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 month .................................or
- Treats a rare condition.................................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 ≈ 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
<table>
<thead>
<tr>
<th>Specialty Trend</th>
<th>Express Scripts</th>
<th>CVS Caremark*</th>
<th>Prime Therapeutics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utilization</td>
<td>-0.4%</td>
<td>+3.6%</td>
<td>+4.8%</td>
</tr>
<tr>
<td>Drug Cost</td>
<td>+18.7%</td>
<td>+15.8%</td>
<td>+12.6%**</td>
</tr>
<tr>
<td>Total SP Drug Trend</td>
<td>+18.4%</td>
<td>+18.6%</td>
<td>+19.1%</td>
</tr>
<tr>
<td>% of Total Spend Specialty Pharmacy</td>
<td>24.5%</td>
<td>19.9%</td>
<td>NR</td>
</tr>
<tr>
<td>Overall Drug Trend</td>
<td>+2.7%</td>
<td>+1.7%</td>
<td>+2.1%</td>
</tr>
</tbody>
</table>

*Utilized Net Findings

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

CVS CAREMARK BOB TREND COMPARISON

Source: CVS Caremark 2013 Drug Trend Focus Report
# Predicted Future Trends in Specialty Pharmaceuticals

## Drug Trend Forecasts, 2013-2015

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

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](http://www.DrugChannels.net)) on May 28, 2013.
# Predicted Future Trend in Specialty Pharmaceuticals

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Company</th>
<th>Sales ($B)</th>
<th>2018E</th>
<th>Company</th>
<th>Sales ($B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humira</td>
<td>Abbvie</td>
<td>$4.4</td>
<td></td>
<td>Humira</td>
<td>$5.6</td>
</tr>
<tr>
<td>Abilify</td>
<td>Otsuka Holdings</td>
<td>4.1</td>
<td></td>
<td>Lantus</td>
<td>5.3</td>
</tr>
<tr>
<td>Seretide/Advair</td>
<td>GlaxoSmithKline</td>
<td>4.0</td>
<td></td>
<td>Enbrel</td>
<td>4.5</td>
</tr>
<tr>
<td>Lantus</td>
<td>Sanofi</td>
<td>4.0</td>
<td></td>
<td>Januvia/Janumet</td>
<td>4.2</td>
</tr>
<tr>
<td>Enbrel</td>
<td>Amgen</td>
<td>4.0</td>
<td></td>
<td>Remicade</td>
<td>4.1</td>
</tr>
<tr>
<td>Cymbalta</td>
<td>Eli Lilly</td>
<td>3.9</td>
<td></td>
<td>Revlimid</td>
<td>3.6</td>
</tr>
<tr>
<td>Remicade</td>
<td>Johnson &amp; Johnson</td>
<td>3.6</td>
<td></td>
<td>Sofosbuvir</td>
<td>3.6</td>
</tr>
<tr>
<td>Rituxan</td>
<td>Roche</td>
<td>3.3</td>
<td></td>
<td>Lyrica</td>
<td>3.0</td>
</tr>
<tr>
<td>Neulasta</td>
<td>Amgen</td>
<td>3.2</td>
<td></td>
<td>Eylea</td>
<td>2.9</td>
</tr>
<tr>
<td>Crestor</td>
<td>AstraZeneca</td>
<td>3.2</td>
<td></td>
<td>NovoRapid</td>
<td>2.8</td>
</tr>
</tbody>
</table>

**Top 10 Total**

- **2012 Total**: $37.6
- **2018E Total**: $39.7

Totals may not sum due to rounding.

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?

