





Specialty Pharmacy Management

Board of Trustees Meeting

May 24, 2013

A Division of the Department of State Treasurer

Presentation Overview

- What are specialty drugs?
- Marketplace trends and projections
- Current benefits and financial summary
- Current specialty drug benefit management strategies
- Future strategies



What are Specialty Drugs?

State Health Plan Definition:

- Covered biotech and biosimilar medications
- Have unique uses for the treatment of complex diseases (Multiple Sclerosis, Rheumatoid Arthritis, Hepatitis)
- Require special dosing or administration
- Require special handling
- Typically prescribed by a specialist provider
- Exceed \$400 cost to the Plan

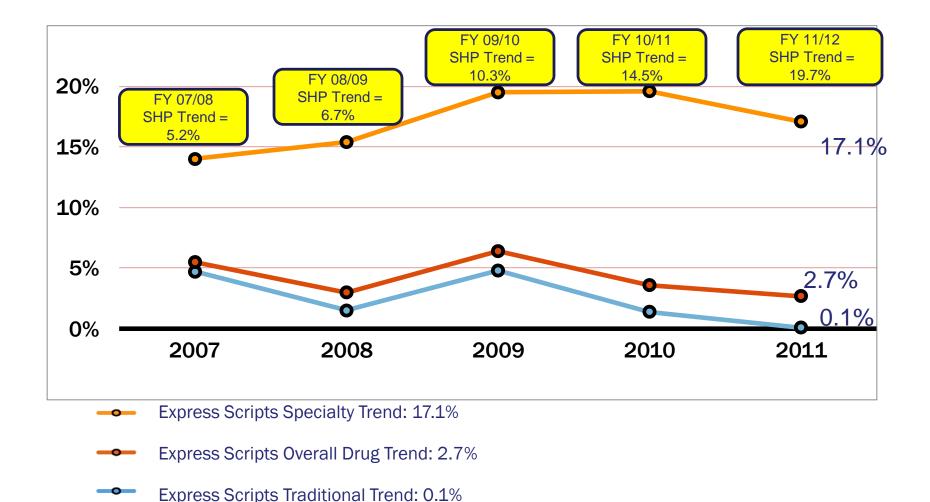
Specialty drugs are in the midst of a tremendous boom, with an annual yearly cost trend of 17%. Currently that is expected to grow to 22% by 2014.

Industry experts have predicted that specialty drugs will represent 45% of pharmaceutical sales by 2017.

Specialty drugs are billed under the pharmacy and medical benefit, and at multiple places of service under the medical benefit.

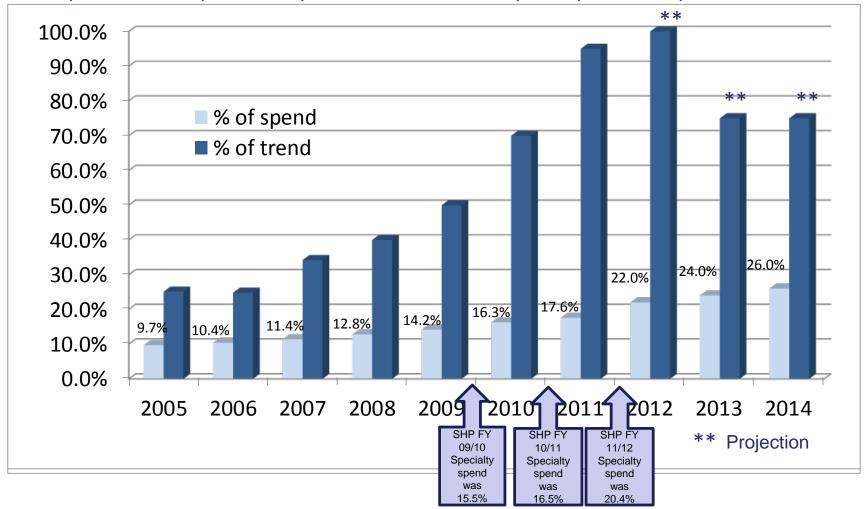


2011 Express Scripts Drug Trend as Compared to State Health Plan



Specialty Pharmacy Trend Projections

As a percent of Express Scripts book of business plan spend and percent of trend:





