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Specialty Drug Management Solutions You Haven't Heard Before

Sarah Martin, ASA, MAAA, CEBS
Vice President, Senior Pharmacy Consultant
Lockton
Kansas City, Missouri

PARTNERS IN EDUCATIONAL EXCELLENCE
International Society of Certified Employee Benefit Specialists
International Foundation of Employee Benefit Plans

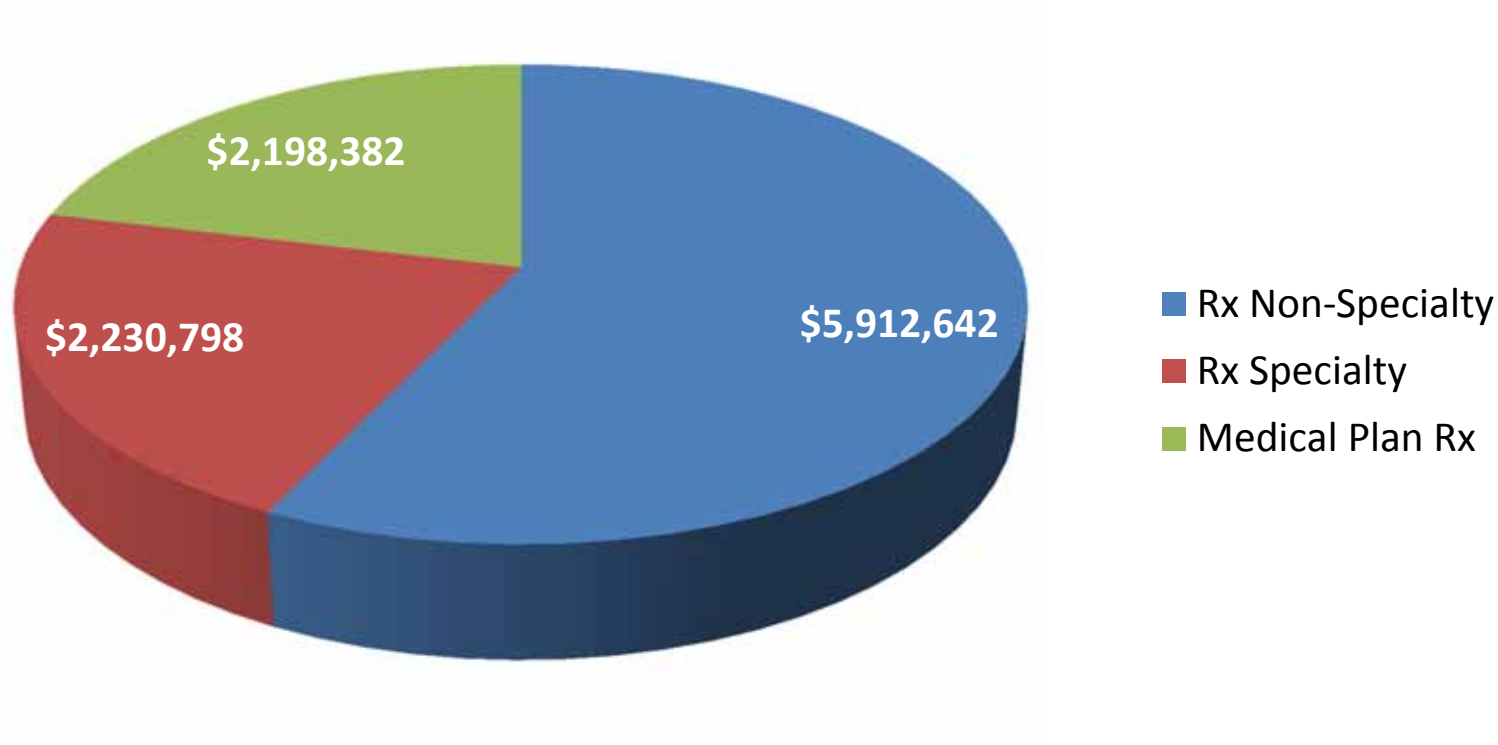
Agenda

- How to use channel and site of care optimization
- Does carving out specialty really work?
- How to predict your future specialty drug spend based on drugs in the pipeline and your population demographic

How to use channel and site of care optimization

CHANNEL ANALYSIS

Do You Know Where Your Drug Spend Is Coming From?



For many employers, there is just as much specialty drug spend on the medical side as on the pharmacy side.