Source: Prime Therapeutics 2012 Drug Trend Insights Report
# 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

<table>
<thead>
<tr>
<th>Therapy Class</th>
<th>PMPY Spend</th>
<th>Utilization</th>
<th>Unit Cost</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflammatory Conditions</td>
<td>$50.62</td>
<td>9.0%</td>
<td>14.0%</td>
<td>23.0%</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>$37.98</td>
<td>0.5%</td>
<td>17.3%</td>
<td>17.8%</td>
</tr>
<tr>
<td>Cancer</td>
<td>$31.98</td>
<td>3.4%</td>
<td>22.3%</td>
<td>25.8%</td>
</tr>
<tr>
<td>HIV</td>
<td>$20.78</td>
<td>-2.1%</td>
<td>11.1%</td>
<td>9.0%</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>$7.82</td>
<td>28.9%</td>
<td>4.8%</td>
<td>33.7%</td>
</tr>
<tr>
<td>Growth Deficiency</td>
<td>$7.41</td>
<td>1.7%</td>
<td>7.7%</td>
<td>9.5%</td>
</tr>
<tr>
<td>Anticoagulant</td>
<td>$6.74</td>
<td>1.7%</td>
<td>0.3%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Pulmonary Hypertension</td>
<td>$5.71</td>
<td>5.1%</td>
<td>6.2%</td>
<td>11.3%</td>
</tr>
<tr>
<td>Respiratory Conditions</td>
<td>$5.56</td>
<td>1.5%</td>
<td>25.7%</td>
<td>27.2%</td>
</tr>
<tr>
<td>Transplant</td>
<td>$4.92</td>
<td>2.2%</td>
<td>-6.9%</td>
<td>-4.7%</td>
</tr>
<tr>
<td>Other</td>
<td>$27.68</td>
<td>-24.9%</td>
<td>43.7%</td>
<td>18.8%</td>
</tr>
<tr>
<td><strong>Total Specialty</strong></td>
<td>$207.19</td>
<td>-0.4%</td>
<td>18.7%</td>
<td>18.4%</td>
</tr>
</tbody>
</table>

Source: Express Scripts  August 2013 Drug Trend Report
## Drug Trends

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

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

<table>
<thead>
<tr>
<th>Benefit Type</th>
<th>Pharmacy Benefit</th>
<th>Medical Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autoimmune</td>
<td>$0</td>
<td>$5.5 million</td>
</tr>
<tr>
<td>Injectable cancer</td>
<td>$200</td>
<td>$3.3 million</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>$400</td>
<td>$3.6 million</td>
</tr>
<tr>
<td>Oral oncology</td>
<td></td>
<td>$1.8 million</td>
</tr>
<tr>
<td>Blood modifiers</td>
<td></td>
<td>$1.4 million</td>
</tr>
<tr>
<td>Anticoagulants</td>
<td></td>
<td>$0.7 million</td>
</tr>
<tr>
<td>Growth hormone</td>
<td></td>
<td>$0.7 million</td>
</tr>
<tr>
<td>Hemophilia</td>
<td></td>
<td>$0.7 million</td>
</tr>
<tr>
<td>Pulmonary hypertension</td>
<td></td>
<td>$0.4 million</td>
</tr>
<tr>
<td>Lung disorders</td>
<td></td>
<td>$0.4 million</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td></td>
<td>$0.3 million</td>
</tr>
<tr>
<td>Enzyme deficiencies</td>
<td></td>
<td>$0.2 million</td>
</tr>
<tr>
<td>Macular degeneration</td>
<td></td>
<td>$0.04 million</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Therapy Class</th>
<th>PMPY Spend</th>
<th>Utilization</th>
<th>Unit Cost</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>$108.39</td>
<td>11.8%</td>
<td>21.1%</td>
<td>32.8%</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>$51.68</td>
<td>8.5%</td>
<td>18.2%</td>
<td>26.7%</td>
</tr>
<tr>
<td>Inflammatory Conditions</td>
<td>$47.69</td>
<td>7.4%</td>
<td>13.0%</td>
<td>20.4%</td>
</tr>
<tr>
<td>HIV</td>
<td>$30.31</td>
<td>1.6%</td>
<td>9.1%</td>
<td>10.7%</td>
</tr>
<tr>
<td>Pulmonary Hypertension</td>
<td>$25.58</td>
<td>9.8%</td>
<td>4.0%</td>
<td>13.8%</td>
</tr>
<tr>
<td>Anticoagulants</td>
<td>$16.57</td>
<td>1.0%</td>
<td>3.7%</td>
<td>4.7%</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>$10.83</td>
<td>63.5%</td>
<td>46.9%</td>
<td>110.4%</td>
</tr>
<tr>
<td>Immune Deficiency</td>
<td>$10.63</td>
<td>34.6%</td>
<td>-0.8%</td>
<td>33.8%</td>
</tr>
<tr>
<td>Blood Cell Deficiency</td>
<td>$10.43</td>
<td>-8.2%</td>
<td>8.0%</td>
<td>-0.2%</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>$9.52</td>
<td>9.1%</td>
<td>2.9%</td>
<td>12.0%</td>
</tr>
<tr>
<td>Other</td>
<td>$32.00</td>
<td>-28.1%</td>
<td>55.2%</td>
<td>27.1%</td>
</tr>
<tr>
<td><strong>Total Specialty</strong></td>
<td><strong>$353.62</strong></td>
<td><strong>-2.7%</strong></td>
<td><strong>26.8%</strong></td>
<td><strong>24.1%</strong></td>
</tr>
</tbody>
</table>

