Purpose

To provide an overview of:

- Specialty Pharmacy
- Managed care organization (MCO) Specialty Pharmacy management strategies
Agenda

- What is Specialty Pharmacy (SP)?
- Why do we manage SP drugs?
- SP Management Strategies
- What MCOs want from Specialty Pharmacies
- The future of SP
Overview of pharmacy costs

- Prescription pharmacy costs account for 16% to 20% of total health care spend

- Average retail prescription cost = ~$70.00
  - Generic = $26
  - Brand = $150
  - Specialty = $1800
What is Specialty Pharmacy?

- Similar to the growth of Physician specialists, SP grew from the market’s demand for “specialization” in drug distribution and clinical management of complex therapies.
- SP’s primary focus is on drug therapy in patients with less common and complex medical conditions.
What is Specialty Pharmacy?

- Definition varies across the industry
- MCOs often define SP drugs as having many, if not all, of the following characteristics:
  - High cost (average ~$1,500 per month)
    - Range from $500 - $30,000 per month
  - Used to treat less common and complex diseases like multiple sclerosis, rheumatoid arthritis, and cancer
  - Requires special training and clinical support for members (pharmaceutical care)
  - The majority are self-injected by members
What is Specialty Pharmacy?

- SP drugs are accessed from many different delivery channels
What is Specialty Pharmacy?

**SP Drug Examples**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Medications</th>
<th>Cost (AWP) PMPY*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple Sclerosis</td>
<td>Avonex Betaseron, Rebif, Copaxone</td>
<td>$20,000 +</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>Peg-Intron, Pegasys, Rebetron</td>
<td>$25,000 +</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
<td>Enbrel, Remicade, Humira, Kineret</td>
<td>$18,000 +</td>
</tr>
<tr>
<td>Growth Hormone</td>
<td>Nutropin, Humatrope, Norditropin</td>
<td>$20,000-25,000 +</td>
</tr>
<tr>
<td>Psoriasis</td>
<td>Amevive, Raptiva, Enbrel</td>
<td>$15,000 +</td>
</tr>
<tr>
<td>Hemophilia</td>
<td>Recombinant Blood Factor Products</td>
<td>$150,000-$200,000 +</td>
</tr>
<tr>
<td>Gaucher Disease</td>
<td>Cerezyme/Ceredase</td>
<td>$250,000 +</td>
</tr>
<tr>
<td>Pulmonary Hypertension</td>
<td>Flolan, Tracleer, Remodulin</td>
<td>$30,000 -100,000 +</td>
</tr>
<tr>
<td>Oncology</td>
<td>Neupogen, Neulasta, Procrit, Aranesp</td>
<td>$10,000-100,000 +</td>
</tr>
<tr>
<td></td>
<td>Gleevec, Tykerb, Revlimid</td>
<td></td>
</tr>
</tbody>
</table>

*AWP = Average Wholesale Price; PMPY = Per Member Per Year*
Why do We Manage SP Drugs?

- SP drugs have significant financial impact on payors (managed care) and it’s growing!
  - SP drug trend is 2-5 times higher than growth in traditional drugs over past 5 years
  - SP drugs now represent ~15 - 20% of total drug spend for many organizations
    - In 2003, SP drugs were ~9% of total drug spend
    - SP drugs often represent <1% of total prescription count
SP Drugs: Low Utilization, High Costs

Total number of prescriptions for Specialty drugs on the Pharmacy Benefit

- Specialty Drugs: 0.57%
- All Other Drugs: 99.43%

Amount Paid for Specialty drugs on the Pharmacy Benefit

- Specialty Drugs: 15.02%
- All Other Drugs: 84.98%

2009 Premera Blue Cross Data
Why do We Manage SP Drugs?

- There are many factors driving SP drug growth:
  - Technological advances
    - Human genome mapping, medical informatics
  - Increased research funding
    - Manufacturers shifting focus from traditional drug development to biotech drugs
  - Expanding use of SP drugs
    - Drug development is transitioning to more common disorders like cardiovascular and diabetes

- These 3 factors result in a very robust SP drug pipeline
  - More than 50% of drugs in development are considered SP drugs
Accredo Pipeline (n=657)

09.09.09-Promising Phase 2 (positive Phase 2 results) Forward, Products Not FDA Approved

