



Overview of Specialty Pharmacy

Kevin Colgan, MA , FASHP
Corporate Director of Pharmacy
Rush University Medical Center

Conflicts of Interest

- Chair, UHC Specialty Pharmacy Committee
- Wife is a Specialty Pharmacist with Express Scripts - Accredo

Overview Agenda

- Why manufacturers and insurers choose Specialty Pharmacy providers
- Market Trends
- Competition
- Limited Distribution Drugs
- Biosimilars
- Where to start

My Definition of a Specialty Pharmaceutical

- Costs > \$750 per monthor
- Treats a rare conditions.....or
- Requires special handling.....or
- Requires special monitoring.....or
- Used in a limited distribution network.....or

Why manufacturers and insurers choose Specialty Pharmacy providers

- Eliminate distribution costs
- Access to data
- REMS
- Integration with a reimbursement hub
- Training patients on how to self- administer drugs
- Advising health plan providers on how to manage and implement access to new pharmaceutical products as they enter the marketplace
- Finding co-payment assistance or alternative coverage for the patient
- Perception of increased quality of patient management

Which of the following are true concerning specialty pharmaceutical drug trends?



A

Anticipated annual growth is $\approx 20\%$

B

Cancer, multiple sclerosis and growth hormone account for 58% of the specialty market

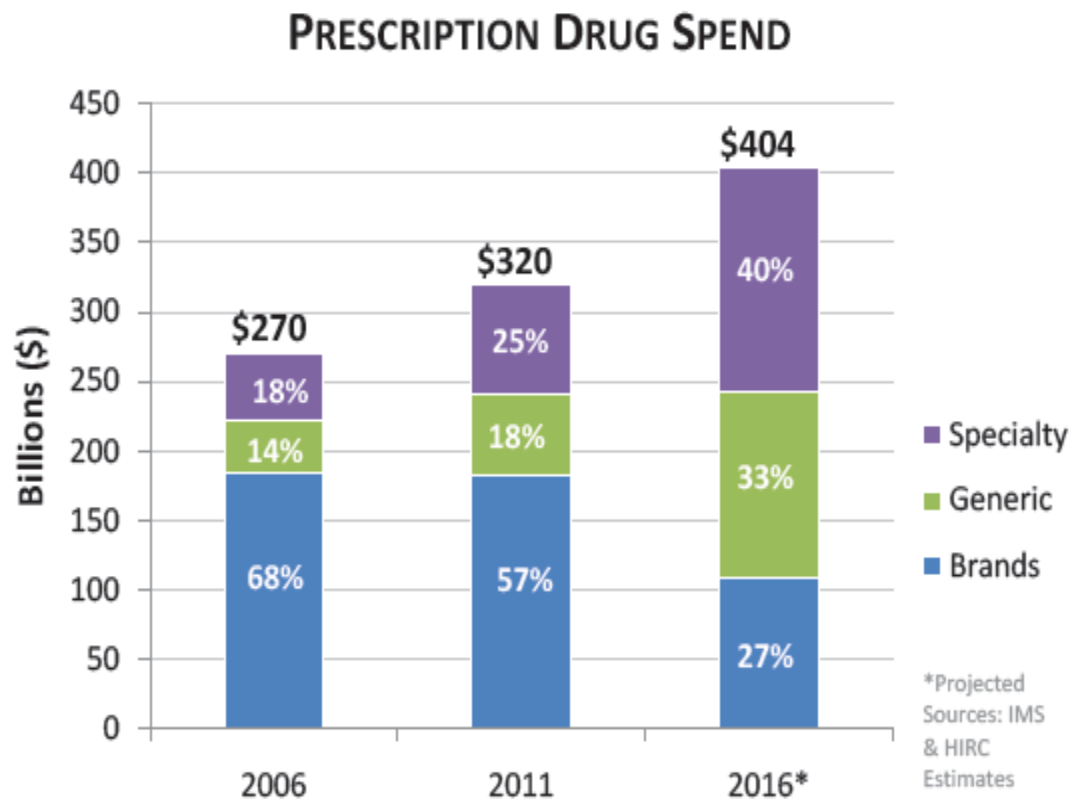
C

Specialty pharmaceuticals are 40% of the US drug market

D

All of the above

Growth of Specialty Market



>50% of late-stage pipeline drugs and >70% of applications for new indications are for specialty drugs