Comparing Specialty: Medical vs. Rx

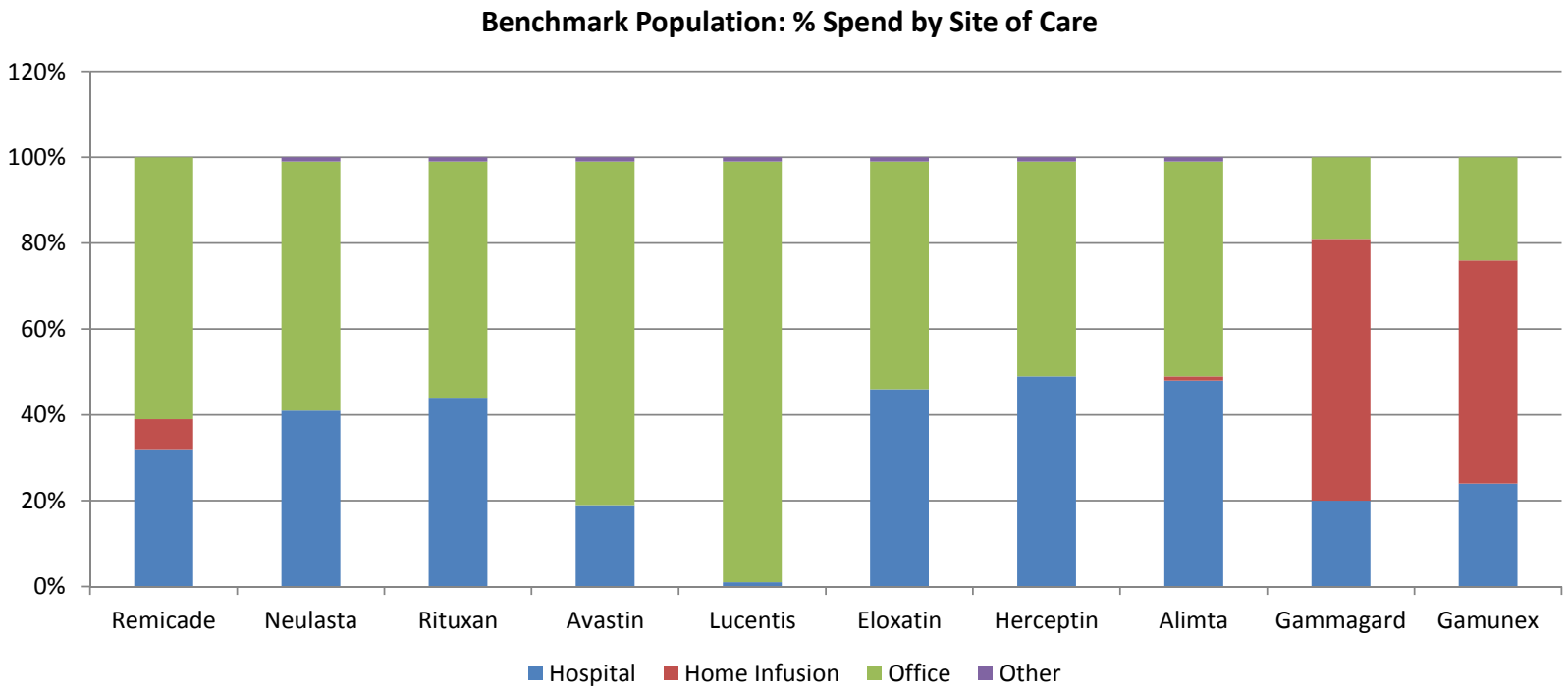
- **Medical Challenges**
  - Administration costs are not measured
  - Specialty rebates are not paid to plan sponsor or measured
  - Little control over site of care and distribution channels
  - Health plan may not assist with specialty Patient Assistance Programs
- **Coordination Challenges**
  - ASP pricing vs. AWP pricing (see chart below)
  - Member cost sharing is often not coordinated across benefits
  - Different vendors are often responsible for Rx vs. pharmacy, even if Rx is "carved-in"
  - Systems may not integrate medical and pharmacy data well

