# Overview of the Specialty Drug Trend

## Succeeding In The Rapidly Changing U.S. Specialty Market

## Specialty drugs are prescribed to treat complex conditions such as cancer, HIV and inflammatory diseases. While these drugs fulfill the promise of modern medicine by enriching and often extending a patient's quality of life, they are typically characterized as expensive therapies having a high cost/unit.

IMS Health defines specialty medicines as ones that meet five or more of the following 8 criteria:

- Biotech product
- Injectable formulation
- REMS program
- Treats a chronic condition
- Specialist-initiated
- Requires special handling (cold-chain)
- Costs in excess of $6K/year
- Limited distribution

Given that specialty drugs are very expensive and currently lack comparable generic alternatives in the U.S., they warrant increased attention from key stakeholders such as payers, providers and policymakers[1]. Although cost is an important consideration, stakeholders also realize the clinical benefit these products bring, which often offsets the overall healthcare costs of treating patients with serious life-threatening conditions.

1 http://www.rxobserver.com/?p=1300

Specialty pharmaceutical spending is on the rise and is expected to increase from approximately $55 billion in 2005 to $1.7 trillion in 2030[2], according to the Pharmaceutical Care Management Association. That reflects an increase from 24% of total drug spend in 2005 to an estimated 44% of a health plan's total drug expenditure in 2030. Several factors are driving the specialty drug spend, including:

- The rising interest in personalized medicine and targeted therapeutics, leading to increased investment in this space. As a result, the specialty drug pipeline is bulging with nearly 700 specialty products currently in development.
- With patent expirations of small molecule drugs and increased generic usage curbing the costs of traditional drugs, specialty drugs now represent a rapidly-increasing share of overall prescription drug spend.
- Price inflation has been a leading driver of the specialty drug trend with prices of some drugs growing at double-digit rates.
- The development and commercialization of biosimilars has been slow due to the expensive and complex manufacturing requirements of biologics, small patient populations and undefined FDA approval pathways. So while some therapeutic categories have multiple options, many specialty drugs including biologics are considered breakthrough therapies with few close substitutes[3]. The lack of generic (biosimilar) competition further contributes to higher prices for these drugs.
- Specialty drugs are frequently administered by medical professionals at higher-cost treatment sites such as hospitals, infusion centers and physician offices. These drugs also require special handling, administration, patient education, and clinical support -- all of which further drive up their cost. As a result of increased medical, laboratory and hospital costs, specialty drugs are currently the fastest growing portion of the overall healthcare bill.

2 http://www.managedcaremag.com/archives/0910/0910.medmgmt.html
3 http://www.cvscaremarkfyi.com/sites/default/files/Insights%202013.pdf


FIGURE 1: INDUSTRY DRIVERS OF RISING SPECIALTY DRUG SPEND

# Growth of the Specialty Pharmacy Channel

Specialty pharmacy, which once occupied only a small niche in the marketplace, has now become the largest growth area in the pharmacy industry. IMS Health data shows a clear trend of increasing utilization for top Rheumatoid Arthritis (RA) and Oral Oncology products in the specialty channel with decreasing utilization in retail channel over the past 5 years (Figure 2). Currently, three pharmacies -- Express Scripts, CVS Caremark and Walgreens -- make up more than 50% of the specialty drug market while the rest of the market is comprised of hundreds of smaller specialty pharmacies, including Diplomat pharmacy and Omnicare's advanced care scripts[4]. However, due to the commoditization of retail pharmacy dispensing, there has been an ever-growing increase in the number of pharmacy providers dispensing specialty drugs, driving up the level of competition. In addition to traditional specialty pharmacies which are independent or owned by pharmacy benefit managers (PBMs), there is a range of new entities entering the specialty pharmacy marketplace. The new players include specialty pharmacies operated by wholesalers, large hospital organizations, physician practices and retail pharmacies. As a result, there has been an emergence of several specialty pharmacy trade associations representing viewpoints from a diverse set of players and further increasing the complexity of this market.