Specialty vs Overall Drug Trends 2012

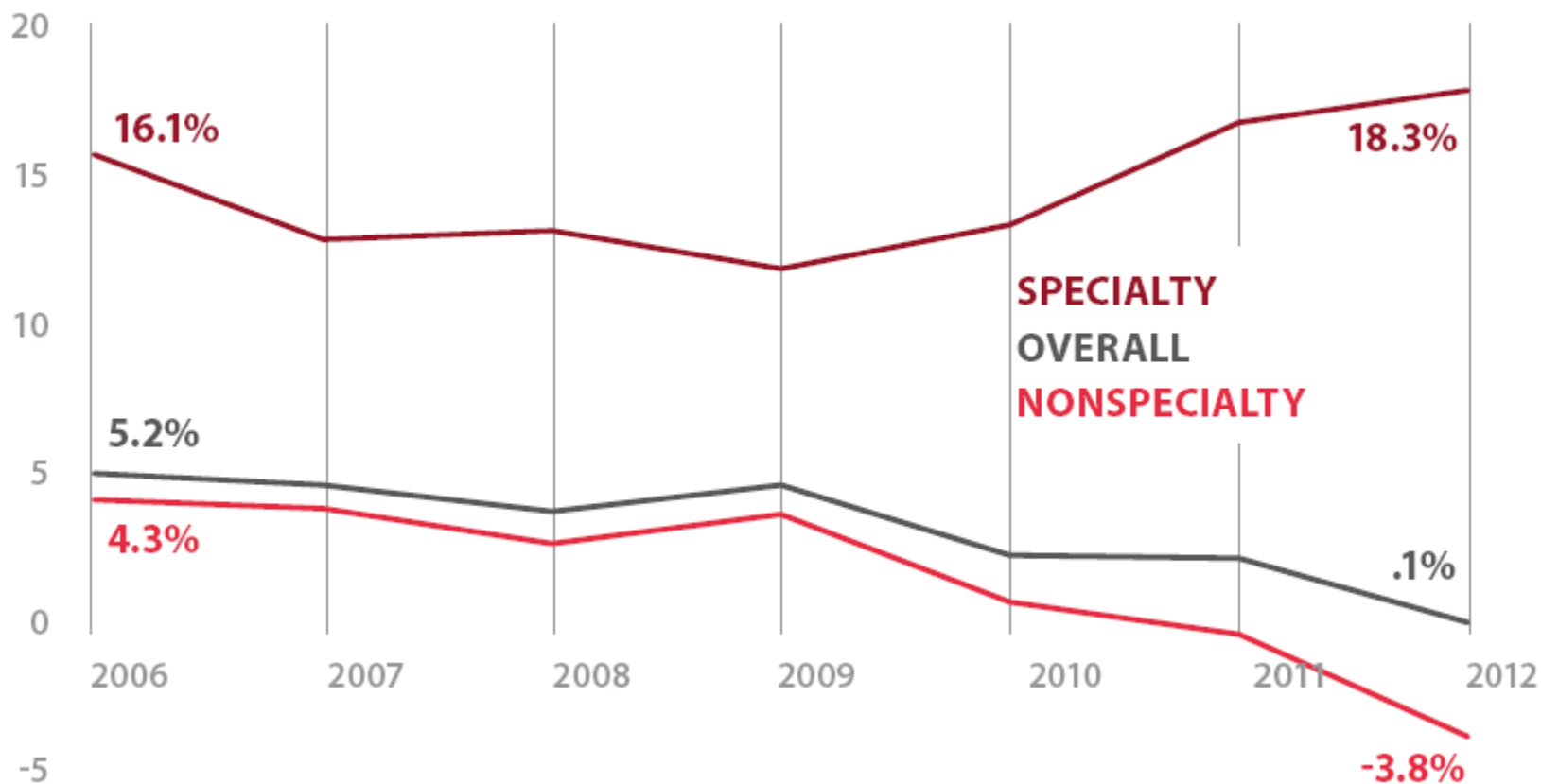
Specialty Trend	Express Scripts	CVS Caremark*	Prime Therapeutics
Utilization	-0.4%	+3.6%	+4.8%
Drug Cost	+18.7%	+15.8%	+12.6%**
Total SP Drug Trend	+18.4%	+18.6%	+19.1%
% of Total Spend Specialty Pharmacy	24.5%	19.9%	NR
Overall Drug Trend	+2.7%	+1.7%	+2.1%

*Utilized Net Findings

** Represents price increase. Does not include mix adjustment for use of higher cost products.

Drug Trends

CVS CAREMARK BOB TREND COMPARISON



Predicted Future Trends in Specialty Pharmaceuticals

Drug Trend Forecasts, 2013-2015

Forecast	2013	2014	2015
Overall Drug Trend			
• CVS Caremark	+1% to +5%	+2% to +7%	+4% to +9%
• Express Scripts	n.a.	n.a.	n.a.
Traditional (Non-specialty) Drug Trend			
• CVS Caremark	-2.5% to +0.5%	-2.5% to +1.5%	0% to +4%
• Express Scripts	-1.0%	-1.7%	-1.4%
Specialty Drug Trend			
• CVS Caremark	+15% to +26%	+17% to +28%	+16% to +26%
• Express Scripts	17.8%	19.6%	18.4%

Source: Pembroke Consulting analysis of company drug trend reports.

n.a. indicates that forecast was not provided.

