



Specialty Pharmacy Managed Care Strategies

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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?

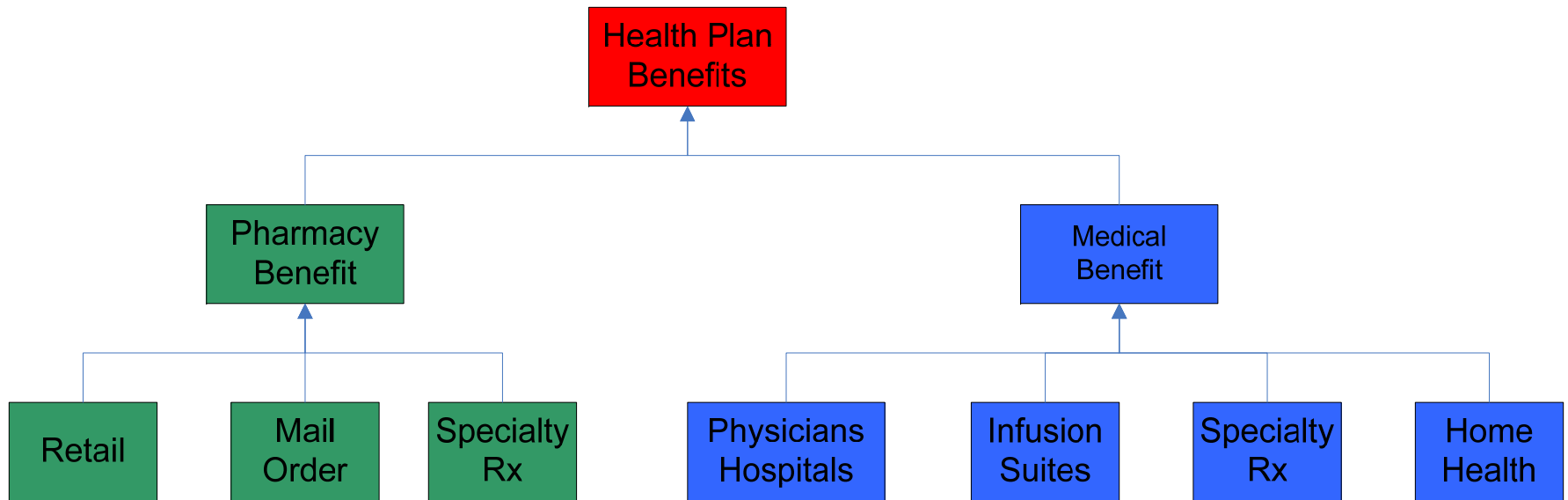
- Similar to the growth of Physician specialists, SP grew from the market's demand for “specialization” in drug distribution and clinical management of complex therapies
- SP's primary focus is on drug therapy in patients with less common and complex medical conditions

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

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

*AWP = Average Wholesale Price; PMPY = Per Member Per Year

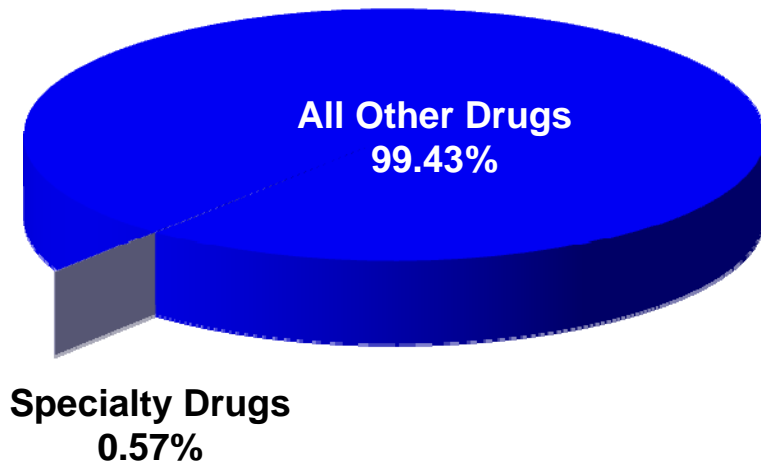


Why do We Manage SP Drugs?

