Innovative Strategies for Managing the Rising Cost of Specialty Drugs
Managing the Rising Cost of Specialty Drugs – Overview

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What is a Specialty Drug?

Derived from living organisms or a very specific molecular process.
Lack a therapeutic or generic equivalent.

**Specialty drugs have several characteristics:**

- Often injectable or infused medications
- Distributed from pharmacies, physician offices and hospitals
- Used to treat chronic and/or complex conditions
- Require significant patient proficiency in self-management or administration
- Limited or exclusive product availability
- Specialized product handling (e.g. refrigeration)
- Cost in excess of $600 for a 30 days’ supply (Medicare definition)
- Subject to Risk Evaluation and Mitigation Strategies

Treat genetic, “orphan” status, or limited chronic conditions.
Growth of Specialty Drugs

Specialty drugs are the fastest growing component of a plan sponsor’s prescription drug costs and is expected to increase 30-40% on an annual basis.

In 2015, the U.S. spent about $110 billion on specialty drugs and biologics.

The spending on specialty drugs is expected to reach $400 billion by 2020.

By the end of 2016, it is expected that specialty drugs will represent 50% of an employer’s drug spend while representing a fraction of an employer’s total number of overall pharmacy claims (1.5%).
Specialty Growth

% Total Claims vs. % Total Drug Cost
The “Top 10” Specialty Conditions

Specialty drugs used to treat 10 different disease states accounts for nearly 50% of a payor’s spending on specialty medications:

1. Inflammatory conditions (e.g. rheumatoid arthritis)
2. Multiple Sclerosis
3. Hepatitis C
4. Cancer
5. Growth deficiency
6. Miscellaneous central nervous system
7. Respiratory conditions
8. Anticoagulant (e.g. hemophilia)
9. Transplant
10. Pulmonary hypertension
Cost Drivers for Specialty Medications

Pharmaceutical manufacturers are looking for the next generation of medications and are developing specialty drugs to treat more common diseases such as diabetes and hypertension.

“Orphan Drugs” used to treat a disease state that affects fewer than 200,000 patients.
- Faster FDA approval process and longer patent protection to entice pharmaceutical manufacturers to invest in “orphan” diseases because of the high cost of research and development for smaller populations
  - New ALS drug (NurOwn) is being fast-tracked by the FDA

Cancer Drugs
- Oncology agents account for 1/3 of specialty drugs in pipeline
- Rising incidence of cancer (estimated to be 75% by 2030)

Specialty drug manufacturers set the price of specialty drugs high to recover R&D costs and because of the expansion of Medicaid and the 340B program which makes it harder to raise prices once a specialty drug is on the market.
Specialty Benefit Architecture

Make sure the right doctor is giving the right drug to the right kind of patient for the right diagnosis in the right type of setting.

Factors driving wasteful spending on specialty drugs include:

----- non-evidence based treatment
----- member non-adherence
----- lack of visibility into medical utilization patterns and spend

According to a recent study conducted by Johns Hopkins and the University of Pennsylvania nearly 30% of cancer treatment did not meet medical evidence based standards or could not be medically justified.

Appropriate and aggressive management of specialty drugs is the key to controlling costs.
Channel Management

Do you know how much you are spending for specialty drugs under your medical benefit? Under your pharmacy benefit?

Should a specialty drug be covered under the medical benefit, the pharmacy benefit or both?

Is it more expensive to fill a specialty drug prescription through the physician’s “buy and bill” program than the specialty pharmacy?

Can the member appropriately and safely administer an injectable specialty drug?

Outpatient hospital is most expensive site of care for administration of specialty drugs generally costing on average 2-3 times as much as the physician’s office, home infusion or the specialty pharmacy.

Plan sponsors can realize greater cost savings by moving specialty drug administration out of the outpatient hospital setting.
Can the member appropriately and safely administer an injectable specialty drug?

Plan sponsors should implement a site-of-care program based not only on the cost of specialty drugs, but also outcomes.

Plan sponsors need to have PBM and health plan work with the benefit plan to establish a set of coverage attributes to eliminate redundancy and conflicts across medical and pharmacy benefits.

