Soaring Specialty Drug Prices: Status & Solutions

Mark Hiatt, MD, MBA, MS
Executive Medical Director

Regence BlueCross BlueShield of Utah
Prices of pharmaceutical drugs have been soaring.

What is the status of this hyperinflation, & what are possible solutions to moderate the rise?

What can you expect, & what can you do about this problem?
Soaring specialty drug prices

- Aging
- Chronic conditions
- Pressures on health care system
- Specialty drug spend
- Preventable hospitalizations

Total health care costs

Unaffordable health care
What is a specialty drug?

- No universally accepted definition
- Historically: expensive, injectable drugs to treat orphan conditions
- The specialty drug landscape is changing → more difficult to define
Specialty drug characteristics

Common qualities of specialty drugs:

- Treat specific, mainly chronic, & often rare conditions
- Prescribed by a specialist
- Injectable drug
- Requires special storage/handling
- Limited distribution (only available from certain pharmacies)
- High-touch patient-management required
- Patients require financial assistance
- Expensive!
Common specialty disease states

- Hepatitis C
- Multiple sclerosis
- Chronic inflammatory diseases (e.g., rheumatoid arthritis, ulcerative colitis, psoriasis)
- Oncology
- HIV
- Hemophilia
- Primary immunodeficiency
Social factors affecting health

Image source: www.bestmasterofscienceinnursing.com
America’s disadvantage

America spent $2.6 TRILLION on healthcare in 2010. That’s more than any other country in the world!

That’s 17.6% of GDP or $8,233 per person

Image source: www.bestmasterofscienceinnursing.com
Healthcare costs: the opportunity
Healthcare costs

With the $2.8 trillion America spends annually you could:

- Buy the 10 most valuable companies in America
  - $2.71 trillion

- ...and put on three London Olympics
  - $45 billion

- ...and still be richer than Warren Buffett
  - $44 billion

Average state health plan employee premiums (2013)
Specialty drug spend

Fastest growing component of healthcare costs

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Drug Spend</th>
<th>Specialty Drug Spend</th>
</tr>
</thead>
<tbody>
<tr>
<td>1980</td>
<td>$12B</td>
<td>$0</td>
</tr>
<tr>
<td>2000</td>
<td>$121B</td>
<td>$1.8B</td>
</tr>
<tr>
<td>2012</td>
<td>$269B</td>
<td>$59B</td>
</tr>
<tr>
<td>2021</td>
<td>$483B</td>
<td>$208B</td>
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</table>

Source: JPMorgan
Managing specialty drugs is critical

50% of the drug pipeline comprises specialty products

10x the average cost of a traditional branded prescription drug

Express Scripts; IMS 2014
Specialty drug costs are soaring

- Specialty drug utilization growing faster than traditional drug utilization
- Patent expirations of traditional drugs and increased generic use
- Specialty drug prices increasing 2.5x faster than traditional
- Higher shipping and handling costs and more expensive site of care for specialty drugs
- Rising interest in targeted and personalized medicines across payers and providers
- High R&D costs and undefined regulatory pathway hamper biosimilars development
- Bulging specialty drug pipeline and launches
- Few close substitutes for specialty products
Price inflation: drugs outpacing general inflation

Average Brand Name Drug Prices vs General Inflation Rate by Year

<table>
<thead>
<tr>
<th>Year</th>
<th>Brand Name Drug Prices (227 top drug products)</th>
<th>General Inflation (CPI-U)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>5.7%</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>5.9%</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>3.2%</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>3.8%</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>8.4%</td>
<td>-0.3%</td>
</tr>
<tr>
<td>2011</td>
<td>9.1%</td>
<td>1.6%</td>
</tr>
<tr>
<td>2012</td>
<td>11.5%</td>
<td>3.1%</td>
</tr>
<tr>
<td>2013</td>
<td>12.3%</td>
<td>2.1%</td>
</tr>
<tr>
<td>2013</td>
<td>12.9%</td>
<td>1.5%</td>
</tr>
</tbody>
</table>
Mergers and acquisitions

Monthly costs of drugs after an acquisition

Drug 1

Drug 2

Drug 3

= date of acquisition
New drug technologies drive increases as well

Figure 11: Specialty drug approvals continue to race ahead
Specialty drug approvals have surpassed traditional drugs in the past five years, and based on the FDA pipeline this trend will continue.