Forecasts are defined by each company as follows:

- CVS Caremark: "per-member per-year (PMPY) gross cost increase"
- Express Scripts: "year-over-year change in per-member, per-year (PMPY) plan costs"

Published on Drug Channels (www.DrugChannels.net) on May 28, 2013.

Predicted Future Trend in Specialty Pharmaceuticals

Top 10 U.S. Drugs, 2012 vs. 2018E

2012			2018E		
Product	Company	Sales (\$B)	Product	Company	Sales(\$B)
Humira	Abbvie	\$4.4	Humira	Abbvie	\$5.6
Abilify	Otsuka Holdings	4.1	Lantus	Sanofi	5.3
Seretide/Advair	GlaxoSmithKline	4.0	Enbrel	Amgen	4.5
Lantus	Sanofi	4.0	Januvia/Janumet	Merck & Co	4.2
Enbrel	Amgen	4.0	Remicade	Johnson & Johnson	4.1
Cymbalta	Eli Lilly	3.9	Revlimid	Celgene	3.6
Remicade	Johnson & Johnson	3.6	Sofosbuvir	Gilead Sciences	3.6
Rituxan	Roche	3.3	Lyrica	Pfizer	3.0
Neulasta	Amgen	3.2	Eylea	Regeneron	2.9
Crestor	AstraZeneca	3.2	NovoRapid	Novo Nordisk	2.8
Top 10 Total		\$37.6	Top 10 Total		\$39.7

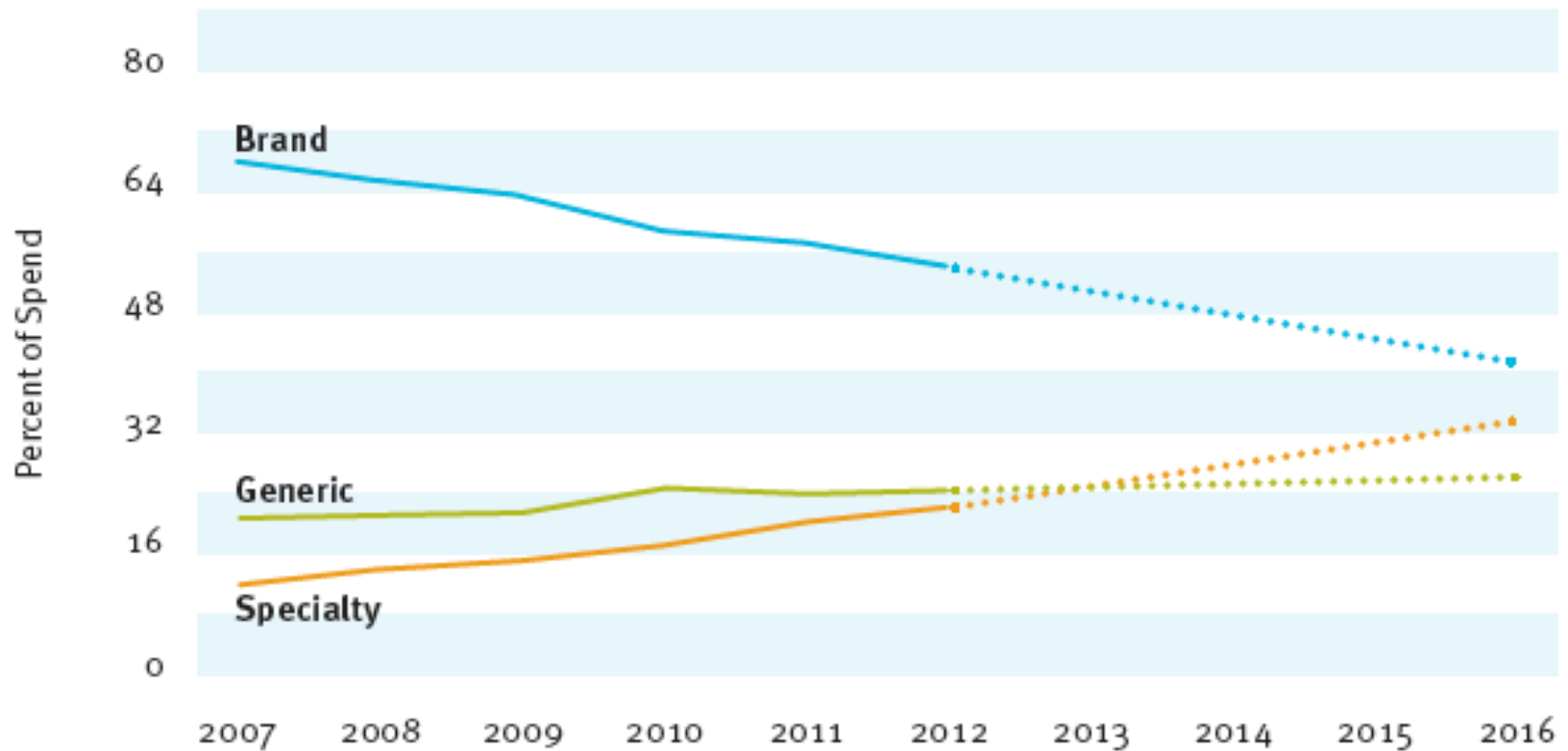
Totals may not sum due to rounding.

