



# Biosimilars: A Pharmacy Benefit Manager (PBM) Perspective

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November 7, 2013

# Agenda

- PBM Industry Insights
- Managing Drug Trend
- Biologic Formulary Management
- Biosimilar Adoption
- Implications for Pharmacists

## CVS Retail Pharmacy

7,400 stores, 5 million served daily  
69M households with ExtraCare® card



## CVS Caremark PBM

2,000 clients, 63M members,  
including 6M Med D, 8M Medicaid  
35M web visits in 2012

## Specialty Pharmacy

700K specialty patients  
2.7M+ scripts annually  
Access through 7,400 CVS retail,  
12 mail service pharmacies



## Clinical Innovation

Accordant Health Services  
Genetic Benefit Management  
Pharmacy Advisor®  
Behavior Change Research

## Mail Service Pharmacy

2 mail service pharmacies  
50M+ scripts annually



## MinuteClinic®

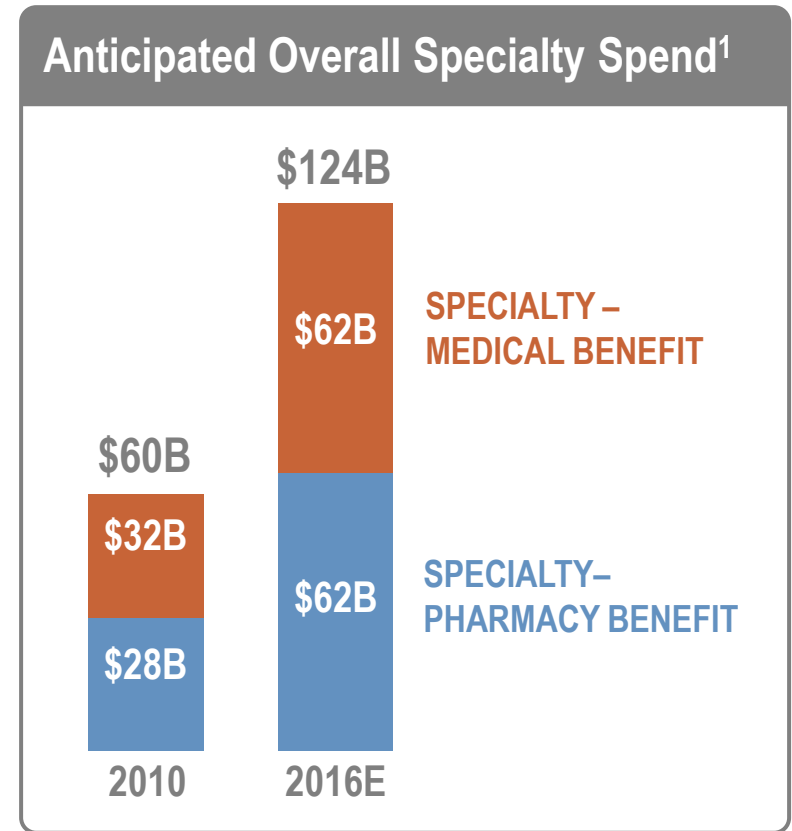
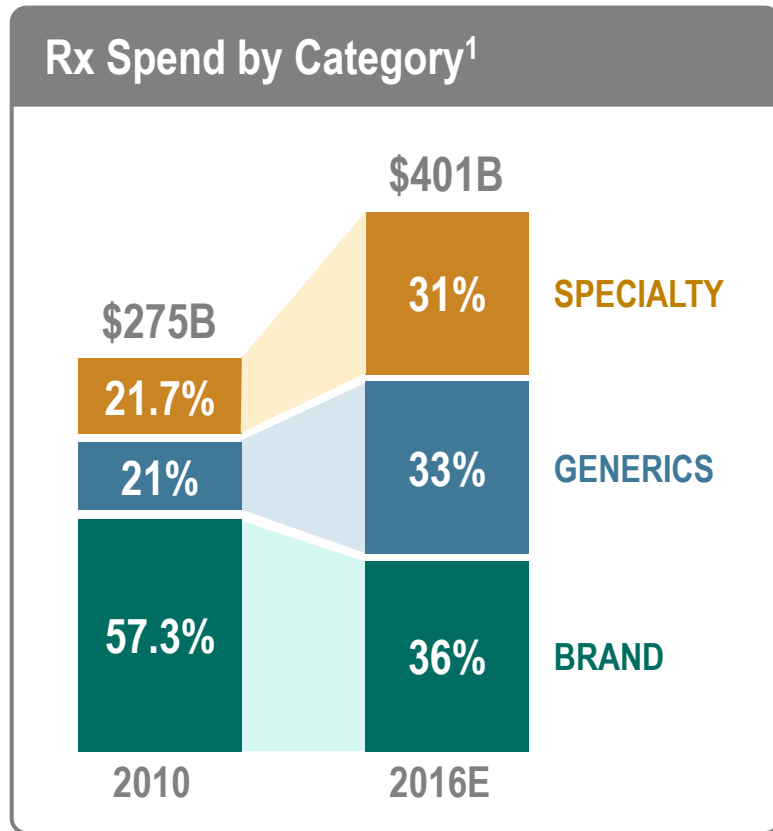
650 clinics, 14M patients served,  
affiliated with 20 major health systems