Source: PwC Health Research Institute research based on data from the FDA, Express Scripts, Catamaran, and Thomson Reuters.
Nov/Dec 2013: Olysio and Sovaldi approved

Oct 2014: Harvoni approved

Dec 2014: Viekira Pak approved

Revolutionizing Hepatitis C treatment

Total Cost
Medical benefit drugs: more difficult to manage
Upcoming specialty drug budget busters

Source: Walgreens
Specialty drug management
Challenges to managing specialty drugs

- Double-digit growth in specialty spend
- Lack of outcomes data for specialty drugs
- Managing across medical & pharmacy benefits
- Manufacturer copay coupons

A variety of methods are required to manage specialty drug costs
Specialty drug management strategies

**Formulary/UM**
- Formulary status
- Prior authorization/reauthorization
- Step therapy
- Quantity limits

**Benefit Design**
- Tiered copayments/cost-shares
- Specialty pharmacies

**Contracting**
- Provider reimbursement
- Manufacturer rebates

**Clinical Case Management**
- Care management via specialty pharmacy
- Health plan case management
- Cycle management program/split fill program
Formulary management

*Be vigilant about managing drugs – make sure the right patients are receiving the right treatment*

All new drugs (traditional & specialty) evaluated by Pharmacy & Therapeutics (P&T) committee

- Determines which drugs are included/excluded on the preferred drug list using the best available evidence
- Goal: provide members with medications that present the best treatment value in terms of efficacy, safety & cost
- Foundation of clinical management strategy
Utilization management

Steers patients to preferred, cost-effective products; reduces inappropriate utilization

- **Prior Authorization**
  - Defines the appropriate population for treatment
  - Appropriate dose or length of therapy
  - Step therapy
  - Monitor efficacy and/or safety through re-authorization

- **Step Therapy**
  - Ensures use of generics or other 1st-line alternatives

- **Quantity limits, dose optimization**
Drug pipeline update: specialty drugs for a common condition

PCSK9-inhibitors
1st specialty drugs approved for high cholesterol in high-risk patients

Category
Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors

Products
#1) PRALUENT (alirocumab)
#2) REPATHA (evolocumab)

Approval Dates
07/24/2015
08/27/2015

Notes
• Evidence shows that they lower LDL (bad cholesterol)
• No evidence showing they improve important outcomes (death, heart attacks)
# Proactively managing the specialty drug pipeline

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Therapeutic Use</th>
<th>Supply Limit</th>
<th>Step Therapy</th>
<th>PA</th>
<th>Genetic Testing</th>
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</thead>
<tbody>
<tr>
<td>Kanuma</td>
<td>Lysosomal Acid Lipase Deficiency</td>
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<td>Not being considered</td>
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<tr>
<td>Keytruda</td>
<td>Lung Cancer</td>
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<td>Repatha</td>
<td>Hypercholesterolemia</td>
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<tr>
<td>Nucala</td>
<td>Asthma</td>
<td></td>
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<tr>
<td>Drisapersen</td>
<td>Duchenne Muscular Dystrophy</td>
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<tr>
<td>Cinquil</td>
<td>Asthma</td>
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<tr>
<td>Eteplirsen</td>
<td>Duchenne Muscular Dystrophy</td>
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<tr>
<td>Rociletnib</td>
<td>Lung Cancer</td>
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<tr>
<td>Strensiq</td>
<td>Hypophosphatasia</td>
<td></td>
<td>Not being considered</td>
<td></td>
<td>Not being considered</td>
</tr>
</tbody>
</table>

▲ = strategy under consideration  ● = strategy strongly considered
Biosimilars

$250 BILLION COULD BE SAVED IN THE NEXT DECADE IF THESE 11 BIOSIMILARS ARE APPROVED

Challenges:
- Legal issues (patent dance)
- Physician acceptance
- Pricing
- Substitutability

Source: Express Scripts
Encourage adoption of biosimilars when evidence shows they are interchangeable with branded drugs

- Regence will evaluate the evidence of all FDA-approved biosimilars
- Formulary status & utilization management will take into account evidence of similarity to the branded product & product cost
Support an integrated approach to benefit design & reimbursement across pharmacy & medical benefits

- Tiered cost-share, copayments
- Limiting to a 30-day supply
- Management of medical benefit drugs
  - Clinical management
  - Site-of-care management
  - Reduction of administrative waste

Regence’s integrated PBM services are administered by OmedaRx
Medical + pharmacy benefits = valuable programs

UNMANAGED MEDICAL DRUG SPEND. WHAT'S THE TOLL?