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
  - \( \approx 500 \) 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**

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

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 reflect an organization's commitment to meet high standards of quality and safety.

<table>
<thead>
<tr>
<th>ACROMEGALY</th>
<th>DUPUYTREN'S CONTRACTURE</th>
<th>HEMOPHILIA, cont.</th>
<th>HIV MEDICATIONS</th>
<th>HORMONAL THERAPIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>octreotide acetate</td>
<td>Xiaflex*</td>
<td>Kogenate FS</td>
<td>abacavir tab (ZIAGEN)1,2</td>
<td>Eligard</td>
</tr>
<tr>
<td>(SANOSTATIN)1</td>
<td></td>
<td>Monoclate-P</td>
<td></td>
<td>Firmagon</td>
</tr>
<tr>
<td>Sandostatin LAR</td>
<td></td>
<td>Meronine</td>
<td>Aptivus</td>
<td>leuprolide acetate</td>
</tr>
<tr>
<td>Somatuline Depot*</td>
<td></td>
<td>NovoSeven2</td>
<td>Atripla</td>
<td>(LUPRON)3</td>
</tr>
<tr>
<td>Somavert*</td>
<td></td>
<td>Profilnine SD</td>
<td>Compiera</td>
<td>Lupron DepoP</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proplex T</td>
<td>Crixivan</td>
<td>Supprelin LA*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Recombinate</td>
<td>didenosine (VIDEX, VIDEK)1,2</td>
<td>TreistaR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Refacto</td>
<td>Edurant</td>
<td>Vantas</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RiaSTAP</td>
<td>Egrifta*</td>
<td>Vladrin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stimate</td>
<td>Emtriva</td>
<td>Zoladex</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wileate</td>
<td>Epzicom</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Xyntha2</td>
<td>Fuzeron</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intolerance</td>
<td></td>
</tr>
</tbody>
</table>

ALCOHOL DEPENDENCY
Vivitol

ALLERGIC ASTHMA
Xolair*

GROWTH HORMONE & RELATED DISORDERS

IMMUNE DEFICIENCIES
Limited Distribution Drugs

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 one of the following: (1) a self-injectable medication (non-insulin); (2) a medication that requires special handling, special administration or monitoring; or (3) a high cost medication. The University 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 UM Specialty Drug List may be dispensed in quantities up to a 90-day supply. Specialty medications in the Immunosuppressive category may be dispensed in quantities up to a 34-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 near the drug name. To obtain medication PA, physicians can call the MedImpact Contact Center at 800-692-9718. UM prescribers should fax specialty drug prescriptions to the University Specialty Pharmacy at 734-764-3066 or call toll-free 877-597-3070. Medications marked with (LD) are limited distribution drugs which may not be available at UM Pharmacies or Wellpark. Check with your doctor for information on how to obtain these medications. Medications marked with (UM only) are currently only covered at UM Pharmacies. For more information, other physicians can call Medimpact at 800-692-9718 or visit http://ummedimpact.com/um. Telecommunications Relay Service (TRS) is available for persons who are deaf by dialing 711.