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# Fortune 18 company: resources and capital investments to better engage client members and manage costs

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# ■ Specialty Spend Expected to Double by 2016



**By 2016, eight of the top 10 drugs could be specialty<sup>2</sup>**

1. CVS Caremark BOB Data, CMS, IMS Health Report, US Census Bureau, Reuters, Credit Suisse, Buck Consultants, Health Affairs and National Health Spending Projections.

2. Kaiser Commission on Medicaid and the Uninsured; Kaiser Family Foundation; September 2011

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# Specialty Pharmacy Drug Trend

2011–2013E Specialty Pharmacy Compared to Non-Specialty Trend<sup>1,2</sup>



**Innovative management strategies are needed to achieve optimal value from specialty investments.**

1. Caremark book of business trend cohort; CVS Caremark Analysis, CVS Caremark Specialty Analytics, 2012.

2. 2011 CVS Caremark non-specialty drug trend, 2011 Caremark BOB trend cohort. Enterprise Analytics, 2012.

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# ■ Price, Mix and Utilization: Primary Drivers of Drug Trend



## Price

Overall cost of drug including what the client and member pay

### Influencers

- Inflation
- Source of drug
- Lack of product competition
- Site of service



## Drug Mix

Proportion of brand and generic drugs being dispensed

### Influencers

- Generics
- Formulary
- Pharmaceutical marketing
- New agents



## Utilization

Intensity of drug use; approval of new drugs or indications

### Influencers

- Changes in treatment guidelines
- Demographic and/or economic changes

# Specialty Pharmacists and Infusion Nurses Improve Access, Outcomes

## Expert CareTeams specializing in specific therapy classes

Pharmacists are better able to support members because they understand their challenges

## Personalized ongoing, high-touch member outreach

Educate members on condition and therapy; frequently assess adherence and effectiveness



## Physician outreach to help members start and stay on therapy

Provide alerts on adverse side effects or have dropped therapy

## High quality home infusion nursing care

National in-home and ambulatory nursing access and care coordination. Supports initiatives to move patients to the most cost effective site of care

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## Specialty pharmacy patients are 36% more likely to remain on therapy.<sup>1</sup>

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1. CVS Caremark vs. Other Specialty; Caremark Data Warehouse 2011, CVS Caremark Enterprise Analytics, 2012.

