Pharmacy Benefit Drug Trends and Pipeline

Casey Robinson, PharmD, MBA, Cigna
Pharmacy Management
Disclosure and Conflict of Interest

Dr. Robinson declares no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings and honoraria.
Pharmacist Objectives

At the conclusion of this program, the pharmacist will be able to:

• 1. Discuss current pharmacy benefit spend and trends
• 2. Evaluate how pharmacy benefit spend is managed today
• 3. Recognize drugs in the FDA pipeline and where pharmacy benefit spend will be in the future
At the conclusion of this program, the technician will be able to:

- 1. Discuss current pharmacy benefit spend and trends
- 2. Evaluate how pharmacy benefit spend is managed today
- 3. Recognize drugs in the FDA pipeline and where pharmacy benefit spend will be in the future
• True or False:
  – Pharmaceuticals make up 50% of total health care spend.
Pre-test Questions

• All of the following are characteristics of specialty drugs EXCEPT?
  A) Expensive
  B) Brand Name Only
  C) Require Close Monitoring
  D) Treat Complex Disease States
• Payers implement what strategies to control costs?
  A) Adherence programs
  B) Formulary Positions
  C) Value Based Contracts
  D) B & C
  E) A, B, & C
Pre-Test Questions

• Biosimilars
  – A) are interchangeable with a branded product
  – B) require an NDA for approval
  – C) are highly similar to an FDA approved product
  – D) cost roughly 20% of the reference product
Pharmacy Benefit Drug Trends and Pipeline
CURRENT STATE OF SPEND
The Players in Managed Care Pharmacy

- **Payer**
  - Benefits (medical, Rx drugs)
  - Premium
  - MAC-, AWP-, or WAC-based negotiations
  - Data Reports
  - Preferred formulary placement
  - Discount / Rebates
  - Contract

- **Provider**
  - Service
  - Co-pay
  - Patient Info, PA request
  - Prescription

- **Pharmacy**
  - Drugs
  - Co-pay

- **Wholesaler**
  - Drugs
  - Chargeback
  - Contracts

- **PBM**
  - Claims
  - Rebates
  - Payment
  - PA

- **Manufacturer**
  - WAC-based
  - Contracts

- **Beneficiary**
  - Drugs

- **Gateways**
  - To the Future of Pharmacy

Amcp.org
In 2015, US Health Care spending reached $3.2 Trillion
- 10% of overall spend was on prescription drugs
  - Other areas of spend:
    - Hospital Care: 32%
    - Physician/Clinical Services: 20%
- Spending on prescription drugs outpaced all other services
  - Prescription Drug Spend Trend
    - 2014: 12.4%
    - 2015: 9.0%
  - Hospital Care Trend
    - 2014: 4.6%
    - 2015: 5.6%
  - Physician/Clinical Services Trend
    - 2014: 4.8%
    - 2015: 6.3%
Current Top Therapeutic Classes by Spend

- Inflammatory Conditions
- Oncology
- Diabetes
- Multiple Sclerosis
- HIV
- Hepatitis C
- Asthma
The Growth of Specialty Drugs

• What is a specialty drug?
  – There is no standard definition for a specialty medication, but drugs in this category typically share one or more of the following characteristics:
    • They are expensive
      – The average monthly cost to payers and patients for a specialty medication is $3,000, ten times the cost for non-specialty medications.
    • They can be difficult to administer
      – They are often given by injection or infusion to treat complex, chronic conditions such as rheumatoid arthritis, multiple sclerosis and psoriasis
    • The drugs may require special handling, including temperature control
    • Patients taking these medications may need ongoing clinical assessment to manage challenging side effects.

Managed Care Pharmacy, Navarro
Current Top Therapeutic Classes by Spend - Specialty

- Inflammatory Conditions
- Oncology
- Diabetes
- Multiple Sclerosis
- HIV
- Hepatitis C
- Asthma
Current Top Therapeutic Classes by Spend - Specialty

- **Inflammatory Conditions**
  - Humira, Enbrel, Stelara
- **Oncology**
  - Keytruda, Revlimid
- **Diabetes**
  - Glumetza, Tresiba, Toujeo, Lantus, Levemir
- **Multiple Sclerosis**
  - Tecfidera, Copaxone
- **HIV**
  - Truvada, Stribild
- **Hepatitis C**
  - Harvoni
- **Asthma**
  - Advair, Dulera
MANAGING SPEND
Tools Used by Payers to Control Costs