	Pharmacy	Office, Clinic, Home Infusion	Outpatient Hospital
Claim Layout	National Council for Prescription Drug Programs (NCPDP)	HCFA 1500 Medicare standard	UB 92
Drug Code	National Drug Code (NDC-11) Unique to drug, manufacturer, form, strength, and size	HCPCs, J codes, Q codes Unique to drug or drug class J code is specific to generic ingredient and quantity	Revenue code 3-digit code indicates where and what type of service Does not identify drug level information
Pricing Benchmark	Average wholesale price (AWP)	Average sales price (ASP)	Percent of billed charges
Transparency	High	Medium	Low

Challenges with Blocking JCodes

- Typically we want professionally administered drugs to run through the medical plan (in Jcodes) and self-administered drugs to run through the Rx plan
- Even if we think we can source a drug less expensively through the Rx plan, there are challenges associated with blocking Jcodes and requiring medications to run through the Rx/PBM plan instead of the medical plan
- White bagging
  - The drug is purchased from the PBM through the Rx plan and sent directly to the physician at the site of care for administration
  - Physicians may have a problem with this because they did not purchase the drug from their source and they do not make any revenue off of the drug
  - The physician may charge an additional administration fee anyway
- Brown bagging
  - The drug is purchased from the PBM through the Rx plan and the patient brings the drug in to the site of care to have it professionally administered
  - Many physicians refuse to do this because of the liability associated with administering a drug the patient brings in themselves (they don't know for sure if the drug is correct, how the drug has been stored, if it has been kept at the correct temperature, etc.)

Candidates for Site of Care Optimization



Remicade is one example of a drug that can be administered in the outpatient hospital setting or the office setting. Significant savings can often be realized by moving to the office setting.

Top Medical Specialty Spend

Site of Care Optimization Details—Example

Drug	J Code	Outpatient Hospital			Office			Lowest Cost Site of Care	Feasibility of Moving Site of Care	Maximum Savings Potential
		Total Allowed	Procedure Count	Avg Allowed/ Procedure	Total Allowed	Procedure Count	Avg Allowed/ Procedure			
Remicade	J1745	$34,562	5	$6,912	$411,081	64	$6,423	Office	Moderate	$2,445
Orencia	J0129	$70,725	10	$7,072	$20,251	10	$2,025	Office	Moderate	$50,470
Velcade	J9041	$51,417	23	$2,236	$32,300	19	$1,700	Office	Low	$12,328
Botox	J0585	$30,597	9	$3,400	$20,886	21	$995	Office	Moderate	$21,843

- Professionally administered drugs may be difficult to move from one site of care to another, particularly if the doctor or oncologist is associated with a particular site.
- Further discussion with the medical carrier on each drug above would be necessary to understand the potential of changing site of care.

Medical Specialty Opportunities

Site of Care Optimization Clinical Considerations

- There are challenges associated with changing a current patient's site of care
- In general, chemotherapy site of care should be left to the physician
- Many physician practices are now owned by hospital systems
  - These physicians may be incentivized to utilize their hospital outpatient facilities to administer a drug
- How do we change site of care?
  - Through prior authorization process
  - Recommend alternate site after the first infusion
  - Incent patients to use an alternative site with lower cost share
  - Communications to patients about more convenient and lower cost site of care without incentives
  - Health plan has to be on board
  - Physician has to be on board

Does carving out specialty pharmacy really work?

SPECIALTY PHARMACY CARVE-OUT

Laundry List of Possible Solutions

- Specialty solutions are not “one size fits all”
- Specialized solutions for: Each patient, Each disease, Each employer

Compliance monitoring & reporting	Appropriate supply limits	Formulary exclusions	Retail vs. exclusive specialty arrangements
Pharmacogenomics and “precision medicine”	Split fills	Patient contracts	Pricing guarantees
Control auto-ship	Clinical coaching	No first fill at retail	Specialty rebate strategies
Exclude at launch	Peer-to-peer consultation with physician	Injections training	Contractual definitions
Manufacturer assistance tracking	New physician payment models	Channel optimization	Technology tools for compliance monitoring
Preferred products	Targeted step therapy	Site of care optimization	Required continuous lab tests
Biosimilars planning	Meaningful prior authorization process	Duration management	Evidence-based guidelines
Evidence-based guidelines	Provider education coordination	Companion diagnostics	3rd party prior authorization

Why Carve Out?

