

Expensive Drugs Are Making Us Sick!

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On with the Show...

Specialty Drugs

More complex than most prescription medications

Used to treat patients with serious and often life-threatening conditions

May be taken orally but often injected or infused

May have special administration, storage, and delivery requirements

Often self-administered in the patient's home

Can be given in a doctor's office, infusion center or hospital

Cannot routinely be dispensed at a typical retail community pharmacy

Specialty Drug Cost Trends

1990: 10 Specialty Drugs

2015: 300 Specialty Drugs

2016: 25 new drugs expected to receive FDA approval

Under Development: 700 Specialty Drugs

2012 Specialty Drug Spend: \$87 billion (3.1% of National Health Spend)

Anticipated 2020 Specialty Drug Spend: \$400 billion (9.1% of NHS)

Specialty Drug Cost Trends

1% of prescriptions written but 25% of the \$263.3 billion prescription drug spend

63% percent increase in patients who are on at least one specialty drug

30.9% increase in spending on specialty medications:

- **Hepatitis C**
- **Compounded medications**

2015: Another Good Year for FDA approvals

28: Average novel drug approvals from 2006-2014

45: Novel new drugs approved in 2015:

16 First in Class Drugs

21 Rare/Orphan Disease Drugs

39: Approved on First Cycle of Review

27: Approved under expedited time frames

Price Increases: Turing Not Alone

Daraprim: HIV/Toxoplasmosis Drug

AWP Price Increased from \$13.50 to \$750 (5000%)

Valeant: Isuprel/Nitropress

Isuprel Vial: \$215 to \$1,346 (500%)

Nitropress Vial: \$402.50 to \$805.61 (200%)

Rodelis Therapeutics: Cycloserine

\$500 to \$10,800 for 30 capsules (2160%)

Darzalex (Daratumumab)

- FDA approved November 2015
- Indicated for treatment of Multiple Myeloma
- Anti CD-38 Monoclonal Antibody
- Orphan Drug Designation

- 4th line therapy:
 - Must have received a Proteasome Inhibitor/Immunomodulatory Agent or
 - Double-refractory to a PI and an Immunomodulatory Agent

- Single Agent treatment

Darzalex (Daratumumab)

- IV: 16 mg/kg once every week for 8 weeks, then once every 2 weeks for 16 weeks, then once every 4 weeks
- Available in 100/400 mg single use vials
- Treatment should continue until disease progression or unacceptable toxicity
- **Reasonable Costs for 400 mg vial: \$3,960**
- **Reasonable Costs for first 12 months of therapy: \$273,240**

Portrazza (Necitumumab)

- **FDA approved November 2015**
- **Indicated for treatment of Non Small Cell Lung Cancer**
- **Monoclonal Antibody**
- **EFGR Inhibitor**
- **Orphan Drug Designation**
- **First Line Therapy**
- **Given in combination with Gemzar/Cisplatin**

Portrazza (Necitumumab)

- IV: 800 mg on days 1 and 8 of each 3 week cycle
- IV Gemzar 1250 mg/m² on days 1 and 8 and IV cisplatin 75mg/m² on day 1 of each 3-week cycle
- Treatment should continue until disease progression or unacceptable toxicity
- Reasonable Costs for 800 mg vial: \$8,800
- Reasonable Costs for 12 months of therapy: \$299,200

Adynovate (Factor VIII, recombinant human pegylated)

- **FDA approved December 2015**
- **Indicated for treatment in Congenital Hemophilia A**
 - **Prevention and treatment of bleeding episodes**
 - **Routine Prophylaxis**
- **Not indicated for perioperative management**
- **Not indicated in Acquired Hemophilia A or Von Willebrand Disease**

Adynovate (Factor VIII, recombinant human pegylated)