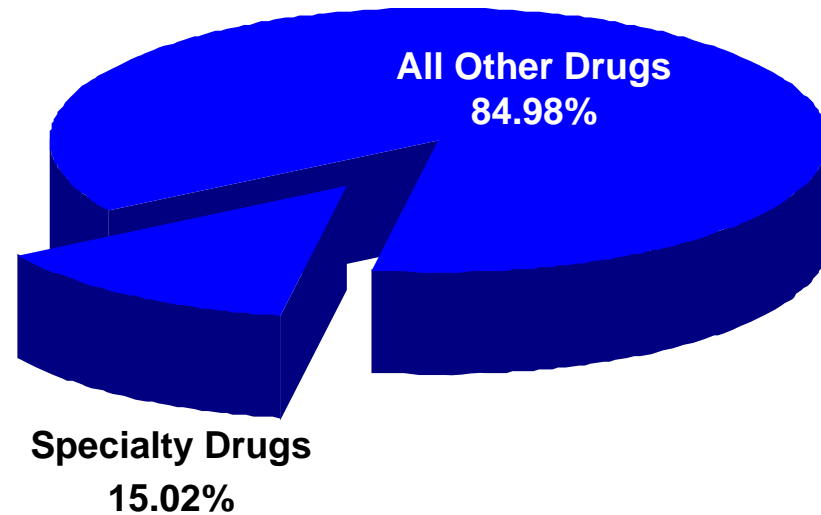
- SP drugs have significant financial impact on payors (managed care) and it's growing!
 - SP drug trend is 2-5 times higher than growth in traditional drugs over past 5 years
 - SP drugs now represent ~15 - 20% of total drug spend for many organizations
 - In 2003, SP drugs were ~9% of total drug spend
 - 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



Amount Paid for Specialty drugs on the Pharmacy Benefit



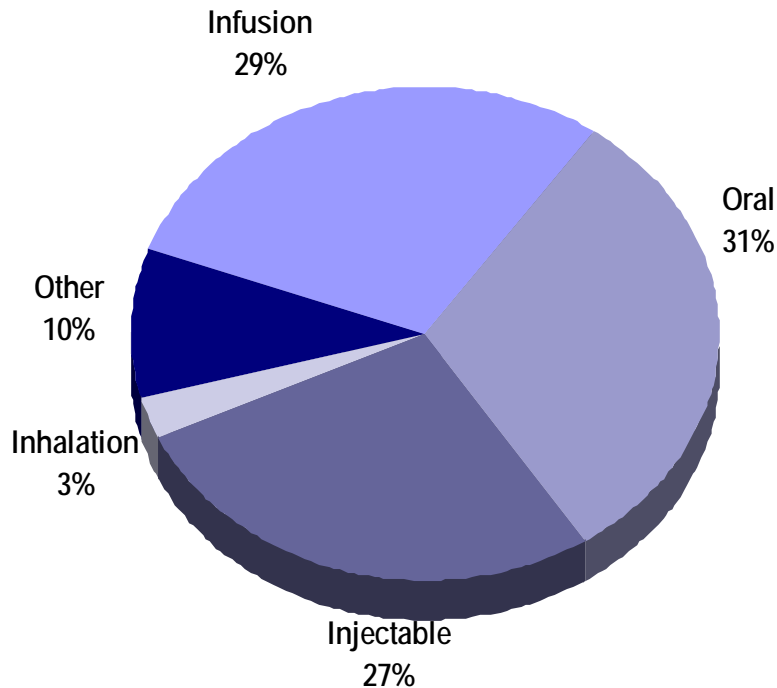
Why do We Manage SP Drugs?

- 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)

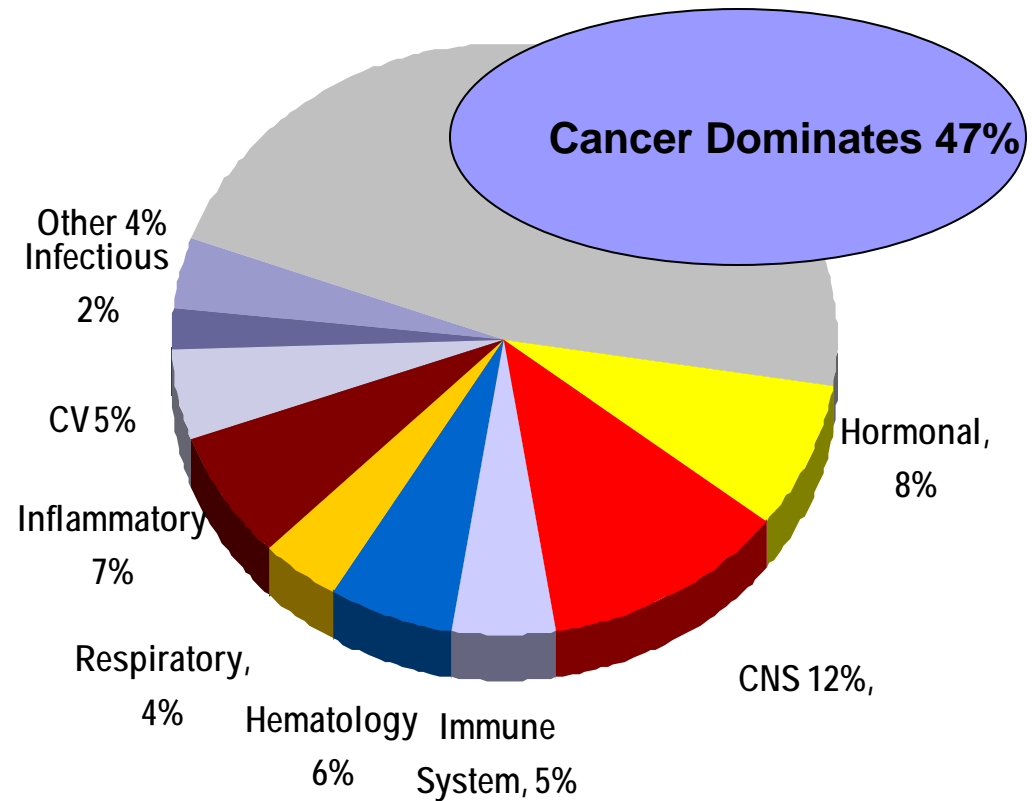
09.09.09-Promising Phase 2 (positive Phase 2 results) Forward, Products Not FDA Approved