4 http://obroncology.com/obrgreen/article/The-Evolving-Dynamics-of-Specialty-Pharmacy-in-Oncology

The increasing availability of specialty pharmacy providers that can deliver high-cost, high-touch services has led to a greater variety of options for manufacturers to consider as they determine their specialty pharmacy network. Manufacturers generally make distribution decisions on a product-specific basis, since specialty pharmaceuticals have unique needs that may change throughout the product lifecycle. Access to data, therapeutic area expertise, patient population size, patient access, distribution control and administrative support are all factors that manufacturers consider when determining their specialty pharmacy network. While the industry is still booming, specialty pharmacy providers need to focus on differentiation of services to remain competitive and address evolving marketplace needs.

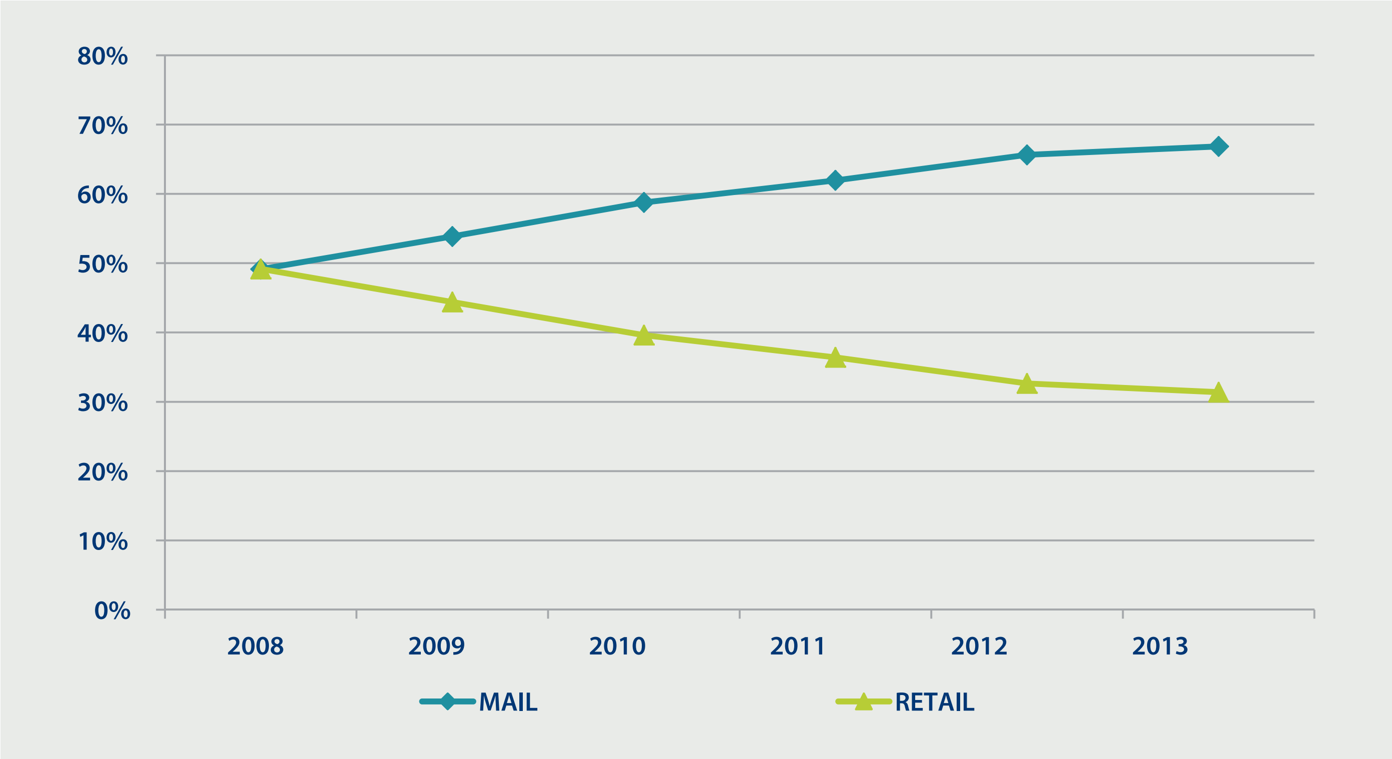


FIGURE 2: NPA TRX VOLUME TOP RA AND ORAL ONCOLOGY PRODUCTS

## Commercial Decision-Making in the New Landscape

Access and distribution are both critical components in determining the commercial success of specialty products and are influenced by key factors. These factors include distribution sites authorized by the manufacturer, requirements of the health plan and the route of administration. Emerging specialty pharmacy business models and distribution practices pose new challenges to commercial decision-making as manufacturers strive to develop a customer-driven sales approach. On the other hand, intensified cost pressures and payer cost-containment techniques challenge the degree of access granted to specialty products. As manufacturers navigate the new landscape to achieve optimal distribution and access for specialty products, it is becoming even more important to identify and allocate their resources across channels that provide the highest return. With the emergence of new payment and care delivery