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# ■ Formulary Strategy Guiding Principles

- **Maintain clinical integrity**

- Target classes with sufficient generic availability, brands that are clinically interchangeable; evaluate specialty classes with similarity between chemical entities
- Safeguards in place for members requiring medical necessity exceptions; fewer than 2% of claims for removed products required a medical necessity exception\*

- **Secure competitive pricing for clients**

- Continually assess marketplace to identify opportunities for plan sponsors and members to save money through lower cost alternatives

- **Educate and engage members**

- Ensure members have access to the drugs they need to stay healthy and the resources necessary to support transition

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**Support clients' goals to reduce trend while providing comprehensive coverage for members**

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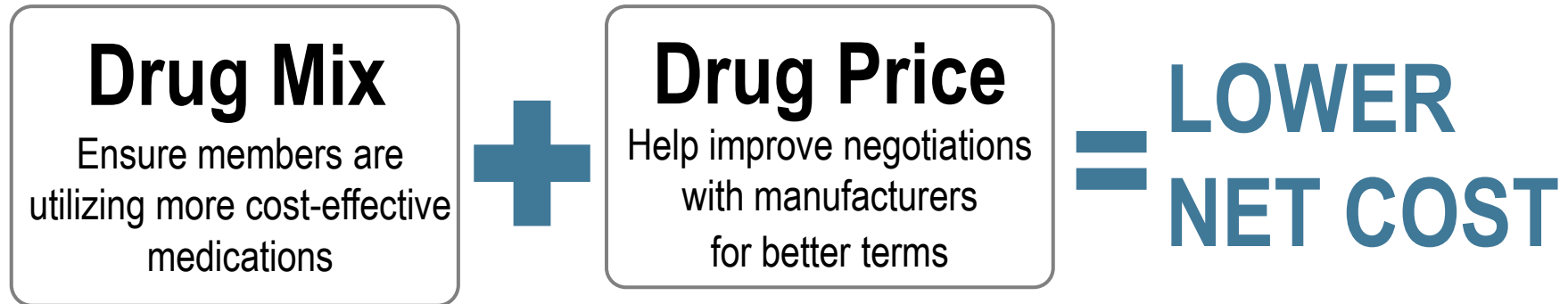
\*After 2013 formulary changes were implemented

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# ■ Formulary Can Enhance Plan Design and Help Mitigate Trend Increase

- Effective formulary strategy can help address specific influencers associated with two key trend drivers:



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**2013 average savings per transitioned prescription:  
Plan – \$42.72; Members – \$24.32**

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# ■ Utilizing Specialty Preferred Drug Plan Design

## Preferred Drug List

- Follows traditional three-tier benefit design
- Plan members incur higher copay on non-preferred drugs

## Step Therapy

- Preferred drug use required prior to non-preferred drug
- Real-time, evidence-based protocols and claims history for approval
- 24 month look-back period
- Clinical exceptions considered and reviewed
- Grandfathering is recommended for most therapies