Route of Administration



Therapeutic Category

Cancer, 47%



Pipeline Management

2010-2011 Near-Term Specialty Pipeline Drugs

**Rheumatoid*
Arthritis**
ocrelizumab

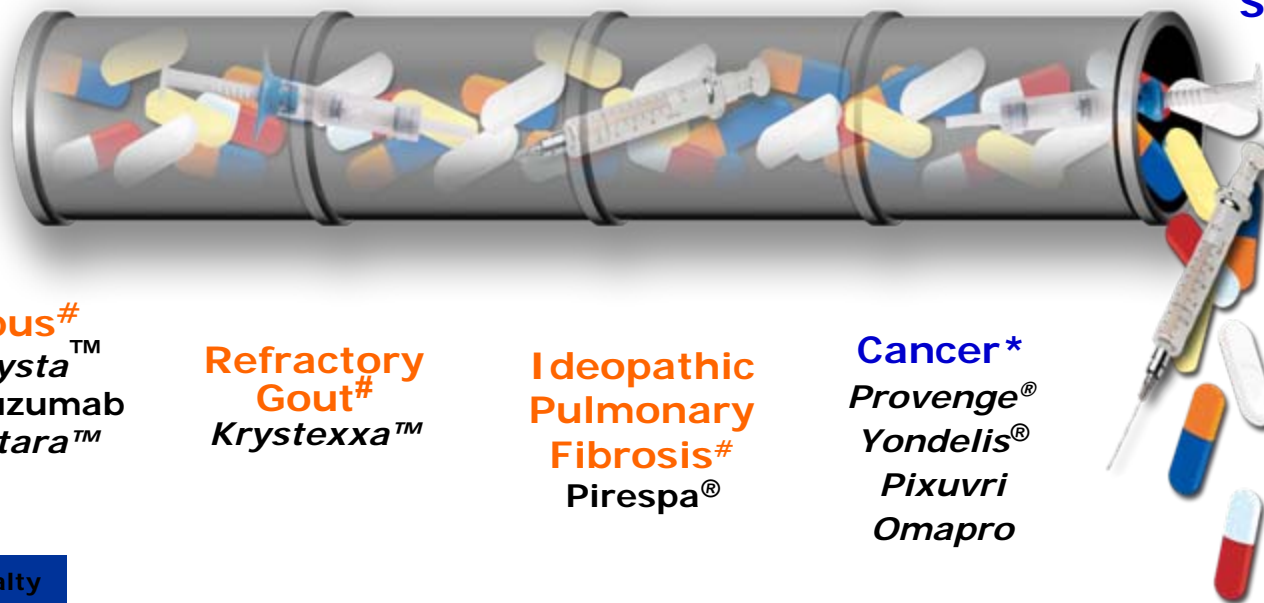
**Gaucher's
Disease***
*Vela*TM
*Uplyso*TM

Osteoporosis*
*Prolia*SM

Cystic Fibrosis
Cayston[®]
TIP

**Respiratory
Syncytial Virus***
Numax[®]

**Multiple
Sclerosis***
Ampriva[®]
fingolimod
*Movectro*TM



Lupus#
*Benlysta*TM
epratuzumab
*Prestara*TM

**Refractory
Gout#**
*Krystexxa*TM

**Ideopathic
Pulmonary
Fibrosis#**
Pirespa[®]

Cancer*
Provenge[®]
Yondelis[®]
Pixuvri
Omapro

**Hereditary
Angioedema***
*Firazyr*TM
Rhucin[®]

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Current specialty
therapies

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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



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