percentage of U.S. Physician Practices Owned by Physicians and Hospitals, 2003 to 2011

Source: Medical Group Management Association (MGMA) Physician Compensation and Production Surveys, 2003 to 2011 reports based on 2002 to 2010 data.
## Shift of drug administration to hospital outpatient-coded site of care

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Remicade</td>
<td>1</td>
<td>23%</td>
<td>20%</td>
<td>23%</td>
<td>32%</td>
<td>12%</td>
<td>8%</td>
<td>7%</td>
<td>7%</td>
<td>1%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>64%</td>
<td>71%</td>
<td>69%</td>
<td>61%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neulasta</td>
<td>2</td>
<td>25%</td>
<td>30%</td>
<td>31%</td>
<td>41%</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
<td>0%</td>
<td>1%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
<td>72%</td>
<td>68%</td>
<td>67%</td>
<td>58%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rituxan</td>
<td>3</td>
<td>26%</td>
<td>32%</td>
<td>36%</td>
<td>44%</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
<td>0%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
<td>71%</td>
<td>66%</td>
<td>63%</td>
<td>55%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avastin</td>
<td>4</td>
<td>20%</td>
<td>18%</td>
<td>18%</td>
<td>19%</td>
<td>3%</td>
<td>2%</td>
<td>1%</td>
<td>0%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
<td>76%</td>
<td>79%</td>
<td>81%</td>
<td>80%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lucentis</td>
<td>5</td>
<td>1%</td>
<td>0%</td>
<td>1%</td>
<td>1%</td>
<td>8%</td>
<td>4%</td>
<td>3%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>91%</td>
<td>96%</td>
<td>95%</td>
<td>98%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eloxatin</td>
<td>6</td>
<td>28%</td>
<td>29%</td>
<td>38%</td>
<td>46%</td>
<td>2%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
<td>68%</td>
<td>69%</td>
<td>59%</td>
<td>53%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Herceptin</td>
<td>7</td>
<td>23%</td>
<td>28%</td>
<td>36%</td>
<td>49%</td>
<td>1%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>2%</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
<td>74%</td>
<td>70%</td>
<td>63%</td>
<td>50%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alimta</td>
<td>8</td>
<td>30%</td>
<td>38%</td>
<td>42%</td>
<td>48%</td>
<td>2%</td>
<td>0%</td>
<td>0%</td>
<td>1%</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
<td>66%</td>
<td>60%</td>
<td>56%</td>
<td>50%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gammagard</td>
<td>9</td>
<td>22%</td>
<td>19%</td>
<td>18%</td>
<td>20%</td>
<td>63%</td>
<td>66%</td>
<td>65%</td>
<td>61%</td>
<td>1%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>14%</td>
<td>15%</td>
<td>17%</td>
<td>19%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gamunex</td>
<td>10</td>
<td>21%</td>
<td>21%</td>
<td>19%</td>
<td>24%</td>
<td>55%</td>
<td>56%</td>
<td>58%</td>
<td>52%</td>
<td>1%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>23%</td>
<td>23%</td>
<td>23%</td>
<td>24%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*2011 and 2012 allow/claim exclude AMD ICD9 code claims. Percentages are based on claim counts.
Hospital outpatient site of care increasing:
1) 340B ‘profit’,
2) hospital purchase of MD practices, driven by
3) reduced MD Rx reimbursement, and
4) MD office ‘economic referrals’
Some providers view 340B as a way to enhance bottom lines.

<table>
<thead>
<tr>
<th>Year</th>
<th>340B Revenues</th>
<th>340B Expenditures</th>
<th>340B Gross Profit</th>
<th>Gross Profit without 340B*</th>
<th>Gross Margin without 340B*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>$83.3</td>
<td>$43.4</td>
<td>$39.9</td>
<td>$20.8</td>
<td>25%</td>
</tr>
<tr>
<td>2009</td>
<td>$89.0</td>
<td>$42.4</td>
<td>$46.6</td>
<td>$25.9</td>
<td>29%</td>
</tr>
<tr>
<td>2010</td>
<td>$109.7</td>
<td>$50.7</td>
<td>$59.0</td>
<td>$32.2</td>
<td>29%</td>
</tr>
<tr>
<td>2011</td>
<td>$131.8</td>
<td>$54.8</td>
<td>$76.9</td>
<td>$33.4</td>
<td>25%</td>
</tr>
<tr>
<td>2012</td>
<td>$135.5</td>
<td>$65.9</td>
<td>$69.7</td>
<td>$21.4</td>
<td>16%</td>
</tr>
<tr>
<td>Total</td>
<td>$549.3</td>
<td>$257.3</td>
<td>$292.0</td>
<td>$133.6</td>
<td>24%</td>
</tr>
</tbody>
</table>

* Based on figures reported in Duke’s statement to the Charlotte Observer, April 2, 2013. See text for details.