models, considerations of non-supply chain stakeholders are increasingly shaping manufacturer distribution decisions. We believe it is important for manufacturers to account for payer preferences as they determine distribution networks for their specialty products. Depending on the organization, payers may favor one specialty pharmacy provider over another based on their ability to reduce inappropriate utilization, reduce drug acquisition cost and improve compliance and persistency[5]. Since payers generally have the ability to influence member use of specific specialty pharmacy providers, payer preferences around network decisions may have a significant impact on distribution.

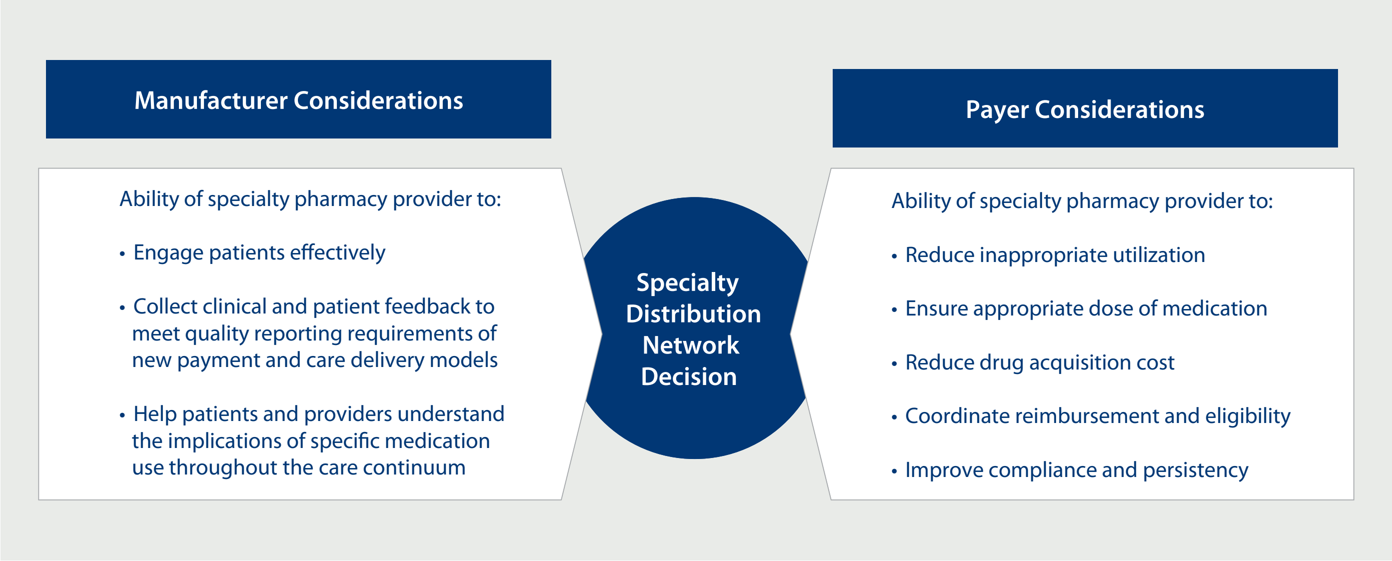


FIGURE 3: MANUFACTURER AND PAYER CONSIDERATIONS IN DETERMINING AN OPTIMAL SPECIALTY PHARMACY NETWORK

5 http://www.specialtypharmacytimes.com/publications/specialty-pharmacy-times/2012/December-2012/Specialty-Pharmaceuticals-Manufacturers-Must-Consider-a-New-Supply-Chain

## Measuring the Impact of Channel Decisions

As more of the burden of healthcare costs is transferred to patients' shoulders, adherence to expensive and inconvenient specialty treatment regimens is expected to deteriorate. The implications of non-adherence are significant for manufacturers both in terms of revenue impact and health outcomes. In this respect, specialty pharmacy providers are developing more strenuous interventions, and specialty providers' ability to bolster compliance is becoming a significant differentiator[6]. Evolving adherence programs, along with integrated care delivery systems, also place the specialty pharmacist in the central role of these patients' continuum of care[7]. However, given the number of patient outreach programs and value-added services being offered by specialty pharmacy networks to increase patient adherence, there is limited published data on the impact of interventions on outcomes for patients taking specialty medications.