• Coverage Positions/Formulary Management
• Utilization Management
• Benefit Design
• Rebate Management
• Outcomes Based Contracts
Coverage Positions/Formulary Decisions

- Value Based Formularies
  - Tiering
  - Closed Periods
  - Exclusions of Egregiously Priced Drugs
  - “Lifestyle” exclusions
Utilization Management

- Prior Authorizations
- Step Therapy
- Case Management
  - $77 PMPY savings with integrated management
- Mandatory Generics
Plan Design

• High Deductible Health Plans
• Coinsurance vs Copays
• Value Based Incentive Care vs Affordable Care
• Limited Networks
• 340B Pricing Arrangements
Rebates

Controversial topic within drug pricing

Moneys paid by the manufacturer to a payer based on utilization

<table>
<thead>
<tr>
<th>Drug</th>
<th>IMS estimated U.S. sales ($Bil)</th>
<th>Company reported U.S. sales ($Bil)</th>
<th>Estimated rebates (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipitor</td>
<td>$7.7</td>
<td>$5.0</td>
<td>35%</td>
</tr>
<tr>
<td>Plavix</td>
<td>$6.8</td>
<td>$6.6</td>
<td>3%</td>
</tr>
<tr>
<td>Nexium</td>
<td>$6.2</td>
<td>$2.4</td>
<td>61%</td>
</tr>
<tr>
<td>Abilify</td>
<td>$5.2</td>
<td>$4.0</td>
<td>24%</td>
</tr>
<tr>
<td>Advair</td>
<td>$4.6</td>
<td>$4.0</td>
<td>13%</td>
</tr>
<tr>
<td>Seroquel</td>
<td>$4.6</td>
<td>$3.3</td>
<td>27%</td>
</tr>
<tr>
<td>Singulair</td>
<td>$4.6</td>
<td>$3.5</td>
<td>23%</td>
</tr>
<tr>
<td>Crestor</td>
<td>$4.4</td>
<td>$3.1</td>
<td>30%</td>
</tr>
<tr>
<td>Cymbalta</td>
<td>$3.7</td>
<td>$3.2</td>
<td>14%</td>
</tr>
<tr>
<td>Humira</td>
<td>$3.5</td>
<td>$3.4</td>
<td>2%</td>
</tr>
</tbody>
</table>

Sources: IMS Health, company statements, analyst reports
Outcomes Based Contracts

• “Put your money where your mouth is.”

• Contracts based on drug performance in real world

• Examples:
  – Hepatitis C
  – Diabetes
  – Heart Failure
WHAT IS COMING?
FDA Novel Drug Approvals

Calendar Year

- 2012: 39
- 2013: 27
- 2014: 41
- 2015: 45
- 2016: 22
- 2017: 23
Growth of Orphan Drugs

USA, EU & Japan Designations per Year (1983-2016)

- USA Designations per Yr
- EU Designations per Yr
- Japan Designations per Yr

Strong Increase from 2003

WW Orphan Sales as a % of WW Rx Sales (excl. Generics)

+11.1% CAGR 2017-2022
FDA Approvals: 1999-2016
## FDA Activity 2017

<table>
<thead>
<tr>
<th>Drug</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emflaza (deflazacort) for Duchenne muscular dystrophy</td>
<td>• FDA approval 2/9/17&lt;br&gt;• Oral&lt;br&gt;• $89K/customer/year (drug is available ex-US and families have accessed for ≈ $1,500 per year&lt;br&gt;• Marathon Pharmaceuticals developed and gained approval using studies from early 1990s&lt;br&gt;• Public, political, PhRMA outcry over pricing&lt;br&gt;• Product sold to PTC Therapeutics, re-priced at $35K</td>
</tr>
<tr>
<td>Dupixent (dupilumab) for moderate to severe atopic dermatitis/eczema</td>
<td>• FDA approval 3/28/17&lt;br&gt;• Self-administered injection&lt;br&gt;• First specialty drug for this very common condition&lt;br&gt;• $37K/customer/year</td>
</tr>
<tr>
<td>Ocrevus (ocrelizumab) for MS</td>
<td>• FDA approval 3/28/17&lt;br&gt;• HCP-administered IV infusion&lt;br&gt;• First drug approved for a less common form of MS (PPMS); also approved in common RRMS&lt;br&gt;• $65K/customer/year&lt;br&gt;• Top US sales forecast for 2017 drugs&lt;br&gt;  • 2017: $328M&lt;br&gt;  • 2022: $2.4B</td>
</tr>
</tbody>
</table>
# FDA Pipeline