Published on Drug Channels (www.DrugChannels.net) on April 9, 2013.
Growing payer awareness of higher cost in hospital outpatient-coded site of care

### Exhibit 12
2012 Top 10 Medical Specialty Medication - Allowed Cost per Unit

<table>
<thead>
<tr>
<th>Rank</th>
<th>HCP Code</th>
<th>Product Brand Name</th>
<th>Therapy Class</th>
<th>% Specialty Allowed Cost</th>
<th>Physician Office</th>
<th>Hospital Outpatient</th>
<th>Average 2012 RJ AWP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>J1745</td>
<td>Remicade</td>
<td>Autoimmune</td>
<td>9.6%</td>
<td>$70.90</td>
<td>$116.96</td>
<td>$89.21</td>
</tr>
<tr>
<td>2</td>
<td>J2505</td>
<td>Neulasta</td>
<td>Hematopoietic Growth Factors</td>
<td>6.0</td>
<td>3,389.14</td>
<td>5,191.09</td>
<td>4,371.96</td>
</tr>
<tr>
<td>3</td>
<td>J9310</td>
<td>Rituxan</td>
<td>Oncology</td>
<td>5.3</td>
<td>651.94</td>
<td>1,048.84</td>
<td>755.78</td>
</tr>
<tr>
<td>4</td>
<td>J9035</td>
<td>Avastin</td>
<td>Oncology</td>
<td>5.3</td>
<td>71.97</td>
<td>117.53</td>
<td>72.09</td>
</tr>
<tr>
<td>5</td>
<td>J9355</td>
<td>Herceptin</td>
<td>Oncology</td>
<td>4.6</td>
<td>87.62</td>
<td>141.56</td>
<td>87.32</td>
</tr>
<tr>
<td>6</td>
<td>J9263</td>
<td>Eloxatin</td>
<td>Oncology</td>
<td>3.4</td>
<td>11.31</td>
<td>19.34</td>
<td>9.63</td>
</tr>
<tr>
<td>7</td>
<td>J2323</td>
<td>Tysabri</td>
<td>Multiple Sclerosis</td>
<td>3.0</td>
<td>12.97</td>
<td>17.58</td>
<td>14.68</td>
</tr>
<tr>
<td>8</td>
<td>J7192</td>
<td>Advate</td>
<td>Hemophilia &amp; Related Bleeding Disorders</td>
<td>2.3</td>
<td>2.13</td>
<td>2.95</td>
<td>1.56</td>
</tr>
<tr>
<td>9</td>
<td>J9171</td>
<td>Taxotere</td>
<td>Oncology</td>
<td>2.0</td>
<td>16.05</td>
<td>36.16</td>
<td>22.24</td>
</tr>
<tr>
<td>10</td>
<td>J1569</td>
<td>Gammagard</td>
<td>Immune Deficiency</td>
<td>1.7</td>
<td>47.43</td>
<td>84.31</td>
<td>69.70</td>
</tr>
</tbody>
</table>

Top 10 HCPCS Total: 43.2%

Source: Millman’s HCG Commercial database.
ACOs

Accountable Care Growth in 2014: A Look Ahead

David Muhlestein
January 29th, 2014
Health Affairs Blog
Some ACOs address specific diseases—i.e., medical oncology

**Integrated Payer/Provider Initiatives**

- Nearly half of MCOs reported pursuing **new integrated payer/provider initiatives** with oncologists to improve cancer care, such as
  - Forming an oncology accountable care organization (ACO)
  - New risk-sharing arrangements/payment models
- The percentage of oncology practice revenue tied to **global payment arrangements** has been increasing steadily over the past 3 study periods, as has the percentage of practices negotiating such an arrangement

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage of Practices</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>7.4%</td>
</tr>
<tr>
<td>2011</td>
<td>38.0%</td>
</tr>
<tr>
<td>2012</td>
<td>50.0%</td>
</tr>
</tbody>
</table>

*THE 2013 GENENTECH ONCOLOGY TREND REPORT*
ACO Pharmacy benefit management is a work in progress

- ACO self-assessment survey fielded in late 2012 concluded: “...for most of the surveyed ACOs significant improvements are needed if these organizations are to optimize medication use and improve patient outcomes” (J Manag Care Pharm. 2014; 20(1):17-21)
- “With our ACO, which began January 1, 2013, as a partnership with Walgreens, we are targeting improvements in the care of patients with high blood pressure, chronic obstructive pulmonary disease and congestive heart failure.” (Scott&White Hospital Llano 2013 Implementation Strategy)
ACO SPRx management also a work in progress

• University HealthSystem Consortium (UHC) is an alliance of >100 academic medical centers and nearly 250 of their affiliate hospitals
  • UHC will launch an SPRx program to provide patients with access to the SPRx they need at the hospitals where they are treated.
  • The program will help members succeed in an ACO environment by coordinating care and services among inpatient settings, outpatient settings, infusion clinics, and pharmacies.
  • The program will use a data repository based on medical record data to track patient outcomes to promote the best therapeutic regimens and identify patients who have not responded to therapy.
Market evolution and provider risk assumption will dictate where prescribing control resides.
Risk-based payment has several potential downsides.