Current Specialty Drug Benefit

- All non-acute specialty medications covered under the pharmacy benefit must be obtained through Accredo, except for oncology medications.
- Pharmacy co-insurance of 25% up to \$100 max per 30 day supply.
- Most infused specialty medications are covered under the medical benefit managed by BCBSNC.
- When biosimilars become available the Plan may impose a higher specialty copay for non-preferred specialty medications. The maximum copay for the non-preferred specialty medications could be set higher than the preferred per 30-day supply.

Financial Summary*

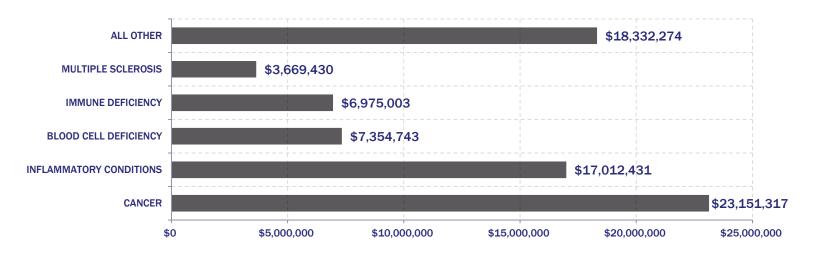
	7/11-3/12	7/12-3/13
Specialty Rx Plan Cost	\$108,233,392	\$120,662,841
Total PBM Plan Cost	\$535,473,480	\$550,265,155
Specialty Rx % of Plan Cost	20.2%	21.9%
Specialty Plan Cost PMPM	\$18.05	\$20.13
Members using specialty medication	8897	8896

^{*}Pharmacy Benefit only

- Average cost of specialty drug = \$3989/30 days
- Inflation is the top driver of trend some drugs have double digit inflation rates

Medical Specialty Claims

Top 5 Therapy Classes

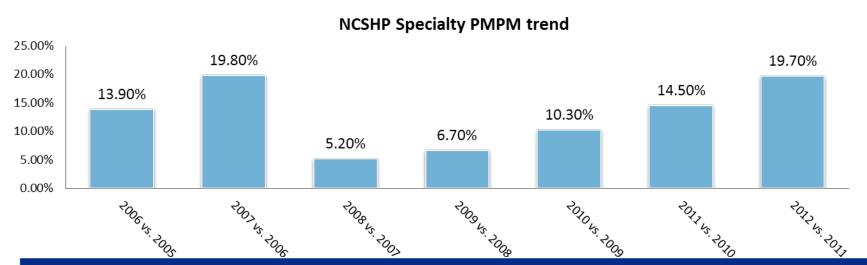


Rank	Therapy Class	Amount Allowed		Claims	
1	CANCER	\$23,151,317	30%	25,034	32%
2	INFLAMMATORY CONDITIONS	\$17,012,431	22%	7,494	10%
3	BLOOD CELL DEFICIENCY	\$7,354,743	10%	9,708	12%
4	IMMUNE DEFICIENCY	\$6,975,003	9%	1,749	2%
5	MULTIPLE SCLEROSIS	\$3,669,430	5%	1,253	2%
	ALL OTHER	\$18,332,274	24%	33,033	42%
TOTAL SPEND		\$76,495,199		78,271	

Based on spend from September 2011 through August 2012



Strategies Implemented and the Affect on Trend



Timeline of Specialty Management Strategies Enacted

<u>2012</u>: Fertility PTPA and Fertility Pureplay lock on 4/1/12. Medical/Pharmacy coverage delineation on 7/1/12. Hep-C PTPA to be implemented on 10/1/12, along with PA rules for IVIG, Acthar, and Firazyr.

2011: PA for PAH Drugs and Accredo Clinical Days Supply. Step Therapy for RA drugs implemented 11/1/11.

<u>2010</u>: Forteo Step Therapy implemented 4/1/10; **Note**: Pharmacy trend for Specialty is artificially lower in 2010 due to movement of IVIG to medical on 3/1/10 and *Synagis* to medical on 7/1/10.