IT'S CRITICAL

47% of specialty drug spend is uncontrolled because it's managed through the medical benefit.

MEDICAL LACKS PHARMACY'S OVERSIGHT

1 in 5 PA requests are medically unnecessary. 15% of medical drug claims are paid inaccurately.

THE TOLL THIS YEAR

$9 BILLION WASTED on uncontrolled specialty costs.

MEDICAL BENEFIT MANAGEMENT BRIDGES THE GAP

• Guaranteed savings
• Management across pharmacy & medical
• Improved health outcomes
• Lower cost of care
• Reduced administrative costs
• Up-to-date clinical information

PLAN SPONSORS

PATIENTS

PROVIDERS

Advantages

- Lower drug costs
- Improved patient outcomes through care management
- More data on utilization & outcomes
- Management across benefits

Walgreens Specialty Select program

- Access
- Medical vs. pharmacy benefit
- Drug cost
- Practical considerations
Care management

*Educate members about coverage options & support services, like those offered by specialty pharmacies*

- Adherence is an issue for all chronic medications
- Larger problem with specialty drugs due to administration & drug costs
- A comprehensive approach to patient care is required to optimize drug therapy – many types of services offered by specialty pharmacies
- Adherence should be monitored closely to improve patient outcomes & reduce waste
## Examples of care management programs

<table>
<thead>
<tr>
<th></th>
<th>Multiple Sclerosis</th>
<th>Chronic Inflammatory Diseases</th>
<th>Oral Oncology</th>
<th>Hepatitis C</th>
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</thead>
<tbody>
<tr>
<td><strong>Adherence Monitoring</strong></td>
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<td>✓</td>
<td>✓</td>
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<td><strong>Side Effect Management</strong></td>
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<td>✓</td>
<td>✓</td>
<td></td>
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<tr>
<td><strong>Monthly Adherence &amp; Compliance Calls</strong></td>
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<td>✓</td>
<td>✓</td>
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<tr>
<td><strong>Full Clinical Assessments</strong></td>
<td>Monthly</td>
<td>Monthly</td>
<td>Monthly</td>
<td>Monthly</td>
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<tr>
<td><strong>Complete Medication History</strong> (Walgreens One Patient View)</td>
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<td>✓</td>
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<td><strong>Data Collection</strong></td>
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<td></td>
<td>Relapses</td>
<td>Disease Flares</td>
<td>Type of Cancer</td>
<td>Genotype</td>
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<tr>
<td></td>
<td>Use of assistive devices (DME)</td>
<td>Monitoring for Infection</td>
<td>Pain</td>
<td>Viral Load Collection</td>
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<tr>
<td></td>
<td>Depression Screening</td>
<td>Depression Screening</td>
<td>Fever</td>
<td>Length of Therapy</td>
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<tr>
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<td>Fatigue Screening</td>
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<td>Depression Screening</td>
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<td>Anemia Screening</td>
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<td>HAV/HBV status</td>
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<td>ETR/SVR achieved</td>
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<td>✓</td>
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<td><strong>Client Reporting</strong></td>
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<td>✓</td>
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<tr>
<td><strong>Client Trigger Reports (Case Managers)</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Source: Walgreens Specialty Pharmacy
Hepatitis C medication adherence

- Managed by a specialty pharmacy
- Not managed by a specialty pharmacy

Source: Walgreens Specialty Pharmacy
What else can you do?

- Integrate high-quality case management, step therapy & prior authorization to help manage cost & outcomes.

- Use knowledgeable service providers who understand your market trends, patient population & challenges.

- Share clinical resources with employees to improve personal health accountability & engagement.

http://www.specialtyrxtoolkit.com/
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