- **On Demand Therapy: Dosage/duration of treatment depend on:**
 - Severity of Factor VIII deficiency
 - Location/extent of bleeding
 - Clinical condition
- **Prophylaxis: 40 to 50 units/kg twice per week**
- **Reasonable Costs Per IU: \$3.65**
- **Reasonable Costs for 12 months of therapy: \$1.28M**

Kovaltry (Recombinant Coagulation Factor VIII)

- **FDA approved March 2016**
- **Indicated for treatment in Congenital Hemophilia A**
 - **Prevention and treatment of bleeding episodes**
 - **Perioperative management**
 - **Routine Prophylaxis**
- **Not indicated for Von Willebrand Disease**

Kovaltry (Recombinant Coagulation Factor VIII)

- **On Demand Therapy: Dosage/duration of treatment depend on:**
 - **Severity of Factor VIII deficiency**
 - **Location/extent of bleeding**
 - **Clinical condition**
 - **Type of Surgery**
- **Prophylaxis: 20-40 IU/kg 2-3 times per week**
- **Reasonable Costs Per IU: \$3.75**
- **Reasonable Costs for 12 months of therapy: \$1.3M**

Zepatier (Elbasvir/Grazoprevir)

- **FDA approved January 2016**
- **Indicated for treatment of Hepatitis C: Genotypes 1 & 4**
- **NS5A Inhibitor and NS3/4A Inhibitor**
- **Given with or without Ribavirin**

- **HCV genotype 1a: Patients should be tested for NS5A resistance-associated polymorphism prior to initiation of treatment to determine dosage regimen and duration**

Zepatier (Elbasvir/Grazoprevir)

- **Oral: One tablet daily with or without Ribavirin for either 12 or 16 weeks**
- **Genotype 1a: Treatment-naïve or Peginterferon/Ribavirin experienced without baseline NS5A polymorphisms: 12 weeks**
- **Genotype 1a: Treatment-naïve or Peginterferon/Ribavirin experienced with baseline NS5A polymorphisms: 16 weeks given with Ribavirin**
- **Genotype 1b: Treatment-naïve or Peginterferon/Ribavirin experienced: 12 weeks**
- **Genotype 1a or 1b: Peginterferon/Ribavirin/HCV NS3/4A Protease Inhibitor experienced: 12 weeks given with Ribavirin**

Zepatier (Elbasvir/Grazoprevir)

- **Oral: One tablet daily with or without Ribavirin for either 12 or 16 weeks**
- **Genotype 4: Treatment-Naïve: 12 weeks**
- **Genotype 4: Peginterferon/Ribavirin experienced: 16 weeks given with Ribavirin**
- **Reasonable Costs for 84 tablets (12 week course of therapy): \$120,120**

Venclexta (venetoclax)

- **FDA approved April 2016**
- **Indicated for treatment of Chronic Lymphocytic Leukemia**
- **Monoclonal Antibody**
- **BCL-2 Inhibitor**
- **Orphan Drug Designation**

- **2nd Line Therapy**
 - **Indicated for the treatment of relapsed/refractory CLL in patients with the 17p deletion who have received one prior therapy**

Venclexta (venetoclax)

- **Oral: Given according to a 5 week ramp-up session:**
 - **Week 1: 20 mg daily**
 - **Week 2: 50 mg daily**
 - **Week 3: 100 mg daily**
 - **Week 4: 200 mg daily**
 - **Week 5 and beyond: 400 mg daily**
- **Treatment should continue until disease progression or unacceptable toxicity**
- **Reasonable Costs for 120-100 mg tablets (30 day supply of 400 mg daily dose): \$21,032**
- **Reasonable Costs for 12 months of therapy: \$255,889**

Take Home Points

Review specialty drugs for disease appropriateness

Review specialty drugs for dosage/frequency/duration

Review claims for inflated charges

Review any claims that are questionable to you

ACT ON FINDINGS!

DO NOT STAY WITH STATUS QUO!

Hope you enjoyed this presentation!

**For questions/assistance:
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