2009: All chronic Specialty medications to be filled at Accredo and implemented Specialty Coinsurance Tier on 7/1/09.

<u>2008</u>: Implemented PA for MS Agents, *Revlimid/Thalomid* and Psoriasis Agents on 11/1/08. Main impact of the 11/1/07 Out of State Specialty provider removal was realized during 2008.

2007: Out of State Specialty providers removed from network on 11/1/07. Impact seen in 2008.

2006: No Specialty Strategies were implemented during this time.



Management Strategies

	2011-2012	2013-2014	2015 →
Unit Cost (AWP)	Improve pricing with current vendor	Re-evaluate pricing with annual market check	Bid for specialty pharmacy vendor
Network	Pharmacy - one vendor Medical - Limited vendors	Home infusion preferred network	Exclusive network (1-2) fo pharmacy and medical New CPC Vendor
Utilization Management	Additional prior authorization rules to include quantity limits and step therapy	rules to include quantity limits and step therapy	Incorporate genomic testin
Formulary/Specialty List	Expand list to include HIV &Transplant Increase rebates with preferred specialty products	Include oncology Increase rebates earned under pharmacy and medical benefit	Exclusive Rebates
Care Management	Coordination and referrals between Accredo and Active Health	management Improve medication	Integrated care manageme and data with all vendors
Buy and Bill/ Provider Reimbursement	Align reimbursement with specialty discount rates & remove prescribing reimbursement incentives	Eliminate specific drugs and TCs	Manage/limit buy and bill (exc. ONC)
Benefit Design	25% up to \$100 for pharmacy benefit	specialty tier Copay parity all channels	Place of service copay tier and incentives to cost- effective channels
Channel Management	Clearly delineate medical vs. pharmacy benefit Address self- administrable/rare disease	Include oncology Home infusion preferred network	Incent cost-effective channel for office-administered medications
Claims Adjudication	J-Code	J-Code + NDC crosswalk	J-Code + NDC crosswalk
Oncology Management	BCBSNC cost management program Active Health referrals to Accredo	Medical Channel Mgmt (Anemia, self-inj) Clinical coverage rules	Pharmacogenomic testing
Total Savings Range	(5%)	(5-10%)	(15+%)
i/11 spm	Denotes priorities		



Key Trends in Specialty

Specialty Pipeline¹



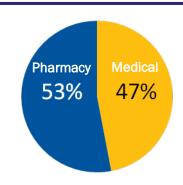
- 600+ drugs in the pipeline over the next5-8 years
- Oncology represents about 45% of the pipeline
- 35% of oncology and 64% of non-oncology may be self-administered

Biosimilars²



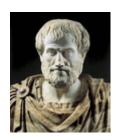
- 46 biotech products with patent expirations through 2020*
- \$31.5 billion biosimilar opportunity
- Interchangeable alternatives will greatly affect management options and cost

Medical Spend³



- Significant amount of specialty drug spend is on the medical benefit
- Frequently administered in high cost places of treatment
- Limited ability to apply critical health and safety checks

Bioethics



- Specialty pipeline will continue to produce high- cost drugs
- Growing impact on the viability of Benefit Plans
- Question of coverage for a small number of high cost patients vs. the whole patient population

³ Express Scripts 2011 Drug Trend Report



¹ Accredo Pipeline Database, Promising Phase II and Higher. Extracted October 4, 2011.

² U.S. Drug spend estimates are based on IMS Health data for 2009 (if available), manufacturer reported U.S. sales or a percent of manufacturer reported worldwide annual sales of the drug. Market availability of biosimilars based on expected patent expiration dates current as of November 2010 plus two years. Changes may occur due to litigation, patent challenges, or other factors. *Includes all drugs with patent expirations through 2011.