Sources: Pembroke Consulting analysis of *World Preview 2013*, *Outlook to 2018*, EvaluatePharma, July 2013.

Published on Drug Channels (<http://www.DrugChannels.net>) on August 13, 2103.

When will Specialty Pharmacy Eclipse 50% of the Total Drug Spend?

Fig. 17 Pharmacy Benefit Spend, by Drug Type (projected)



Health Systems Business Case:

With this kind of growth don't we need a SP in an ACO environment?

Commercial Insurance Drug Trend

SPECIALTY TREND BY THERAPY CLASS

Components of Trend for the Top 10 Commercial Specialty Therapy Classes, Ranked by PMPY Spend, 2012

		TREND		
THERAPY CLASS	PMPY SPEND	UTILIZATION	UNIT COST	TOTAL
Inflammatory Conditions	\$50.62	9.0%	14.0%	23.0%
Multiple Sclerosis	\$37.98	0.5%	17.3%	17.8%
Cancer	\$31.98	3.4%	22.3%	25.8%
HIV	\$20.78	-2.1%	11.1%	9.0%
Hepatitis C	\$7.82	28.9%	4.8%	33.7%
Growth Deficiency	\$7.41	1.7%	7.7%	9.5%
Anticoagulant	\$6.74	1.7%	0.3%	2.1%
Pulmonary Hypertension	\$5.71	5.1%	6.2%	11.3%
Respiratory Conditions	\$5.56	1.5%	25.7%	27.2%
Transplant	\$4.92	2.2%	-6.9%	-4.7%
Other	\$27.68	-24.9%	43.7%	18.8%
TOTAL SPECIALTY	\$207.19	-0.4%	18.7%	18.4%

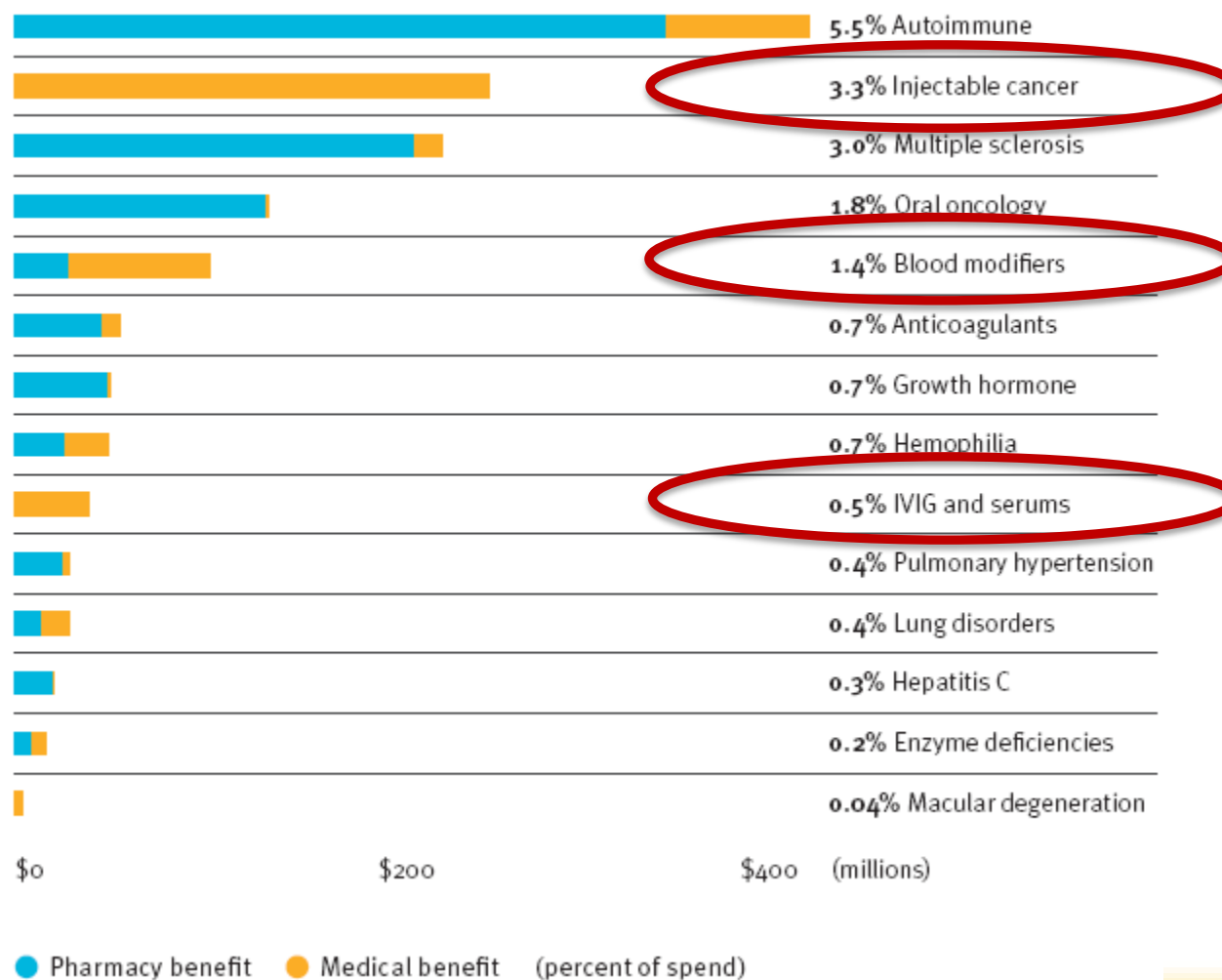
Source: Express Scripts August 2013 Drug Trend Report