## Closed Formulary

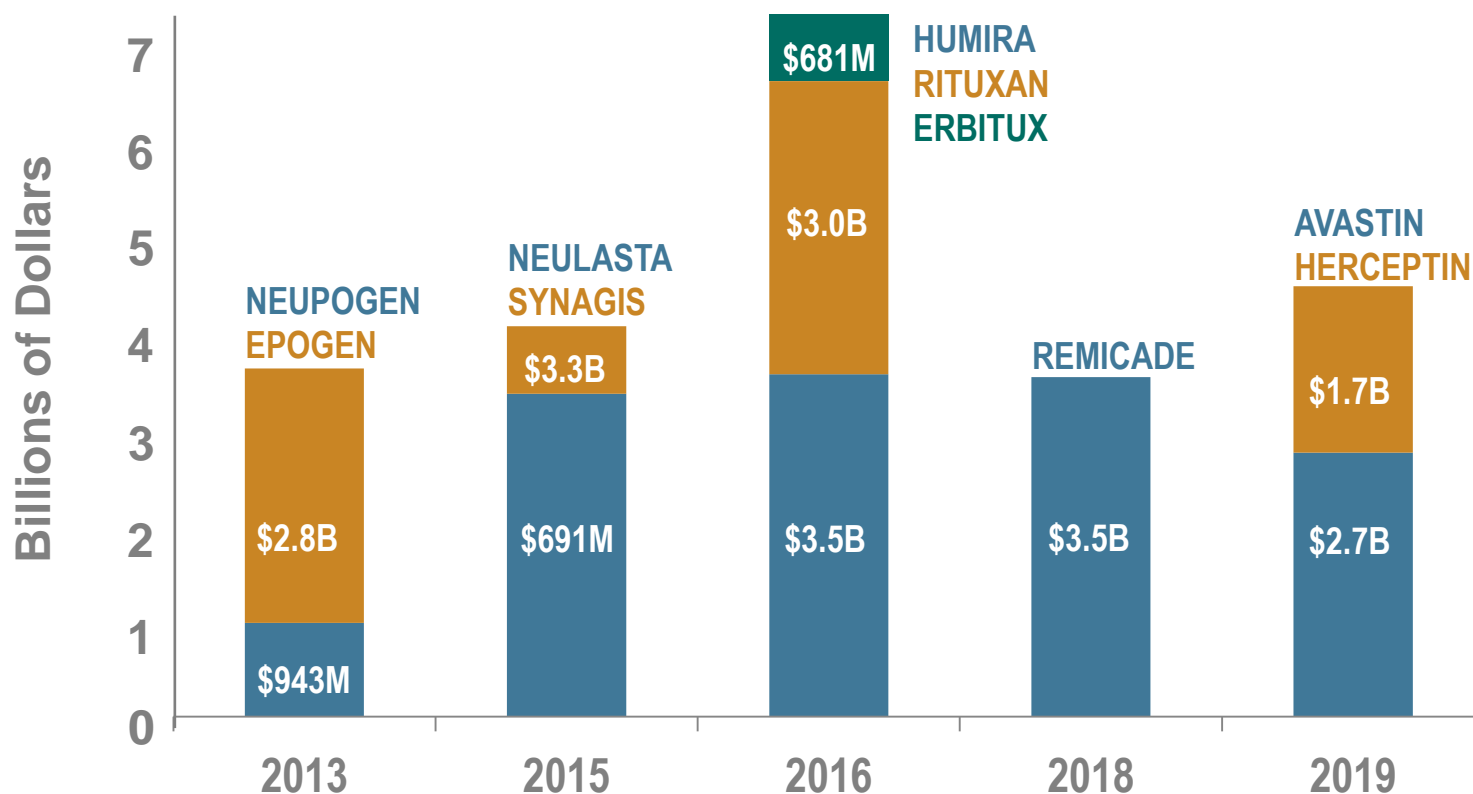
- Prescribed drug must be in the formulary for members to receive coverage
- Clinical exceptions considered and reviewed

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**Encourage clinically appropriate prescribing at the lowest net cost without sacrificing clinical outcomes**

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# Anticipated Biologic Patent Expirations



Initially, biosimilars are expected to have a 10 to 20 percent discount compared to the reference brand.

\*Based on 2011 IMS sales data

Gal R. Biosimilars: Reviewing US law and US/EU patents; bottom up model suggests 12 products and \$7-\$8B market by 2020. Bernstein Research. 26 May 2011.

This page contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

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# ■ Factors Impacting Biosimilar Adoption

- Biosimilar price differential
- Interchangeability
- Client benefit design:
  - Benefit coverage (pharmacy versus medical)
  - Member cost share differentials
  - Application of step therapy and restrictive formularies
- Physician acceptance behaviors
- Ease and effectiveness of payor conversion programs

# ■ Implications for Pharmacist Education

- Specialty Pharmacy market requirements and dynamics
- Unique regulatory requirements (i.e. REMS)
- Disease and therapy-specific education
- Complex drug regimens (i.e. specialty and non-specialty)
- Adherence management and outcomes improvement
- Drug waste management
- Prior authorization (PA) use and effectiveness
- Coordination of care (i.e. pharmacy and case management)

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**Additional education is required to prepare pharmacists for the biologic and biosimilar challenges**

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## PBM Summary

- Biologics have become the priority agenda for managing drug trend
- Biosimilars represent hope for payors as a means to mitigate trend through reduced cost
- Traditional management strategies can be leveraged to capture value
- Today's formulary approaches are being refined to maximize value from future Biosimilar approvals
- Additional pharmacist education is needed to prepare them for the world of biologics and their biosimilars