Near-term Pipeline Highlights

Cystic fibrosis

Bronchitol™ Levofloxicin Inh

> Clotting factors/ hematology

rFXIII Semuloparin

Cancer ~45% of pipeline

Actimid™ Clearazide® regorafenib carfilzomib Marqibo® ponatinib Zaltrap™ afatinib bosutinib Pixuvri™ cabozantinib tivozanib enzalutamide BiovaxID® Omapro™ trastuzumab-DM-1 perifosine

Cushing's syndrome

Pasireotide

Fabry disease

Amigal®

Familial amyloid polyneuropathy

Tafamidis

Familial Hypercholesterolemia

Lomitapide *Kynamro* ® **Gaucher disease**

Eliglustat

Growth hormone

LB03002 (sustained release)

Multiple sclerosis

Teriflunomide BG-12 *Lemtrada™* Daclizumab **Ocular**

Cystaran™ Voclosporin

Pulmonary arterial hypertension

QT 1571 Macitentan

Rheumatoid arthritis

Tofacitinib Fostamatinib Sarilumab Secukinmab

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Allovectin-7®

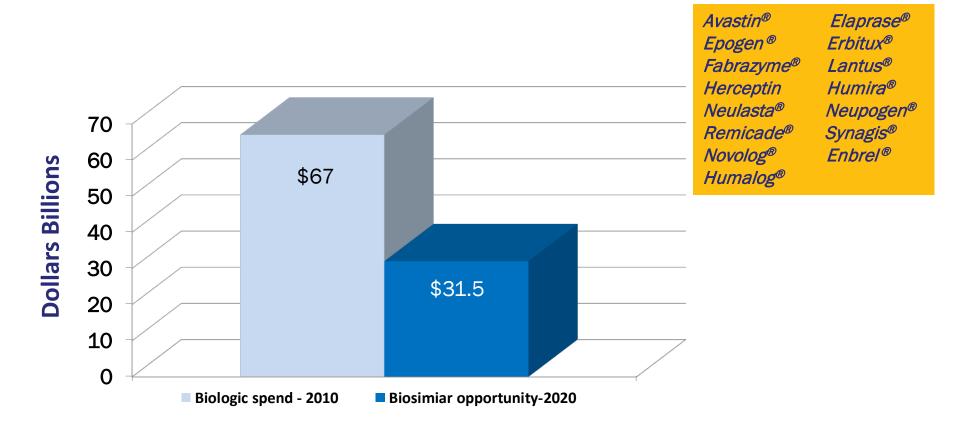
Examples of New Drugs 2012-2013

Drug	Route	Indication	Estimated annual cost*	Prevalence/comments
Tafamidis	Oral	Transthyretin Familial Amyloid Polyneuropathy (TTR-FAP)	\$75,000	8000 worldwide
Terifunomide	Oral	Multiple Sclerosis	\$45,000	350,000-400,000 Active metabolite of leflunomide
Tofacitinib	Oral	Rheumatoid arthritis	\$30,000	≈ 1.3 millionOral once or twice daily JAK-3 inhibitor
Dimethyl fumerate (BG-12)	Oral	Multiple Sclerosis	\$45,000	350,000-400,000 Oral drug given 3x daily
Gattex™ (teduglutide)	SC	Reduce need for IV feeding in patients with short bowel syndrome	\$20,000	10,000-15,000 SBS patients on home TPN for SBS Daily SC injection
Metreleptin	SC	Diabetes and/or hypertriglyceridemia in patients with rare forms of lipodystrophy	\$75,000	~2000 patients worldwide Analog of the human hormone leptin
Pasireotide	SC	Cushing syndrome/Acromegaly	\$30,000	3,000-5,000/15,000 – Very rare disorders; Somastatin analog (like lanreotide) with twice daily dosing



Biosimilars Opportunity

Biosimilars in development with possible patent expiration for reference product by 2020



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Future Potential Strategies

1) Benefit design

- Biosimilar/Preferred Specialty tier coinsurance
- Copay parity under pharmacy and medical channels

2) Medical management

- Reimbursement methods medication and cognitive services
- Site of care management preferred home infusion network

3) Utilization management

- Additional prior authorization rules
- Incorporate genomic testing

4) Oncology management

- Limited retail network
- Care management programs
- Utilization management

