
Specialty Drugs – An Update

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What is a Specialty Drug?

- There is no industry standard definition.
- A commonly used definition is based on cost and the unique nature of the drugs:
 - High Cost and.....
 - Treats a rare condition OR
 - Requires special handling OR
 - Uses a limited distribution network OR
 - Requires ongoing clinical assessment.



Historical shifts in Specialty Drugs

10 to 20 years ago....

- Injectables only
- 1990 - 10 specialty drugs
- Treatments for:
 - Multiple Sclerosis
 - Cancer
- Majority provided within “medical” benefit in hospital or physician office setting

Today....

- Many are oral or inhaled agents
- Hundreds of specialty drugs
- Treatments added:
 - Arthritis
 - Pain
 - Hepatitis C
 - Psoriasis
- Advent of oral and familiarity with injections have shifted delivery to “pharmacy” benefit at home



Current Specialty Drug Saturation

Nationally, less than 1% of members use specialty drugs, but....

- Specialty drugs make up 15% to 20% of the pharmacy benefit.
- When the specialty drugs provided through the medical benefit are added in, they represent 30% of total drug spend.



Specialty Drug Pipeline

- The majority of new drugs approved are specialty drugs.
- Of the 25 new specialty drugs, 13 were for cancer.
- 40% of all drugs in pipeline right now are specialty drugs.
- Projections show that the current specialty drug saturation will grow to between 35% and 45%, almost half of which will be for treatment of cancer.
- It's estimated that 3.2M Americans have Hepatitis C, yet millions more are undiagnosed. As few as 4% of the population that has the disease is actually being treated. Expected increases in the percentage treated will drive trend.



Specialty Drug Pipeline, continued

- Inflammatory Drugs – Focus on developing oral drugs for rheumatoid arthritis, psoriasis and irritable bowel disease. Specialty drugs for lupus and gout in development.
- Multiple Sclerosis – Focus on getting approvals for other specialty drugs that are currently approved for other diseases/conditions.
- Cancer – Focus on oral drugs.
- HIV – Focus on oral and vaccine.
- Hepatitis C – Focus on oral and direct antivirals.
- Cystic Fibrosis – Focus on inhaled and oral drugs.



Specialty Drug Cost Trend

- Over the past 8 years, 18.5% of trend has been driven by utilization. As more drugs have become available for more conditions, utilization has increased.
- National trends for Specialty Drugs run between 18% and 22%.
- These high specialty drug trends have not driven total drug trends higher because they've been offset by the increased number of generic drugs that have recently become available.



Managing Specialty Drugs

While there is no single answer as to how to manage specialty drugs, there are a number of strategies to consider:

- Step Therapy – There are usually 5 to 10 non-specialty drugs in the same therapeutic class as each specialty drug with lower costs that can be tried first.
- Develop a higher specialty drug copay tier.
- Develop “preferred” tiers for select specialty drugs.
- Develop performance guarantees from manufacturers.
- Manage the oncology benefit more actively.
- Create closed specialty formularies that are determined to be of lower clinical or economic value which would only be covered by exception.



Generics are on their way, but it will take a while

- Generics are called “biosimilars” or “biologics”.
- Biosimilars should push prices for specialty drugs down, but the expensive manufacturing process means that they may not yield savings as sizable as those achieved by conventional generic drugs.
- Achieving therapeutic equivalence for biosimilar manufacturers and assessing therapeutic equivalence for regulators are likely to be difficult, given the complex nature of this class of drugs.
- It will be an uncertain number of years before biosimilars can make an impact on competition and cost, because specialty drugs are granted 12 years of market exclusivity and often are protected by patents lasting years beyond that.