Risks for stakeholders by payment type will largely depend on the incentive for providers to be efficient in the treatment process and lower the number of episodes of care.
Topics

1. Overview of specialty pharmaceuticals (SPRx)
2. Payer approaches to managing SPRx
3. Provider issues in managing SPRx
4. Insurance coverage issues related to managing SPRx
5. Patient role in managing SPRx
6. Case study: Hepatitis C
7. Breakouts
Employers likely to migrate towards IRS ‘safe harbor’ benefit designs at 60% MV

- ACA does not require large self-insured employers to cover all EHBs
- EHBs included must provide a Minimum Value of 60% of total cost, or ER can meet ‘safe harbor’ designs (Internal Revenue Bulletin, 6/3/13)
  - A plan with a $3,500 integrated medical and drug deductible, 80% plan cost sharing, and a $6,000 maximum out-of-pocket limit for employee cost sharing.
  - A plan with a $4,500 integrated medical and drug deductible, 70% plan cost sharing, a $6,400 maximum out-of-pocket limit, and a $500 employer contribution to an HSA.
  - A plan with a $3,500 medical deductible, $0 drug deductible, 60% plan medical expense cost sharing, 75% plan drug cost sharing, a $6,400 maximum out-of-pocket limit, and drug copays of $10/$20/$50 for the first/second/third prescription drug tiers, with 75% coinsurance for specialty drugs (meaning patient pays 25%).
Expect more CDHPs (AKA high deductible plans)

<table>
<thead>
<tr>
<th>Number of employees</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>Very likely to offer in 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small employers (10-499)</td>
<td>9%</td>
<td>15%</td>
<td>16%</td>
<td>20%</td>
<td>22%</td>
<td>23%</td>
<td>34%</td>
</tr>
<tr>
<td>All large employers (500+)</td>
<td>20%</td>
<td>20%</td>
<td>23%</td>
<td>32%</td>
<td>36%</td>
<td>39%</td>
<td>64%</td>
</tr>
<tr>
<td>Employers with 5,000 or more</td>
<td>35%</td>
<td>41%</td>
<td>42%</td>
<td>45%</td>
<td>51%</td>
<td>55%</td>
<td>78%</td>
</tr>
</tbody>
</table>

Source: Mercer’s National Survey of Employer Sponsored Health Plans, 2013

Abbreviation: CDHP = consumer-directed health plan (high deductible health plan w/health savings account)
2) WHAT DID THE ADMINISTRATION AGREE TO?

In a May 2 document, labeled Frequently Asked Questions about Affordable Care Act Implementation, the administration essentially gave its blessing to large or self-insured employers to use reference pricing in designing health plan benefits. It also said that employers offering drug coverage can use generic drugs to set reference prices. If a worker chooses a brand-name drug instead, the worker would pay the difference. The administration said the generic version of the drug must be medically appropriate, as determined by the individual’s doctor.

5) DOES IT SAVE MONEY AND FOR WHOM?

Fronstin and other economists say reference pricing can save money for employers when applied to high-cost services where there are big pricing variations and consumers have the time and information to shop for the best option. It won't work, for example, with emergency care, or other situations where consumers have no time or ability to compare prices. Because the approach relies on market pressure, it also would not work well in areas with only a few medical providers, or where price and quality information is not made available, either by the providers or the employers using reference pricing. Nor would it work well if consumers face no financial consequences for selecting the costlier options. An analysis of the California effort found that CalPERS saved an estimated $5.5 million in 2011 and 2012 from the joint replacement surgery program, with more than 85 percent of the savings coming from hospitals lowering their prices to meet the cap. Whether savings from reference pricing are passed onto consumers in the form of stable or lowered premiums remains to be seen.
In 2013, ~23% of employer drug formularies had ≥4 tiers.
Employers likely to increase use of co-insurance for ≥ 4th tiers.
subject to cost-share minimum or maximum or both
Private Exchange: New employer option to deliver health benefits
Will Group Employer Health Plans Become Extinct?