95% of Specialty Drugs fit into either the medical or pharmacy benefit.
Most specialty drugs are covered under standard benefit plan designs

**Standard Plan Designs:**
- Typically are not an equitable cost share
- Make it difficult to manage specialty product selection and utilization
- Can result in waste and/or excess drug on hand

**Specialty Plan Designs:**
- Specialty Copay Tiers
  - 4th tier for preferred Specialty Drugs
  - 5th tier for non-preferred Specialty Drugs
- Set copay levels to maximize compliance and outcomes
- Days supply limitations
- Utilize specialty formulary to drive market share
- Refill Too Soon edit
- Prior Authorization and Step Therapy edits
Establish clinically sound, evidence based criteria for all “naïve” specialty drug prescriptions.

Limit days supply to 30-days except where member may need to take a specialty drug for maintenance (e.g. RA, MS, etc.).

Utilize pharmacogenomics and bio-markers/molecular testing.

Managing off-label uses and knowing what limitations your pharmacy benefit plan design should say about coverage for off-label use.

 Appropriately structured utilization management could result in an initial 7-10% savings on specialty drug spend.
Clinical Management and Outcomes

Minimum clinical management requirements should be established.

Comprehensive initial clinical assessment on each naïve patient.

Live contact with patient prior to each refill.

Side effect and clinical effectiveness assessment with each refill.

Annual Comprehensive Profile Review of all medications (Specialty, Rx and OTC)

• Assess effectiveness and outcomes
• Evaluate compliance and adherence
• Eliminate duplication
• Assess dosages

Ultimate goal is to decrease costs without clinical sacrifice.
Biosimilars: A Remedy for High Cost Specialty Drugs?

Biosimilar specialty drugs are therapeutically similar to the originator drug, however since these drugs are “brewed” they are not chemically equivalent to the originator drug and are thus not generically substitutable.

While the specialty drug pipeline is robust, there are also 39 specialty drugs losing patent protection through 2018 (e.g. Copaxone; some cancer drugs; and drugs for autoimmune diseases).

Plan sponsors need to plan ahead since biosimilars/specialty generics could become a part of a pharmacy benefit plan design (e.g. Step therapy? Prior authorization?) since interchangeability for specialty brand drugs will lead to greater cost savings (20% less).

Caveat: Members may be required to switch back from a biosimilar to the specialty brand drug for therapeutic reasons because biosimilars are not exactly the same.

The new “Shell Game”—PBM’s may try to exclude rebates on biosimilars from specialty rebate guarantee.
Employers may see a reduction of 2.6%-7.6% of their total prescription drug spend because of introduction of biosimilars in the U.S. market.

According to CMS, pricing of biosimilars should be about 15%-30% lower than the reference biologic.

$250B could be saved in the next decade if 11 biosimilars (mostly targeting cancer) enter into the market since they have the potential of being mass-produced at a lower cost if safety and efficacy is validated.

Will market for biosimilars shrink as sales of blockbuster specialty drugs decline?

The use of biosimilars and price differences are not known and are the two main factors in determining savings.

In the future formularies and benefit design may change to steer more patients to biosimilars provided there are acceptable treatment outcomes.
PBM Contract—Key Specialty Drug Terms and Provisions

Definitions

Specialty Pharmacy Provider Criteria

Ability to Audit Pharmacy Operational Standards

Pricing and Rebate Guarantees

Performance and Outcome Guarantees

Specialty Drug List
Managing Rising Costs of Specialty Drugs

Key Take Aways

Appropriate and aggressive management of specialty drugs is the key to controlling costs.

Examine specialty benefit architecture and decide whether a specialty drug should be covered under the medical or pharmacy benefit.

Consider implementing preferred and non-preferred specialty tier copays.

Limit days supply to 30-days except where member may need to take a specialty drug for maintenance (e.g. RA, MS, etc.).

Assess clinical outcomes to make sure specialty drug is working.

Plan ahead for release of new to market specialty brand drugs and biosimilars.

Having appropriate terms and conditions regarding specialty drugs, services and Specialty Drug List are critical.