<table>
<thead>
<tr>
<th>DATE</th>
<th>DRUG</th>
<th>CONDITION</th>
<th>BENEFIT</th>
<th>US SALES, 2022¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/2017</td>
<td>Neratinib (Nerlynx)</td>
<td>Breast cancer; TKI that blocks EGFRs, HER1, HER2, HER4</td>
<td>Rx / Oral Specialty</td>
<td>518M</td>
</tr>
<tr>
<td>8/2017</td>
<td>Sofosbuvir/velpatasvir/voxilaprevir</td>
<td>Hepatitis C; pangenotypic but expect indication will target prior treated DAA failures</td>
<td>Rx / Oral Specialty</td>
<td>376M</td>
</tr>
<tr>
<td>8/2017</td>
<td>glecaprevir/pibrentasvir (Maviret)</td>
<td>Hepatitis C; pangenotypic; 8 week treatment in majority of population</td>
<td>Rx / Oral Specialty</td>
<td>803M</td>
</tr>
<tr>
<td>9/2017</td>
<td>Tisagenlecleucel-t (CTL019)</td>
<td>Leukemia/ALL; immunotherapy; new CAR-T (chimeric antigen receptor) technology recodes patient’s own T cells; 1X inpatient administration</td>
<td>Med / Inj Specialty</td>
<td>402M ↓</td>
</tr>
<tr>
<td>3Q2017</td>
<td>Emicizumab</td>
<td>Hemophilia A prophylaxis; first long-acting SC bypassing agents for patients with or without inhibitors</td>
<td>Rx / SC inj Specialty</td>
<td>1.0B</td>
</tr>
<tr>
<td>10/2017</td>
<td>Ataluren (Translarna)</td>
<td>Duchenne’s muscular dystrophy; skips the nonsense mutation &amp; produce normal protein (dystrophin); endpoint is 6MWT; slowed disease progression</td>
<td>Rx / Oral Specialty</td>
<td>302M ↑</td>
</tr>
<tr>
<td>11/2017</td>
<td>Gusekumab</td>
<td>Chronic plaque psoriasis; IL-23 inhibitor (Stelara); SC inj Q16 wks; compared to Stelara &amp; Humira</td>
<td>Rx / SC inj Specialty</td>
<td>827M</td>
</tr>
<tr>
<td>DATE</td>
<td>DRUG</td>
<td>CONDITION</td>
<td>BENEFIT</td>
<td>US SALES, 2022³</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
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<td>-----------------</td>
</tr>
<tr>
<td>12/2017</td>
<td>Semaglutide</td>
<td>Diabetes; long-acting once weekly GLP-1 analogue</td>
<td>Rx / SC inj</td>
<td>1.0B</td>
</tr>
<tr>
<td>4Q2017</td>
<td>Benralizumab</td>
<td>Asthma; same MOA as Cinqair &amp; Nucala</td>
<td>Med? / SC inj Specialty</td>
<td>441M</td>
</tr>
<tr>
<td>1/2018</td>
<td>Ibalizumab</td>
<td>HIV; adjunctive therapy for multidrug-resistant HIV</td>
<td>TBD / IV or SC Specialty</td>
<td>204M</td>
</tr>
<tr>
<td>6/2018</td>
<td>Cannabidiol (Epidiolex)</td>
<td>Dravet or Lennox-Gastault syndromes (childhood forms of epilepsy); estimated 1:20-40,000; oral liquid form; non-psychoactive</td>
<td>Rx / Oral</td>
<td>703M</td>
</tr>
<tr>
<td>2H2018</td>
<td>Burosumab</td>
<td>X-Linked Hypophosphatemia (XLH); hereditary form of rickets where vitamin D is ineffective; mAb that decreases excretion of phosphate; SC inj</td>
<td>Rx / Inj</td>
<td>411M</td>
</tr>
</tbody>
</table>
## FDA Pipeline