Drug Trends

Biotech Class	Ave Cost/Rx	Top Drugs/ Market Share		Percent Covered Under Medical Benefit 2012	Percent Covered Under Medical Benefit 2011
Anti-inflammatory	\$2213	Humira	43%	31.9%	31.8%
		Enbrel	42%		
Multiple Sclerosis	\$3584	Capoxone	34%	10.5%	9.6%
		Avonex	19%		
		Rebif	15%		
Cancer	\$3682	Methotrexate	18%	76.5%	77.6%
		Gleevec	12%		
		Xeloda	10%		
		Revlimid	10%		
		Lupron Depot	9%		

Prescription vs. Medical Drug Benefit

Fig. 20 Total Specialty Drug Spend, by Benefit Type, 2Q2010–2Q2011



Source: Prime Therapeutics 2012 Drug Trend Insights Report

Medicare Drug Trend

SPECIALTY TREND BY THERAPY CLASS

Components of Trend for the Top 10 Medicare Specialty Therapy Classes, Ranked by PMPY Spend, 2012

		TREND		
THERAPY CLASS	PMPY SPEND	UTILIZATION	UNIT COST	TOTAL
Cancer	\$108.39	11.8%	21.1%	32.8%
Multiple Sclerosis	\$51.68	8.5%	18.2%	26.7%
Inflammatory Conditions	\$47.69	7.4%	13.0%	20.4%
HIV	\$30.31	1.6%	9.1%	10.7%
Pulmonary Hypertension	\$25.58	9.8%	4.0%	13.8%
Anticoagulants	\$16.57	1.0%	3.7%	4.7%
Hepatitis C	\$10.83	63.5%	46.9%	110.4%
Immune Deficiency	\$10.63	34.6%	-0.8%	33.8%
Blood Cell Deficiency	\$10.43	-8.2%	8.0%	-0.2%
Osteoporosis	\$9.52	9.1%	2.9%	12.0%
Other	\$32.00	-28.1%	55.2%	27.1%
TOTAL SPECIALTY	\$353.62	-2.7%	26.8%	24.1%

Source: Express Scripts August 2013 Drug Trend Report

Which of the following are true concerning specialty pharmaceutical drug trends?



A

Anticipated annual growth is $\approx 20\%$

B

Cancer, multiple sclerosis and growth hormone account for 58% of the specialty market

C

Specialty pharmaceuticals are 40% of the US drug market

D

All of the above

Insurance Trends

- Increase in prior authorization (PA)
- Shift to co-insurance versus copay
- Blocking copay coupons
 - ≈500 pharmaceutical brands participate in copay offset programs
 - Usually found in regions with the most restrictive PA program
 - United Healthcare announced that pharmacies in its Specialty Pharmacy Designate Network will no longer redeem coupons for Extavia, Gilenya, Cellcept, Humira, Victrelis, and PegIntron.
- Adding benefit tiers – 4 tier design
- Income-based benefit design
- Performance guarantees from manufacturers

Insurance Trends

- Risk arrangements with providers (P-4-P for following national guidelines)
- More comparative data in crowded categories (RA, MS)
- Cancer treatment – preferred agents in specific categories
- Having office administered drug purchased from the plan's specialty pharmacy
- Integration of pharmacy and medical benefits for specialty
- High deductible plans are now the primary benefit offering for 13% US employers – up from 3% in 2006 (Source: CVS Caremark 2013 focus)
- Step therapy & quantity limits
- *Reference pricing – utilized in other countries*

Insurance Trends

Fig. 24 **Example Best-Practice Benefit Design**

Tier	Drug type	Copay/Coinsurance
1	Generics	\$5 – 15
2	Preferred brand	\$40
3	Preferred specialty/ Non-preferred brand	\$75 – 100
4	Non-preferred specialty	50% coinsurance with \$200 max; min. at least \$50 greater than tier 3

True or False:



Contracting with a regional specialty pharmacy is an option for gaining access to provider contracts and limited distribution drugs?