- Can your PBM/carrier do everything on the laundry list that you want them to do?
  - Are they good at it?
  - Are they incentivized to do it?
- As PBMs/carriers push clients towards exclusive specialty fulfillment, independent specialty pharmacies want to keep business and are willing to compete for it.
- When your PBM owns specialty drug fulfillment, are they the best entity to also perform utilization management and prior authorization?
- Some groups want another entity to perform the prior authorization and direct the PBM to fill the script.
- Do you do this for all specialty drugs or just certain disease states?
- Can a hospital system in your area provide specialty drug fulfillment services and care to your members?
- “Best in Class” specialty pharmacies

Why Not Carve Out?

- Adds another vendor
- Adds another data feed
- Might complicate the patient/provider experience
- Your PBM/carrier will likely increase costs somewhere else if they lose the specialty pharmacy business
- For carriers, synergies may exist in an integrated model as certain specialty drugs are filled on the medical side
- How is a specialty drug defined? You must be specific about which drugs are specialty and which are covered by the PBM and which are covered by the specialty vendor
- Your specialty vendor must have access to limited distribution drugs

Can Your PBM Track Manufacturer Assistance?

- If they cannot, this alone may be sufficient reason to carve out specialty pharmacy
- All Rx member cost share now counts toward either a combined medical/Rx out-of-pocket maximum or a stand-alone Rx out-of-pocket maximum
- If a drug manufacturer pays $495 of a member's $500 copay, you want $5 to count towards their OOP max, not $500!
- Some progressive PBMs are making changes to clients' plan designs to maximize the manufacturer assistance on a drug-specific level

How to use your medical data to predict specialty drug spend in the future

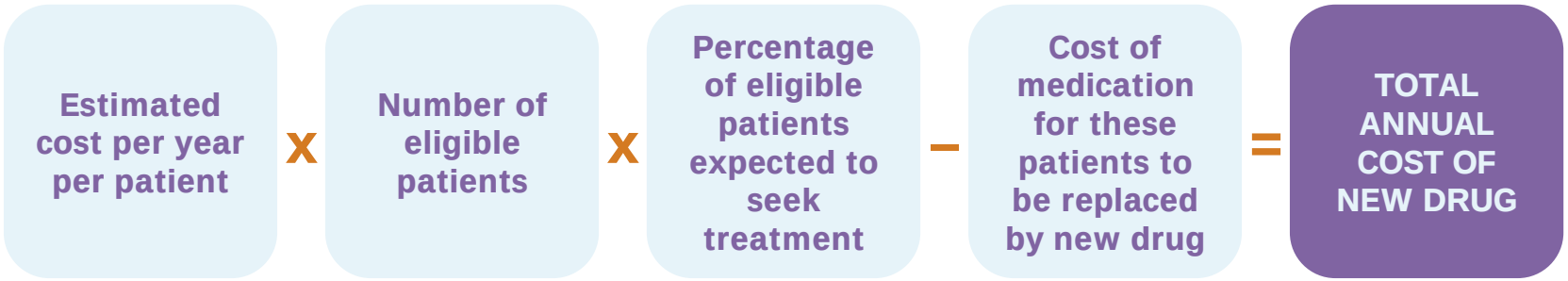
PREDICTIVE MODELING

Why Predictive Modeling?

- Looking at historical Rx claims data and assuming that pattern will continue doesn't make sense given the pipeline of specialty drugs
  - Remember hepatitis C?
- Industry benchmarks are little help to a small or mid-size self-funded plan because specialty spend and utilization are highly variable
  - The smaller your enrollment, the more important this is
- Predictive modeling can help determine what level of stop loss coverage makes the most sense

What Is Predictive Modeling?

The use of claims data to estimate the impact of future specialty drug claims based on the plan's existing disease state and demographic profile



Info from FDA and PBM pipeline reports

Your medical claims data and ICD9 codes

Info from FDA and prescribing information

Your Rx claims data

Cystic Fibrosis (CF) Example

- Lumacaftor (Vertex) was approved in July 2015
- Treats cystic fibrosis in patients with two copies of the F508del mutation, ages 12 and over
  - Breakthrough therapy → New type of treatment, not a "me too" drug
  - Orphan drug → Treats a very small population (often results in drug being more expensive in order to recoup costs)
  - Pharmacogenetic test → Not necessarily everyone with the disease will benefit from the drug, testing needed
- Probabilities:
  - 30,000 people in the U.S. have CF
  - Globally, nearly half of people with CF have two copies of the F508del mutation
  - Study will be conducted in those ages 6-11, so could be approved for younger patients
- Cost estimate: $300,000/year
- What current treatment would this replace? Is anyone currently taking Kalydeco?
  - Kalydeco is only effective for approximately 7% of CF patients
  - Kalydeco costs $300,000/year