<table>
<thead>
<tr>
<th>DATE</th>
<th>DRUG</th>
<th>CONDITION</th>
<th>BENEFIT</th>
<th>US SALES, 2022¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>Bremelanotide (Rekynda)</td>
<td>Female sexual arousal disorder; new class called melanocortin agonists; SC injection; no interaction with alcohol; positive top-line efficacy results</td>
<td>Rx / Inj</td>
<td>19M</td>
</tr>
<tr>
<td>3Q2018</td>
<td>Anacetrapib</td>
<td>Hypercholesterolemia; new class cholesteryl ester transfer protein (CETP) inhibitor</td>
<td>Rx / Oral Specialty</td>
<td>218M</td>
</tr>
<tr>
<td>4Q2018</td>
<td>Lanadelumab</td>
<td>Hereditary angioedema (HAE); SC inj with same MOA as Kalbitor; long-acting prophylactic treatment every 2 weeks</td>
<td>Rx / Inj Specialty</td>
<td>724M</td>
</tr>
<tr>
<td>4Q2018</td>
<td>Ozanimod</td>
<td>Multiple sclerosis in 2018, ulcerative colitis in 2019. Oral; sphingosine-1-phosphate receptor 1 (S1P1) agonist like Gilenya; compared to Avonex; awaiting cardiovascular/tachycardia safety data</td>
<td>Rx / Oral Specialty</td>
<td>1.8B</td>
</tr>
<tr>
<td>4Q2018</td>
<td>Allopregnanolone (Brexanolone)</td>
<td>Breakthrough status for postpartum depression; targets GABA-A receptors</td>
<td>Med / Inj TBD</td>
<td>686M</td>
</tr>
<tr>
<td>2019</td>
<td>Ocaliva &amp; others for NASH (nonalcoholic steatohepatitis) → slide 24</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2020</td>
<td>Aducanumab</td>
<td>Early stage Alzheimer’s; targets beta-amyloid plaque formation</td>
<td>Med / Inj Specialty</td>
<td>1.5B</td>
</tr>
</tbody>
</table>
Biosimilars

• What is a biosimilar?
  – Biosimilars are a type of biological product that are licensed (approved) by FDA because they are highly similar to an already FDA-approved biological product, known as the biological reference product (reference product), and have been shown to have no clinically meaningful differences from the reference product.

• Potential cost savings avenue for biologic drugs
# Biosimilars

**Timing**
- US Supreme Court decision removes 180 day delay between FDA approval and market launch
- Patent challenges will still delay timing of market launch of several biosimilars

**Affordability**
- All currently marketed biosimilars are medical (i.e. HCP administered)
- All 2017 biosimilar launches are medical
- ASP-based pricing and reimbursement for medical injectables causes delay in potential cost savings
- Pharmacy benefit injectables can reflect cost discounts at launch

**Interchangeability**
- No biosimilar currently has interchangeability status - but our coverage approach can be independent of interchangeability status
- FDA has draft guidance for interchangeability
  - Includes requirement for switching studies
  - Will only apply to pharmacist dispensing
Enbrel and Humira biosimilars are likely to see approval in late 2018.

<table>
<thead>
<tr>
<th>Currently on market</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zarxio, Granix (for Neupogen)</td>
<td>Grastofil (for Neupogen)</td>
</tr>
<tr>
<td>Inflectra (for Remicade)</td>
<td>SB2 (for Remicade)</td>
</tr>
<tr>
<td></td>
<td>Lapelga, CHS-1701 (for Neulasta)</td>
</tr>
<tr>
<td></td>
<td>Retacrit (for Epogen, Procrit)</td>
</tr>
</tbody>
</table>
New “Heavy Hitters” in Pipeline

- Dyslipidemia
- Migraine
- NASH
<table>
<thead>
<tr>
<th>Timing</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>5/2016</td>
<td>Generic Crestor launch</td>
</tr>
<tr>
<td>12/2016</td>
<td>Generic Zetia launch</td>
</tr>
<tr>
<td>1/2017</td>
<td>Amgen (Repatha) suing Regeneron &amp; Sanofi (Praluent) for patent infringement. Delaware Court issues injunction preventing Regeneron from continuing to sell Praluent until 2028, but puts injunction on hold for pending appeal. Expect appeals court ruling sometime in 2H2017.</td>
</tr>
<tr>
<td>3/2017</td>
<td>Repatha FOURIER outcomes trial results published</td>
</tr>
<tr>
<td></td>
<td>• Study population (n=27,564) is existing ASCVD (i.e. current indicated population)</td>
</tr>
<tr>
<td></td>
<td>• Key endpoint (26 months): cardiovascular death/myocardial infarction/stroke</td>
</tr>
<tr>
<td></td>
<td>• Statins 9.9% vs Repatha 7.9%</td>
</tr>
<tr>
<td></td>
<td>• 2% absolute risk reduction (ARR)</td>
</tr>
<tr>
<td></td>
<td>• 59% mean LDL lowering (mean LDL = 30mg/dl)</td>
</tr>
<tr>
<td></td>
<td>• No difference in rates of cardiovascular death</td>
</tr>
<tr>
<td></td>
<td>• Amgen announces additional contracting options</td>
</tr>
<tr>
<td>5/2017</td>
<td>Generic Vytorin (combination of Zetia + simvastatin) launch</td>
</tr>
<tr>
<td>1Q 2018</td>
<td>Completion of Praluent ODYSSEY outcomes trial</td>
</tr>
</tbody>
</table>