A

True

B

False

Competition– Everyone has a strategy!

- Large insurers have established their own specialty pharmacy programs – Aetna Specialty, Cigna Tel-Drug, & WellPoint Precision Rx
- Independent retail community pharmacies are organizing into collaborative networks.
- Regional and national chains are launching specialty programs. (Costco, Safeway, Giant Eagle)
- There are 10 private, independent specialty pharmacies on the 2011 Inc. magazine list of the fastest growing companies in the US. (Diplomat, Avella, MedPro Rx)
- Private equity firms are targeting specialty pharmacy for growth capital investments. (Altamont Capital & MODERN HEALTHcare; Bourne Capital Partners, November, 2011 Sector Report)

Market Forces & Competition

- Market consolidation – Express Scripts/Medco, CVS/Caremark, & Walgreens/BioScripts
- These 3 companies generate 65% of the revenues from pharmacy-dispensed specialty drugs
- All have PBMs except for Walgreens
- Benefit Manager Profit is 10 – 15% on Specialty Drugs (New York Times)
- Traditional “buy and bill” specialty pharmaceutical business is being carved away from academic medical center clinics and restricted to preferred specialty pharmacies – “*white bagging*”
- Wholesalers are diversified. McKesson’s Onmark GPO & US Oncology. ABC’s International Oncology Network. Cardinal’s OncoSource Rx and Specialty Pharmacy Alliance

Limited Distribution Drugs

July 2013



Summary:
290 products
84 LD
29% LD

Specialty Pharmacy Drug List

Providing one of the broadest offerings of specialty pharmaceuticals in the industry

If you are a plan member or health care provider, please contact Specialty Customer Care toll-free at 1-800-237-2767 or visit www.cvscaremarkspecialtyrx.com.

With nearly 35 years of experience, CVS Caremark Specialty Pharmacy provides quality care and service. We have a network of pharmacies which includes those with Joint Commission and URAC accreditation. The Joint Commission and URAC are nationally-recognized symbols of quality which reflects an organization's commitment to meet high standards of quality and safety.

ACROMEGALY

octreotide acetate
 (SANDOSTATIN)¹
 Sandostatin LAR
 Somatuline Depot*
 Somavert*

ALCOHOL DEPENDENCY

Vivitrol

ALLERGIC ASTHMA

Xolair*

DUPUYTREN'S CONTRACTURE

Xiaflex*

GASTROINTESTINAL DISORDERS-OTHER

Solesta*

GOUT

Krystexxa*

GROWTH HORMONE & RELATED DISORDERS

HEMOPHILIA, cont..

Kogenate FS
 Monoclate-P
 Mononine
 NovoSeven²
 Profilnine SD
 Proplex T
 Recombinate
 Refacto
 RiaSTAP
 Stimite
 Wilate
 Xyntha²

HIV MEDICATIONS

abacavir tab (ZIAGEN)^{1,2}
 Aptivus
 Atripla
 Complera
 Crixivan
 didanosine (VIDEX,
 VIDEX EC)^{1,2}
 Edurant
 Egrifta*
 Emtriva
 Epzicom
 Fuzeon
 Intolence

HORMONAL THERAPIES

Eligard
 Firmagon
 leuprolide acetate
 (LUPRON)¹
 Lupron Depot²
 Supprelin LA*
 Trelstar²
 Vantas
 Viadur
 Zoladex

IMMUNE DEFICIENCIES

Limited Distribution Drugs

U-M PRESCRIBERS:
FAX ALL SPECIALTY RX TO UM
SPECIALTY PHARMACY: 734-232-3408

UNIVERSITY OF MICHIGAN
U-M Prescription Drug Plan
2013 SPECIALTY DRUG LIST

PRESCRIBERS OUTSIDE U-M:
FAX ALL SPECIALTY RX TO
WELLPARTNER: 877-597-3070

The 2013 University of Michigan Specialty Drug List is a guide to covered medications for you and your physician. A "specialty drug" is a prescription drug that a University of Michigan committee of physicians and pharmacists has determined to be any one of the following: a self-injectable medication (non-insulin); a medication that requires special handling, special administration or monitoring; or, is a high cost oral medication. The U-M Specialty Drug List includes select medications used to treat a variety of clinical conditions. This list is subject to change by the University of Michigan.

Prescriptions for medications on the U-M Specialty Drug List may be dispensed in quantities up to a 34-day supply. Specialty medications in the Immunosuppressive category may be dispensed in quantities up to a 90 day supply.