Cystic Fibrosis (CF) Example

- Assume according to your medical claims data, four members over age 12 have been diagnosed with cystic fibrosis
- Cost estimate: $300,000/year per person
- What current treatment would this replace? Are people currently taking Kalydeco alone now?
  - No one in your population has been taking Kalydeco
- Because the new medication is expected to work for 50% of CF patients, the expected annual cost once the new medication is available is:

*Assumes everyone eligible for the drug will take it

High Cholesterol

- Traditionally treated by fairly low-cost statins
- In July, a new injectable treatment for cholesterol (PCSK9 inhibitors) is expected to hit the market
- Two manufacturers expected to release PCSK9 inhibitors within a month of each other
  - Could spur price competition
  - Pricing is expected to be $4,000-$12,000/year per patient for the new drug
- Doctors are being educated now
- www.cholesterolneversleeps.com by Amgen
  - Out of the 212 million American adults, 71 million have high LDL-C
  - 37 million untreated
  - 23 million treated and at goal
  - 11 million treated and not at goal
- www.cholesterolmatters.com by Sanofi and Regeneron

Who Could Be Eligible for PCSK9 Inhibitors?

Familial hypercholesterolemia = genetically inherited high cholesterol

- Many believe this will be the first category of patients treated
- Genetic form of high cholesterol impacting 620,000* Americans

Beyond familial hypercholesterolemia, others may be eligible

- Patients who can't tolerate statins
- Severe cases where statins are ineffective
- History of coronary artery disease

15-18 million Americans could eventually be candidates for PCSK9 inhibitors, and they aren't all taking statins

- Looking at statin utilization alone is not sufficient—patients who can't tolerate statins aren't going to be taking them. You must look at diagnosis codes in the medical data to identify others with hypercholesterolemia

*CVS Health Raises Concerns about the Potential Impact of New Class of Cholesterol Drugs on the Health Care System, February 17, 2015, www.cvshealth.com

Oncology Is Different

- Predictive modeling is difficult
- The oncology pipeline is exciting, but almost impossible to model for individual employers
  - Low frequency
  - High cost
  - High variability
- Contrast with PCSK9 inhibitors
  - Relatively high frequency as compared to oncology
  - Relatively low cost ($12K vs. $500K)
  - Relatively low variability (cost per patient should be consistent throughout the year and year over year because high cholesterol is a chronic condition)

Specialty Drug Predictive Model
Sample Results

AVERAGE AGE	55.2		28.9		45.5		52.1	
PERCENT SEEKING TREATMENT	HEPATITIS C	CLASS TOTAL	CYSTIC FIBROSIS	CLASS TOTAL	IDIOPATHIC PULMONARY FIBROSIS (BROAD)	CLASS TOTAL	LIPID DISORDERS (EXPANDED)	CLASS TOTAL
100%	22	$1,980,000	1	$225,000	6	$600,000	753	$9,036,000
90%	20	$1,800,000	1	$225,000	6	$600,000	678	$8,136,000
80%	18	$1,620,000	1	$225,000	5	$500,000	603	$7,236,000
70%	16	$1,440,000	1	$225,000	5	$500,000	527	$6,324,000
60%	14	$1,260,000	1	$225,000	4	$400,000	452	$5,424,000
50%	11	$990,000	1	$225,000	3	$300,000	377	$4,524,000
40%	9	$810,000	1	$225,000	3	$300,000	302	$3,624,000
30%	7	$630,000	1	$225,000	2	$200,000	226	$2,712,000
20%	5	$450,000	1	$225,000	2	$200,000	151	$1,812,000
10%	3	$270,000	1	$225,000	1	$100,000	76	$912,000
ESTIMATED COST	$90,000 PER COURSE OF THERAPY		$500,000 PER COURSE OF THERAPY		$100,000 PER COURSE OF THERAPY		$12,000 PER COURSE OF THERAPY	

Recommendations

- Use medical and pharmacy data to compare channel costs (medical benefit vs. pharmacy benefit) and site of care costs (outpatient hospital vs. home vs. physician office)
- Find out what your PBM can do to manage specialty spend and if carving out specialty has advantages
- Keep an eye on the specialty drug pipeline and use predictive modeling to budget for future expense and select appropriate stop loss protection