Three factors that threaten the employer-based system:

1. New Federal Premium Subsidy creates substantial potential for savings to employers/plan sponsors in lower wage industries (retail, food, etc.)

2. Guaranteed Issue (elimination of pre-existing condition exclusions)

3. Highly regulated underwriting rules for insurers in the public exchanges

- Private and Public Exchanges offer the potential for plan sponsors to eliminate risk of medical trends
  - Shift burden of medical trends to individual, federal government and insurers

Benefit consultants’ private health insurance exchanges projected to grow rapidly
Rx & SPRx impact of private exchanges

- Consolidated purchasing power of the big benefit consulting houses (e.g., Mercer, TowersWatson, AON, Buck)
- Less variability in medical & pharmaceutical benefit designs
- More lives under common control, subject to smaller number of and more consistently applied...
  - Drug formularies, including increasing number of tiers including SPRx
  - Pharma manufacturer contracting for discounts, access & programs
  - Prior authorization requirements
  - Evidence-based disease management standards & programs
  - Retail, mail order and specialty pharmacy provider networks
  - “Big data” to identify high cost, non-responder, non-adherent patient
1. Overview of specialty pharmaceuticals (SPRx)
2. Payer approaches to managing SPRx
3. Provider issues in managing SPRx
4. Insurance coverage issues related to managing SPRx
5. Patient role in managing SPRx
6. Case study: Hepatitis C
7. Breakouts
Expect increased SPRx consumerism in response to CDHPs & higher OOP cost share at the POS.

### Cost-Conscious Decision Making, by Type of Health Plan, 2013

(Percentage of Privately Insured Adults Ages 21–64 Who Received Health Care in Past 12 Months)

<table>
<thead>
<tr>
<th>Decision</th>
<th>Traditional</th>
<th>HDHP</th>
<th>CDHP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checked whether plan would cover care</td>
<td>39%</td>
<td>49%*</td>
<td>57%</td>
</tr>
<tr>
<td>Asked for generic drug instead of brand name drug</td>
<td>37%</td>
<td>47%*</td>
<td>50%*</td>
</tr>
<tr>
<td>Talked to doctor about prescription options and costs</td>
<td>26%</td>
<td>34%*</td>
<td>40%*</td>
</tr>
<tr>
<td>Talked to doctor about treatment options and costs</td>
<td>26%</td>
<td>33%*</td>
<td>36%*</td>
</tr>
<tr>
<td>Asked doctor to recommend less costly prescription drug</td>
<td>27%</td>
<td>36%*</td>
<td>38%*</td>
</tr>
<tr>
<td>Developed budget to manage health care expenses</td>
<td>15%</td>
<td>17%</td>
<td>28%*</td>
</tr>
<tr>
<td>Checked price of service before getting care</td>
<td>26%</td>
<td>33%*</td>
<td>39%*</td>
</tr>
<tr>
<td>Used online cost-tracking tool provided by health plan</td>
<td>12%</td>
<td>13%</td>
<td>25%*</td>
</tr>
</tbody>
</table>


- Traditional = health plan with no deductible or <$1,000 (individual), <$2,000 (family).
- HDHP = High-deductible health plan with deductible $1,000+ (individual), $2,000+ (family), no account.
- CDHP = Consumer-driven health plan with deductible $1,000+ (individual), $2,000+ (family), with account.
- Difference between HDHP/CDHP and Traditional is statistically significant at p ≤ 0.05 or better.
Topics

1. Overview of specialty pharmaceuticals (SPRx)
2. Payer approaches to managing SPRx
3. Provider issues in managing SPRx
4. Insurance coverage issues related to managing SPRx
5. Patient role in managing SPRx
6. Case study: Hepatitis C
7. Breakouts
Hepatitis C progression:

Most: Chronic & slow progression

Figure 1. HCV disease progression over 10–15 years (mono-infection)

Source: http://www.correlation-net.org/hep_c_trainers_manual/Module03/3_3_liverdamage.html
Evolution of hepatitis C treatment

**Table 1. Current and future treatments to cure HCV**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Unpegylated IFN + RBV</td>
<td>(3/wk Injec. + 1-2/day pill)</td>
<td>(1/wk Inj. + 1/day pill)</td>
<td>(3/day oral pill + 1/wk Inj. + 1/day pill/s)</td>
<td>2-3 DAAs + Peg-IFN + RBV (1/day oral pill/s)</td>
<td>2-3 DAAs + RBV (1/day oral pill/s)</td>
<td>2-3 DAAs</td>
</tr>
<tr>
<td>Peg-IFN + RBV</td>
<td>(1/wk Inj. + 1/day pill)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PI + Peg-IFN + RBV</td>
<td>(3/day oral pill + 1/wk Inj. + 1/day pill/s)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Daily Pill Burden**