**Route of Administration**

- Infusion: 29%
- Oral: 31%
- Other: 10%
- Inhalation: 3%
- Injectable: 27%

**Therapeutic Category**

- Cancer: 47%
- Hematology: 6%
- Immune System: 5%
- CV: 5%
- Inflammatory: 7%
- Respiratory: 4%
- Other: 4%
- Hormonal: 8%
- CNS: 12%

Cancer Dominates 47%
Pipeline Management
2010-2011 Near-Term Specialty Pipeline Drugs

Rheumatoid Arthritis
ocrelizumab

Gaucher’s Disease*
Vela™
Uplyso™

Osteoporosis*
Prolia™

Cystic Fibrosis
Cayston®
TIP

Rheumatoid Arthritis
ocrelizumab

Multiple Sclerosis*
Ampriva®
fingolimod
Movectro™

Lupus#
Benlysta™
epratuzumab
Prestara™

Refractory Gout#
Krystexxa™

Ideopathic Pulmonary Fibrosis#
Pirespa®

Cancer*
Provenge®
Yondelis®
Pixuvri
Omapro

Respiratory Syncytial Virus*
Numax®

Hereditary Angioedema*
Firazyr™
Rhucin®

Current specialty therapies

New specialty therapies categories

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Why do We Manage SP Drugs?

- SP drug coverage poses significant challenges in reimbursement and coverage
- SP drugs can be covered under:
  - Pharmacy Benefit
  - Medical Benefit
  - Hospital, Outpatient Infusion Center, Provider’s Office, Home Infusion
  - Both!
SP Management Strategies

- To control and minimize the growth of SP drug spending while continuing to provide quality care
- This strategy is often achieved through 2 main components with multiple underlying objectives
  - **Cost Management** – unit and overall costs
    - Drug discounts
    - Channel management
    - Rebates
    - Benefit design options
  - **Utilization Management** – assuring appropriate use
    - Formulary management
    - Prior authorization, quantity level limits
    - Clinical management
    - Genomic testing (future)
SP Management Strategy

- To accomplish the strategy, Managed Care Organizations (MCOs) contract with Specialty Pharmacy vendors
  - Negotiate increased drug discounts
  - Provide efficient distribution channel
  - Some MCOs use SP vendor for utilization management services – prior authorization, formulary management, clinical management
What Managed Care Wants from a Specialty Pharmacy

- Competitive pricing – unit cost discounts
- High levels of customer service
- Promote safe and effective use of SP drugs leading to optimal clinical outcomes
- Eliminate waste and over-usage
- Broad access to SP drugs
- Reporting
Specialty Drug Benefit Designs

- Current benefit designs prevalent in the industry
  - Mandatory use of preferred Specialty Pharmacy vendors
  - Limit days supply to 30-days
  - Separate “tiers” of coverage (e.g. 4th Tier) with distinct copay levels
  - Utilization Management
Specialty Drug Benefit Designs

- Future benefit designs (potential)
  - Expanding use of 4th tier (and more) for specialty drugs
    - Not only distinct copays, but separate deductibles and maximum out of pocket costs
  - Limit first fill quantity (oral oncology agents)
  - Value based benefit designs promoting the use of SP drugs with proven outcomes
The Future of SP

- Continued growth
  - Management strategies might slow growth, but won’t stop it
- Evolution of new products and more targeted therapies for expanding populations
- Genomic testing is just beginning...
  - Ability to target which patients will respond to therapy based on specific markers
  - Expensive
  - Test validity is going to be an issue
Biosimilars (biogenerics)

- Health Care Reform
  - Title VII: Improving access to Innovative Medical Therapies
- Could reduce medication costs considerably
- Patents have already expired for $15B worth of biologics
  - Human insulins
  - Growth hormone
  - Nonpegylated alfa interferons
- Significant barriers exist to market availability
  - Interchangeability
  - Regulatory pathways
  - Patent protection

Source: Accredo Specialty Pharmacy
Conclusion

- SP is growing rapidly and is a concerning segment of the overall drug spend
- The market is looking for ways to minimize the growth through strategies aimed at controlling costs and assuring appropriate utilization
- Future benefit designs will need to account for the rapid growth
Easy Questions