How to Use This List

Show this list to your doctor if you are using any of the specialty medications listed. If a medication requires prior authorization (PA), it is noted next to the drug name. To obtain medication PA, physicians can call the MedImpact Contact Center at 800-681-9578. U-M prescribers should fax specialty drug prescriptions to the U-M Specialty Pharmacy at 734-232-3408 or call toll-free 855-276-3002. Prescribers outside the U-M Health System should fax specialty drug prescriptions to Wellpartner at 877-597-3070 or call toll-free 888-222-8956. Medications marked with (LD) are limited distribution drugs which may not be available at U-M Pharmacies or Wellpartner. Check with your doctor for information on how to obtain these medications. Medications marked with (UM only) are currently only covered at U-M Pharmacies. For more information, members can call MedImpact at 800-681-9578 or visit <https://mp.medimpact.com/umh>. Telecommunications Relay Service (TRS) is available for persons who are deaf by dialing 711.

BEST BUYS: Generic medications (Tier 1) are bold type. Preferred brand name medications (Tier 2) are bulleted (*). All other medications are non-preferred (Tier 3). Visit benefits.umich.edu/plans/drugs/index.html.

Cancer Drugs - Oral

- Afinitor
- Bosulif (PA)
- Caprelsa (vandetanib) (LD)
- Cometriq (LD)
- Erivedge (UM only)
- Gleevec
- Hexalen
- Hycamtin (UM only)
- Iclusig (PA) (UM only)
- Inlyta (UM only)
- Nexavar (UM only)
- Pomalyst (PA) (UM only)
- Revimid (UM only)
- Sprycel
- Stivarga (PA) (UM only)
- Sutent
- Tabloid (thioguanine)
- Tarceva (UM only)
- Targretin (oral capsules)
- Tasigna
- Temodar
- Thalomid (UM only)
- tratinol (capsules)
- Tykerb (UM only)
- Votrient (UM only)
- Xalkori (PA) (UM only)
- Xeloda
- Xtandi (UM only)
- Zelboraf (PA) (UM only)
- Zolanza
- Zytiga

Cancer Drugs - Injection

- Eligard (leuprolide acetate) 7.5 mg subcutaneous; males only
- Firmagon; males only
- Intron-A
- leuprolide acetate (Lupron) - subcutaneous form only
- Sylatron

CAPS (Cryopyrin-Associated Periodic Syndromes)

- Arcalyst (PA) (LD)
- Ilaris (PA) (UM only)
- Kineret (PA)

Cystic Fibrosis

- Cayston (LD)
- Kalydeco (PA)
- Pulmozyme
- Tobi

Growth Hormone

Prior Authorization (PA) required

- Genotropin
- Humatrope
- Increlex (LD)
- Norditropin
- Nutropin (UM only)
- Nutropin AQ (UM only)
- Omnitrope
- Saizen
- Serostim (UM only)
- Tev-Tropin
- Zorbtive (UM only)

Hematopoietic

- Aranesp (PA)
- Epogen (PA)
- Leukine
- Mozobil (PA)
- Neulasta
- Neumega
- Neupogen
- Procrit (PA)
- Promacta (UM only)

Hepatitis B

- Baraclude
- Hepsera
- Tyzeka

Hepatitis C

- Copegus (ribavirin) (UM only)
- Inciweb (PA)
- Infergen
- Pegasys
- PegIntron
- Rebetol (ribavirin) (UM only)
- Ribasphere (ribavirin)
- ribavirin
- Victrelis (PA)

Immunosuppressive

Prescriptions for these medications covered up to a 90 day supply

- CellCept (tier 3; oral solution=tier 2)
- cyclosporine
- cyclosporine modified
- Gengraf (cyclosporine modified)
- mycophenolate mofetil
- Myfortic
- Neoral (cyclosporine)
- Prograf (tacrolimus)
- Rapamune
- Sandimmune (cyclosporine)
- tacrolimus, Hecoria
- Zortress

Infertility

- Crinone
- Endometrin

Maximum lifetime family benefit = \$5,000. Prior Authorization (PA) required if age ≥45 years.