<table>
<thead>
<tr>
<th></th>
<th>RBV (2-6/day)</th>
<th>RBV (2-6/day)</th>
<th>PI (8-12/day)</th>
<th>RBV (2-6/day)</th>
<th>DAA (2-3/day)</th>
<th>RBV (2-6/day)</th>
<th>DAA (2-3/day)</th>
<th>RBV (2-6/day)</th>
<th>DAA (2-1/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Duration</td>
<td>48 wks</td>
<td>48 wks</td>
<td>24-48 wks</td>
<td>12-24 wks</td>
<td>12-24 wks</td>
<td>≤12 weeks</td>
<td>≤12 weeks</td>
<td>≤12 weeks</td>
<td>≤12 weeks</td>
</tr>
<tr>
<td>Cure Rate (HCV)</td>
<td>~30% (43)</td>
<td>~40% (44)</td>
<td>~70% (45)</td>
<td>85-90% (46) (47) (48)</td>
<td>85-100% (49) (50) (51) (52) (53) (54) (55) (56) (57) (58)</td>
<td>&gt;90% (53) (54) (56)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cure Rate (HIV/ HCV)</td>
<td>~8-19% (60) (61) (62)</td>
<td>~30% (61)</td>
<td>60-75% (63) (64) (65)</td>
<td>~80% (66) (67)</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
<td></td>
</tr>
<tr>
<td>Est. Price/Patient</td>
<td>$2-14K</td>
<td>$2-27K</td>
<td>$20-55K</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
<td></td>
</tr>
</tbody>
</table>

**Genotype 1**

<table>
<thead>
<tr>
<th></th>
<th>24 wks</th>
<th>24 wks</th>
<th>N/A</th>
<th>12-24 wks</th>
<th>12-24 wks</th>
<th>≤12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cure Rate (HCV)</td>
<td>~60% (67) (43)</td>
<td>~70% (68) (69)</td>
<td>N/A</td>
<td>~85% (70)</td>
<td>~95% (48) (71)</td>
<td>&gt;90%* (56)</td>
</tr>
<tr>
<td>Cure Rate (HIV/ HCV)</td>
<td>~20% (61)</td>
<td>~60% (61)</td>
<td>N/A</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>Est. Price/Patient</td>
<td>$1-7K</td>
<td>$1-13K</td>
<td>N/A</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
</tr>
</tbody>
</table>

**Genotype 2**

**Hepatitis C Medicines and Diagnostics in the Context of HIV/HCV Co-Infection: A Scoping Report**

UNITAID Secretariat
World Health Organization

OCTOBER 2013

DAA: Direct acting agent (e.g., Sovaldi, sofosbuvir)
PI: Protease inhibitor (e.g., Olysio, simeprevir)
RBV: Ribaviran
IFN: Interferon alfa

Elon Rubinstein, Pharm.D., MPH 060314
At >$80,000 per course of Sovaldi (US price: Lower elsewhere), there will be a high cost impact of full access.
## Table 5 Costs of Current Therapies for Hepatitis C Infection

<table>
<thead>
<tr>
<th>Drug*</th>
<th>Dose</th>
<th>12 Weeks</th>
<th>24 Weeks</th>
<th>44 Weeks</th>
<th>48 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peginterferon alfa-2a</td>
<td>180 mcg subcutaneously once weekly</td>
<td>$6,000</td>
<td>$12,000</td>
<td>—</td>
<td>$24,000</td>
</tr>
<tr>
<td>Ribavirin</td>
<td>1,200 mg daily</td>
<td>$3,000</td>
<td>$6,000</td>
<td>—</td>
<td>$12,000</td>
</tr>
<tr>
<td>Telaprevir</td>
<td>1,125 mg twice daily</td>
<td>$66,155</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Boceprevir</td>
<td>800 mg three times daily</td>
<td>—</td>
<td>$40,120</td>
<td>$73,554</td>
<td>—</td>
</tr>
<tr>
<td>Simeprevir</td>
<td>150 mg once daily</td>
<td>$66,360</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Sofosbuvir</td>
<td>400 mg once daily</td>
<td>$84,000</td>
<td>$168,000</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

### Complete Treatment Regimen

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Cost of Treatment Course</th>
<th>SVR Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sofosbuvir + peginterferon + ribavirin, 12 weeks</td>
<td>$93,000</td>
<td>90%</td>
</tr>
<tr>
<td>Sofosbuvir + simeprevir, 12 weeks</td>
<td>$150,360</td>
<td>&gt; 93%</td>
</tr>
<tr>
<td>Sofosbuvir + ribavirin, 24 weeks</td>
<td>$174,000</td>
<td>76% (genotype 1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>84% (genotype 3)</td>
</tr>
<tr>
<td>Sofosbuvir + ribavirin, 12 weeks</td>
<td>$87,000</td>
<td>&gt; 92%</td>
</tr>
<tr>
<td>Living with compensated cirrhosis</td>
<td>$270,000</td>
<td>--</td>
</tr>
<tr>
<td>Liver transplantation</td>
<td>$577,100</td>
<td>--</td>
</tr>
</tbody>
</table>