BEST BETS: 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/drug/index.html.

Summary:
152 products
25 LD
16.4% LD

Cancer Drugs - Oral
- Alimta
- Bosulif (PA)
- Caprelsa (verdutestan) (LD)
- Cimzia (LD)
- Enbrisk (UM only)
- Osvary (UM only)
- Ofsav (UM only)
- Hurom (UM only)
- Icuit (PA) (UM only)
- Hyza (UM only)
- Nevinlar (UM only)
- Pomest (PA) (UM only)
- Ralumatin (UM only)
- Sorofel (UM only)
- Sivarida (PA) (UM only)
- Suplent (UM only)
- Talcepl (isgavine)
- Tacera (UM only)
- Targetin (oral capsules)
- Tazice
- Tenorad

Cystic Fibrosis
- Clostrin (UM only)
- Lumist (UM only)
- Neoral (UM only)
- Pulmozyme (UM only)
- Tobi

Growth Hormone
- Prior Authorization (PA) required
- Genotropin
- Humatrope
- Nordropin (UM only)
- Nefropin (UM only)
- Omnitrope (UM only)
- Soron (UM only)
- Zoltro (UM only)

Hematopoietic
- Aranesp (PA)
- Epogen (PA)
- Leukine (UM only)
- Mecosil (PA)
- Neukast (UM only)
- Neumaga (UM only)
- Neupogen (UM only)
- Povirin (PA)
- Promacta (UM only)

Hepatitis B
- Bariatric
- Hepsera
- Tyzeka

Hepatitis C
- Colesep (tier 1 oral solution/tier 2)
- Cyclosporine
- Cyclosporine modified
generic (cyclosporine modified)
- mycophenolate mofetil
- Myfortic
- Neoral (cyclosporine)
- Prograf (tacrolimus)
- Rapamune
- Sandimmune (cyclosporine)
- TezORMIUS (UM only)
- Zortress

Infertility
- Glimson
- Endometrin

Information
- Maximum lifetime family benefit = $5,000. Prior Authorization (PA) required if age 245 years.
- Click here for more information
- Brivido (UM only)
- Catrile (UM only)
- Chorionic gonadotropin
- Follicin AQ
- Granirex (Avalos)
- Gonadil (UM only)
- Gonadotropin
- Novarel (chorionic gonadotropin)
- Ovadon
- Promegren (chorionic gonadotropin)
- Reprophen

Multiple Sclerosis
- Amysan (tablets only) (PA) (LD)
- Aubagio (PA) (LD)
- Avonex
- Bevacizumab
- Bivencine
- Cilengi (UM only)
- Diltiazem (UM only)
- Rebif
- Tevadexa (PA) (LD)

Rheumatoid Arthritis/Psoriasis
- Prior Authorization (PA) required
- Citron
- Enbrel
- Humira
- Kineret
- Orencia - subcutaneous form only
- Simponi
- Kejumt

Pulmonary Hypertension
- Adinat (PA)
- Larixir (UM only)
- Revata (UM only)
- sildenafil 20 mg (PA)
- tadaflo (UM only)
- Tyvase (PA) (LD)
- Venta (UM only)

Miscellaneous
- Adrenil (UM only)
- Apakil (LD)
- ASAP (UM only)
- Extral (UM only)
- Ferrilin (UM only)
- Finaster (UM only)
- Foroza (UM only)
- Japuli (UM only)
- Juxtap (UM only)
- Kuivum (UM only)
- Kynumir (PA) (LD)
- Metadone (UM only)
- oxtedosterone acetate
- Onadin (LD) (UM only)
- Rivat (UM only)
- Polmab (UM only)
- Stabil (UM only)

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Faculty/Staff
Fax: 734-936-3300
U-M Prescription Drug Plan
2013 Specialty Drug List
UM Prescribers: Fax all specialty rx to um specialty pharmacy: 734-237-3408
Prescribers outside um: fax all specialty rx to wellpartner: 877-597-3070
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

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

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 folicular 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
Thank you!