[Click here for more information](#)

- Bravelle (UM only)
- Cetrodide (UM only)
- chorionic gonadotropin
- Follistim AQ
- Ganirelix Acetate
- Gonal-f
- Gonal-f RFF
- Gonal-f RFF Pen
- Menopur
- Novarel (chorionic gonadotropin)
- Ovidrel
- Pregnyl (chorionic gonadotropin)
- Repronex

Multiple Sclerosis

- Ampyra (tablets only) (PA) (LD)
- Aubagio (PA) (LD)
- Avonex
- Betaseron
- Copaxone
- Gilenya (PA)
- Rebif
- Tecfidera (PA) (LD)

Rheumatoid Arthritis/ Crohn's Disease/Psoriasis

Prior Authorization (PA) required

- Cimzia
- Enbrel
- Humira
- Kineret
- Orencia - subcutaneous form only
- Simponi
- Xeljanz

Pulmonary Hypertension

- Adcirca (PA)
- Letairis (LD)
- Revatio (PA)
- sildenafil 20 mg (PA)
- Tracleer (LD)
- Tyvaso (PA) (LD)
- Ventavis (PA) (LD)

Miscellaneous

- Actimmune (UM only)
- Apokyn (LD)
- Cafcit (caffeine citrate) - oral solution only
- Exjade (UM only)
- Ferriprox (LD)
- Firazyr (UM only)
- Forteo
- Jakafi (UM only)
- Juxtapid (PA) (LD)
- Kuvan (UM only)
- Kynamro (PA) (LD)
- Metopirone (LD)
- octreotide acetate
- Orfadin (LD)
- Ravioti (LD)
- Rilutek
- riluzole
- Sabril (LD)
- Sandostatin (octreotide acetate)
- Sandostatin LAR Depot (octreotide)
- Sensipar
- Signifor (LD)
- Somatuline Depot (PA)
- Somavert (PA) (LD)
- Synarel
- Xenazine (PA) (LD)
- Xolair (PA) (UM only)
- Xyrem (LD)
- Zavesca (LD)
- Zemplar

Summary:
152 products
25 LD
16.4% LD

True or False:



Contracting with a regional specialty pharmacy is an option for gaining access to provider contracts and limited distribution drugs?

A

True

B

False

Biosimilars

- Spending on 11 drugs estimated to increase from \$33.6 B in 2014 to \$121 B in 2024
- If the FDA were to approve 11 biosimilars spending in 2024 would be \$81.3 B
- Cumulative savings modeled at \$250 B

Table. Drugs Included in Express Scripts' 10-Year Biosimilar Savings Model

Brand	Generic	Manufacturer	Approval	Patent Expiration	2012 Sales
Avastin	Bevacizumab	Genentech	02/06/2004	06/18/2019	\$2,662,842,000
Epogen	Epoetin alfa	Amgen	06/01/1989	05/26/2015	\$2,254,245,000
Herceptin	Trastuzumab	Genentech	09/25/1998	08/27/2019	\$1,837,693,000
Humira	Adalimumab	AbbVie	12/31/2002	12/31/2016	\$4,505,380,000
Intron A	Interferon alfa-2a	Merck	06/04/1986	08/26/2020	\$94,009,000
Neulasta	Pegfilgrastim	Amgen	01/31/2002	10/20/2015	\$3,472,988,000
Neupogen	filgrastim	Amgen	02/20/1991	11/10/2013	\$1,007,172,000
PegIntron	Peginterferon alfa-2b	Merck	01/19/2001	08/26/2020	\$121,828,000
Procrit	Epoetin alfa	Janssen	06/01/1989	05/26/2015	\$1,127,024,000
Remicade	Infliximab	Janssen Biotech	08/24/1998	09/04/2018	\$3,796,422,000
Rituxan	Rituximab	Genentech	11/26/1997	07/05/2015	\$3,183,625,000

Source: Express Scripts

Biosimilars

- Core areas for biologicals include insulin, anti-TNF, Oncology Mab, EPO and MS.
- No US pathway – FDA yet to finalize three draft guidance's
 - EU has had guidance since 2005 – 13 products approved
- Lots of activity
 - Teva is developing its first biosimilar version of rituximab
 - Pfizer has signed a deal with Biocon (India) to manufacture biosimilar insulin
 - Merck has signed a deal with Parexel to bring 5 biosimilar products
 - Biogen Idec, Samsung and Merck have a joint venture
 - Sandoz has five products in Phase III – filgrastim, Pegfilgrastim, EPO, etanercept for psoriasis, rituximab for follicular lymphoma
- Start with one indication and then expand to others (e.g. Rituximab – NHL, CLL, RA)
- Likely more open to new channels of distribution

Part D plans are required by law to
allow “Any-Willing-Provider?”



A

Yes

B

No

Where to start?

- Consider if your health system is large enough – how many prescriptions do you produce?
- What structure is best for you?
 - Do you need a partner for access to SP's and/or payer contracts?
 - Do you need to belong to a network?
- Focus on Medicare if you don't have any commercial contracts for SP – Medicare Prescription Drug, Improvement & Modernization Act of 2003 allows for “Any-Willing-Provider” for PDP. However, PDP can set up restrictive programs to steer patients in-network.
- Focus on cancer, multiple sclerosis and inflammatory diseases – almost 60% of the market
- Focus on opportunity – new group of Hepatitis C and prostate CA drugs are in the immediate pipeline

Part D plans are required by law to
allow “Any-Willing-Provider?”



A

Yes

B

No

Тяк и ти!