* Drug costs are based on wholesale acquisition cost.
For the moment, multi-Rx cocktail is preferred over single drug regimen

Twelve weeks of treatment with Sovaldi (sofosbuvir), Olysio (simeprevir) and ribavirin is more cost effective than 24 weeks of Sovaldi and ribavirin when treating interferon-intolerant people with genotype 1 of hepatitis C virus (HCV).

Publishing their findings in Hepatology, researchers conducted a cost-effective analysis of the respective regimens, both of which are recommended by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) for treating this demographic. Sovaldi/ribavirin is the AASLD’s preferred regimen, although it must be prescribed off-label because it is not specifically approved by the U.S. Food and Drug Administration.

Twenty-four weeks of Sofosbuvir and ribavirin costs about $169,000 and has cure rates between 52 percent and 84 percent. Twelve weeks of Sofosbuvir, Olysio and ribavirin costs about $150,000, with cure rates between 89 and 100 percent.

On average, the Sovaldi, Olysio and ribavirin regimen would yield a cost of $165,336 per person treated considering all the aforementioned variables and would yield 14.69 quality-adjusted life years (QALYs), while Sovaldi and ribavirin would yield a cost of $243,586 and would yield 14.45 QALYs. The former treatment regimen would save $91,590 per cured person when compared with the latter regimen.
US Hepatitis C treatment cost compared to other diseases

Gilead public comments to CTAF report (next slide)
http://www.ctaf.org/sites/default/files/u119/Public_comments_recd_Hep_C1.pdf
Payer faces cost challenge due to high number of untreated patients.
Payers will find SPRx use hard to manage.

Key drivers for global HCV market

<table>
<thead>
<tr>
<th>Factors</th>
<th>Past and Present</th>
<th>Future</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key Market Drivers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increasing Diagnosis</td>
<td>HCV infection is under diagnosed</td>
<td>CDC recommending HCV screening for baby boomers</td>
</tr>
<tr>
<td>Increasing Treatment Rate</td>
<td>Only reserved for patients who have liver damage</td>
<td>Expand to potentially infected individuals under care</td>
</tr>
<tr>
<td>Expanding Access</td>
<td>Many chronically infected people do not have access to care</td>
<td>Access to care is expected to broaden with ongoing reform</td>
</tr>
<tr>
<td>Revolutionizing Therapies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cure rates</td>
<td>30-70%</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>Safety</td>
<td>Flu-like symptoms, anemia, etc</td>
<td>Well tolerated</td>
</tr>
<tr>
<td>Convenience</td>
<td>IFN injection plus BID pills</td>
<td>oral pills (OD or BID)</td>
</tr>
<tr>
<td>Duration</td>
<td>6 mos - 1 yr</td>
<td>2 - 3 mos</td>
</tr>
</tbody>
</table>

Source: Barclays Research
Difficult to manage if evidence-based guidelines support use of new oral hepatitis C therapies (pg 1)

**Recommendations on treatment of HCV infection**

5. *Assessing for HCV treatment*: All adults and children with chronic HCV infection, including people who inject drugs, should be assessed for antiviral treatment. (Strong recommendation, moderate quality of evidence)

6. *Treatment with pegylated interferon and ribavirin*: Pegylated interferon in combination with ribavirin is recommended for the treatment of chronic HCV infection rather than standard non-pegylated interferon with ribavirin. (Strong recommendation, moderate quality of evidence)

7. *Treatment with telaprevir or boceprevir*: Treatment with the direct-acting antivirals telaprevir or boceprevir, given in combination with pegylated interferon and ribavirin, is suggested for genotype 1 chronic HCV infection rather than pegylated interferon and ribavirin alone. (Conditional recommendation, moderate quality of evidence)

8. *Treatment with sofosbuvir*: Sofosbuvir, given in combination with ribavirin with or without pegylated interferon (depending on the HCV genotype), is recommended in genotypes 1, 2, 3 and 4 HCV infection rather than pegylated interferon and ribavirin alone (or no treatment for persons who cannot tolerate interferon). (Strong recommendation, high quality of evidence)
Difficult to manage if evidence-based guidelines support use of new oral hepatitis C therapies (pg 2)