Evaluate Pharma
## Dyslipidemia Key Market Events

<table>
<thead>
<tr>
<th>Timing</th>
<th>Event</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>2H2017</td>
<td>Appeals court ruling on Praluent marketing options subsequent to Amgen patent infringement suit</td>
<td>Preliminary comments by 3 judges favor Regeneron. Repatha could be the sole PCSK9i on the market if Regeneron loses.</td>
</tr>
<tr>
<td>1Q2018</td>
<td>Praluent ODYSSEY outcomes trial results</td>
<td>Low, unless ARR is significantly better than seen in Repatha FOURIER.</td>
</tr>
<tr>
<td>2H2018</td>
<td>FDA decision on anacetrapib (Merck), 1&lt;sup&gt;st&lt;/sup&gt; CETP inhibitor</td>
<td>Low, 2022 forecast is 7.5% of PCSK9i sales.</td>
</tr>
<tr>
<td>2H2018</td>
<td>FDA decision on volanesorsen (Akcea), 1&lt;sup&gt;st&lt;/sup&gt; ApoC-III inhibitor</td>
<td>Low, 2022 forecast is 4.7% of PCSK9i sales.</td>
</tr>
<tr>
<td>TBD</td>
<td>Update to ACC/AHA cholesterol guidelines</td>
<td>TBD</td>
</tr>
</tbody>
</table>
Migraine Market Dynamics

• Estimated 12% of US populations have chronic migraines
• Current treatment
  – Acute migraine: Triptans (e.g. Imitrex) are 1st line treatment
    • Genericized, base drug class
    • Dosage forms include oral, injection, nasal
  – Prevention of migraine: Other drugs such as Beta-blockers, anticonvulsants, antidepressants, Botox
    • Botox: $6K-10K per year
• Pipeline → Shift to specialty
  – Calcium Gene-Related Peptide (CGRP) is a neurotransmitter
    • CGRP is thought to be a key trigger of migraine attacks
  – Reduced the number of migraines per month by about 50%
  – Rx benefit; SC injection once monthly
  – Cost estimated to be $8K-20K per year; $3-4B market in 2022

<table>
<thead>
<tr>
<th>CGRP receptor antagonist monoclonal antibody pipeline</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/Timing</strong></td>
</tr>
<tr>
<td><strong>2022 US Sales ($M)</strong></td>
</tr>
</tbody>
</table>
Migraine Spend Outlook

![Migraine Spend Outlook Chart]

The chart illustrates the US sales outlook for various migraine treatments from 2008 to 2022. Key products include TEV-48125 (TEVA), Erenumab (AMGN), Galcanezumab (LLY), Eptinezumab (Alder BioPharmaceuticals), Erenumab (NVS), Ubrogepant (Allergan), Imitrex (GSK), Relpax (PFE), Lasmiditan (LLY), and Semprana (Allergan). The chart shows a trend of increasing sales, particularly in recent years.
What is NASH?
• Form of nonalcoholic fatty liver disease (NAFLD) that can progress to cirrhosis, liver failure, and cancer
  – Like hepatitis C, no symptoms until advanced disease
  – Projected to be leading cause of liver transplants by 2020
• Both NAFLD and NASH are linked to obesity and diabetes
• US prevalence is estimated as 2-5%
  – ICER report projects 567,000 candidates for treatment
  – Cigna total population estimated at 20,000-30,000
• Diagnosis confirmed with liver biopsy
• Current treatment is lifestyle interventions (diet, exercise), control of diabetes. No current effective drug treatment.
• Goal of treatment → prevent fibrosis → prevent cirrhosis
• Cost: Ocaliva is currently over $69,000 per year
  – Indication-based pricing opportunity