9. **Treatment with simeprevir**: Simeprevir, given in combination with pegylated interferon and ribavirin, is recommended for persons with genotype 1b HCV infection and for persons with genotype 1a HCV infection without the Q80K polymorphism rather than pegylated interferon and ribavirin alone. (Strong recommendation, high quality of evidence)

*Note*: Recommendations 8 and 9 were made without taking resource use into consideration, as pricing information was not available for any country other than the United States at the time this recommendation was formulated.
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the member diagnosed with Chronic Hepatitis C?</td>
<td>Yes: Continue</td>
<td>No: Not Covered*</td>
</tr>
<tr>
<td>2. What is the requested treatment regimen? Sovaldi (sofosbuvir) + ribavirin: Go to #3</td>
<td>Sovaldi (sofosbuvir) + ribavirin + PEG-INF: Go to #7</td>
<td></td>
</tr>
<tr>
<td>3. Is the member with hepatocellular carcinoma awaiting liver transplantation?</td>
<td>Yes: Go to #4</td>
<td>No: Go to #5</td>
</tr>
<tr>
<td>4. Does the member meet MILAN† criteria?</td>
<td>Yes: Approve for up to 48 weeks or until liver transplantation whichever occurs first</td>
<td>No: Not Covered*</td>
</tr>
<tr>
<td>5. What is the genotype? (this question is specific for Sovaldi (sofosbuvir) + ribavirin treatment regimen)</td>
<td>Genotype 1: Go to #5</td>
<td>Genotype 2: Approve for 12 weeks</td>
</tr>
<tr>
<td>6. Is the member ineligible to receive an interferon-based regimen?</td>
<td>Yes: Approve for 24 weeks</td>
<td>No: Not Covered*</td>
</tr>
<tr>
<td>7. What is the genotype? (this question is specific for Sovaldi (sofosbuvir) + ribavirin + PEG-INF treatment regimen)</td>
<td>Genotype 1 or 4: Approve for 12 weeks</td>
<td>Other: Not Covered*</td>
</tr>
</tbody>
</table>

*Requests for non-covered indications or uses will be considered on a case by case basis.

†Milan criteria:
- Tumor size 5cm or less in diameter with single hepatocellular carcinomas OR 3 tumor nodules or less, each 3cm or less in diameter with multiple tumors AND
- No extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor
Some MD specialists suggest reserving therapy due to cost.

1) Even though the CTAF panel voted that the new drugs are likely superior in terms of clinical effectiveness for most patients and offer clinical benefits beyond current treatments, serious limitations in the evidence base remain. Further evidence is needed to more fully evaluate the comparative clinical effectiveness and value of these new treatments.

2) A majority of the CTAF Panel rated the new treatments as “low value” compared with older drugs due to the magnitude of the potential impact on health care budgets of treating large numbers of patients with these high-priced drug regimens. Because the financial impact of using these new drugs to treat all eligible patients with hepatitis C is untenable, policy makers should seek avenues to achieve reductions in the effective price of these medications.

3) Panel members and outside experts nearly all agreed that for both clinical and cost reasons, not every patient with hepatitis C needs to be immediately treated with the new drugs. Informed, shared decision-making about the timing of treatment should be encouraged. Given the circumstances, it is reasonable to consider prioritizing treatment with the new drugs for patients who need urgent treatment and have some evidence of liver fibrosis but do not have advanced liver disease.

4) Additional policy measures to increase the likelihood of clinical benefit from treatment while reducing the financial impact should be considered. Payers seeking to achieve these goals should consider use of prior authorization criteria that a) require patient commitment, b) utilize “futility rules” that define when a lack of early response should lead to discontinuation of treatment, and c) require that the new drugs be prescribed by specialists with experience treating patients with hepatitis C.
More US citizens with insurance coverage

<table>
<thead>
<tr>
<th>Plan</th>
<th>2013</th>
<th>2014</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESI</td>
<td>108.7 (±5.2)</td>
<td>116.9 (±5.1)</td>
<td>8.2 (±3.6)</td>
</tr>
<tr>
<td>Medicaid</td>
<td>12.3 (±2.3)</td>
<td>18.2 (±3.0)</td>
<td>5.9 (±2.8)</td>
</tr>
<tr>
<td>Individual Market</td>
<td>9.4 (±2.1)</td>
<td>7.8 (±1.8)</td>
<td>-1.6 (±1.8)</td>
</tr>
<tr>
<td>Marketplace</td>
<td>- (—)</td>
<td>3.9 (±1.1)</td>
<td>3.9 (±1.1)</td>
</tr>
<tr>
<td>Other</td>
<td>27.5 (±3.7)</td>
<td>20.3 (±3.0)</td>
<td>-7.1 (±1.6)</td>
</tr>
<tr>
<td>Subtotal (Insured)</td>
<td>157.9 (±4.4)</td>
<td>167.2 (±4.1)</td>
<td>9.3 (±3.5)</td>
</tr>
<tr>
<td>Uninsured</td>
<td>40.7 (±4.4)</td>
<td>31.4 (±4.1)</td>
<td>-9.3 (±3.5)</td>
</tr>
</tbody>
</table>

NOTE: All numbers (including margin of error) are in millions of individuals. Numbers in italics reflect margins of error. Margin of error represents a 95 percent confidence interval. Some numbers may not sum perfectly due to rounding.
With insurance coverage, and ACA mandated no-cost screening: Newly ID’ed hepatitis C cases expected increase
In 2013, hepatitis C patient “warehousing”

**Overall Drug Trend Remains Steady**

The overall per-member-per-month drug trend for Catamaran’s book of business was 2.4%, compared to 2.6% in 2012. Price inflation in the unit cost of brand and specialty drugs exerted an upward influence on overall trend. That influence was moderated by generic launches, most notably Lipitor®. Lipitor reached its full potential mid-year, and by year-end reduced Catamaran’s overall trend by 20%. An additional moderating influence was a 42.5% reduction in utilization of hepatitis C drugs, as patients were “warehoused,” waiting for new novel therapy launches.
In 2014, patients demand and MDs prescribe these new therapies.
Most analysts are very bullish on Gilead… due to expected high sales of Sovaldi.

GILD Equity Summary Score
9 Firms† | Methodology

<table>
<thead>
<tr>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Bullish</td>
</tr>
<tr>
<td>Bullish</td>
</tr>
<tr>
<td>Neutral</td>
</tr>
<tr>
<td>Bearish</td>
</tr>
<tr>
<td>Very Bearish</td>
</tr>
</tbody>
</table>

GILD | Stock Analyst Opinions - Fidelity Investments
5/19/2014

Highlights

- We estimate 2014 revenues of $18.4 billion, up 64% from 2013, driven by the launch of Sovaldi (sofosbuvir) for hepatitis C, which was approved in December 2013 in the U.S. and in January 2014 in Europe. Sovaldi sales in the first quarter 2014 was $2.27 billion, well ahead of our forecast of $800 million, as sales reached $2.1 billion in the U.S. and $164 million in Europe. We now forecast 2014 Sovaldi sales of $7 billion but we see some potential delays on new patient starts in the third quarter ahead of the anticipated FDA approval of Sovaldi + Ledipasvir with an October 10 PDUFA date. We also continue to view favorably GILD’s leading U.S. HIV drug market share, and trends toward earlier HIV patient diagnosis and start of anti-viral treatment.

- We see operating margins of 59.7% in 2014 up from 44.5% in 2013 which reflected increased investment for the Sovaldi launch. Margins should also benefit as GILD launches wholly owned HIV pill Stribild, and Sovaldi.

- We project EPS of $4.94 for 2014. As of March 31, 2014, GILD had $6.86 billion in cash and $8.4 billion of debt.
Medicare Reverses Denial Of Costly Treatment For Hepatitis C Patient

By Richard Knox
MAY 15TH, 2014, 3:47 PM

Medicare officials’ fast response in the Bianco case is an indication of the political sensitivity of rejecting potentially life-saving coverage based at least in part on the drugs’ costs. “We want to try to be as helpful as we can to get beneficiaries the drugs that they need,” a Medicare spokesman said earlier this week.

Or to put it the other way around, no one wants to be the first to say that patients who need the drugs can’t get them— in other words, that hepatitis C has pushed the nation into explicit rationing of life-saving care.
Topics

1. Overview of specialty pharmaceuticals (SPRx)
2. Payer approaches to managing SPRx
3. Provider issues in managing SPRx
4. Insurance coverage issues related to managing SPRx
5. Patient role in managing SPRx
6. Case study: Hepatitis C
7. Breakouts
Breakouts

**Issues to consider**

1. Judgment call: Social equity vs your company budget?
2. Priority of addressing the best role for the new oral hepatitis C therapy?
3. Is there ‘low hanging fruit’? If so, what and where is it?
4. If evidence-based guidelines suggest using the new agents, how would you factor cost into the coverage decision?
5. Address directly or ask contracted PBM, health plan or disease management vendor?
6. Process through which to make benefit design, provider network and coverage policies? Employer vs contracted vendor roles?

**Consider these issues from the perspective of**

- Breakout group#1: Self-insured employer’s human resource director
- Breakout group#2: Health plan or PBM pharmacy director
Elan Rubinstein, Pharm.D., MPH
EB Rubinstein Associates
elan.b.rubinstein@gmail.com
www.ebrubinsteinassociates.com