<table>
<thead>
<tr>
<th>Drug</th>
<th>Timing</th>
<th>Mechanism of Action</th>
<th>Route</th>
<th>2022 US Sales (M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>obeticholic acid (Intercept)*</td>
<td>2019</td>
<td>Farsenoid X receptor agonist</td>
<td>Oral</td>
<td>682</td>
</tr>
<tr>
<td>Elafibranor (Genfit)</td>
<td>2019</td>
<td>PPAR-alpha agonist</td>
<td>Oral</td>
<td>NA</td>
</tr>
<tr>
<td>Selonsertib (Gilead)</td>
<td>2020</td>
<td>Apoptosis signal regulating kinase (ASK) 1 inhibitor</td>
<td>Oral</td>
<td>16</td>
</tr>
<tr>
<td>Cenicriviroc (Allergen)</td>
<td>2021</td>
<td>Chemokine receptor 2, 5 antagonist</td>
<td>Oral</td>
<td>NA</td>
</tr>
</tbody>
</table>
NEXT STEPS: GENE THERAPY
What is gene therapy?

• A novel approach to treat, cure, or ultimately prevent disease by changing the expression of a person’s genes
How does gene therapy work?

Voretigene (SPK-RPE65) for Leber’s congenital amaurosis
- Ultra-rare inherited retinal disease that causes 20% of childhood blindness
- Estimate of 3,500 cases in US and EU5
# Diseases Targeted by Gene Therapy

<table>
<thead>
<tr>
<th>Area</th>
<th>Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>Lung, ovarian, pancreatic, brain cancer</td>
</tr>
<tr>
<td></td>
<td>Leukemia</td>
</tr>
<tr>
<td></td>
<td>Lymphoma</td>
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<tr>
<td></td>
<td>Melanoma</td>
</tr>
<tr>
<td>Monogenic diseases</td>
<td>Immunodeficiency diseases</td>
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<tr>
<td></td>
<td>Lipoprotein lipase deficiency</td>
</tr>
<tr>
<td></td>
<td>Retinal diseases</td>
</tr>
<tr>
<td></td>
<td>Duchenne muscular dystrophy</td>
</tr>
<tr>
<td>Infectious disease</td>
<td>HIV</td>
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<td></td>
<td>Hepatitis C</td>
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<tr>
<td></td>
<td>HPV</td>
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<tr>
<td>Cardiovascular</td>
<td>Angina</td>
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<tr>
<td></td>
<td>Peripheral vascular disease</td>
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<tr>
<td>Neurological</td>
<td>Alzheimer’s</td>
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<tr>
<td></td>
<td>ALS</td>
</tr>
<tr>
<td></td>
<td>Parkinson’s</td>
</tr>
</tbody>
</table>
Post Test: Question #1

• True or False:
  – Pharmaceuticals make up 50% of total health care spend.

• Per CMS, drug spend made up 10% of total health care spend in 2015 and is continuing to rise faster than other areas.
Post Test: Question #2

- All of the following are characteristics of specialty drugs EXCEPT?
  A) Expensive
  B) Brand Name Only
  C) Require Close Monitoring
  D) Treat Complex Disease States

  There is no set definition for specialty, but the industry does not limit specialty drugs to brands only. (example: Generic Gleevec)
Post Test: Question #3

- Payers implement what strategies to control costs?
  
  A) Adherence programs
  B) Formulary Positions
  C) Value Based Contracts
  D) B & C
  E) A, B, & C

  Adherence programs actually increase dispensing of drugs, so that would increase costs. However, that isn’t necessarily a bad thing!
Biosimilars

- A) are interchangeable with a branded product
- B) require an NDA for approval
- C) are highly similar to an FDA approved product
- D) cost roughly 20% of the reference product

Interchangeability does not exist for biosimilars and the reference product; an NDA is not required through the biosimilar approval pathway and costs are higher than 20% of the reference product. The biosimilar must show that it is “highly similar” to the reference product for FDA approval.
Take Home Points

- Drug spend is growing at a faster rate than other areas of spend in health care
- Managed Care partners use several different approached to control costs
- The growth of specialty drugs within new disease states is impactful to the future of pharmacy spend
Dr. Robinson can be reached via email at caseyrobinson911@gmail.com