Payers also find it challenging to quantify the value received from their investment in the various programs implemented through the specialty pharmacy channel. While improved compliance and persistency is a leading priority for health plans in their management of specialty pharmaceutical costs, a recent EMD Serono report indicates that less than 44% of plans have been offered performance guarantees for adherence, pharmacy and medical cost savings, and outcomes by their specialty pharmacy provider[8]. Although payers rank adherence measurement, tracking patient interventions and patient outcomes among the specialty pharmacy services most valuable to them, they also identify these service offerings as lacking from their specialty pharmacy providers.

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6 http://www.imshealth.com/imshealth/Global/Content/Document/IMS%20in%20the%20News%20Documents/Changing_the_channel_Developments_in_Distribution.pdf
7 http://www.burrillreport.com/article-payers_target_rising_specialty_drug_spend.html
8 EMD Serono Specialty Digest 9th Edition 2013

We suggest that one way to help determine the relative importance of different channels in driving brand performance is comparing adherence metrics between patients receiving therapy in the retail channel and those receiving therapy in the specialty pharmacy channel. These adherence metrics will help measure the overall value created from the specialty pharmacy across different products and therapeutic areas. Since patient adherence is a common goal for both manufacturers and payers, the ability to quantify the value of adherence programs is important in designing and implementing successful product strategies. Overall, as specialty pharmaceutical costs continue to rise and relationships between key stakeholders increase in complexity, specialty manufacturers will need to rely on a broad base of evidence on prescribing practices, sales and prescription activity, treatment pathways and patient outcomes to help understand how specialty products are being prescribed, distributed and used so as to make effective commercial decisions[9].

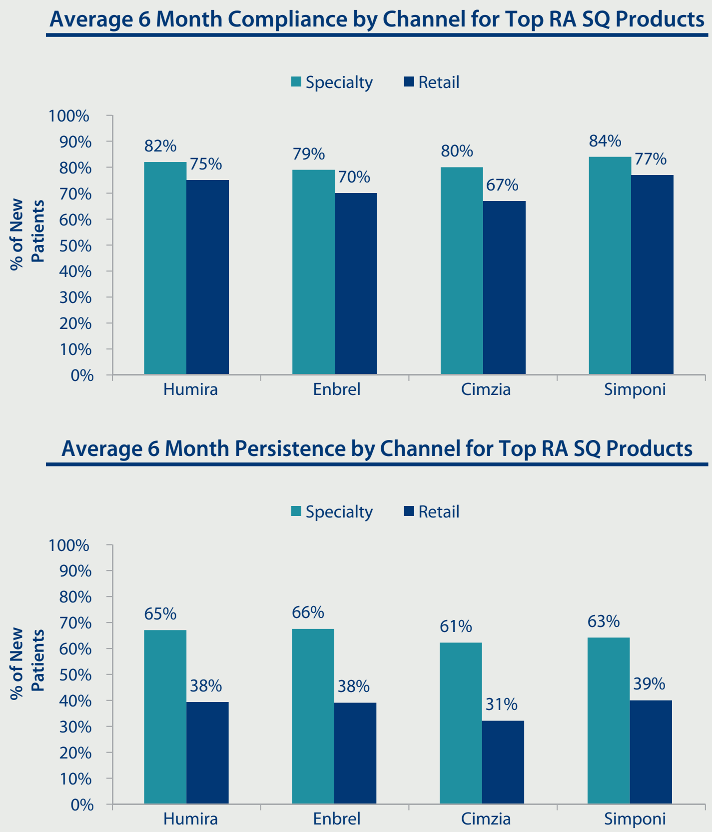


FIGURE 4: AVERAGE 6 MONTH ADHERENCE METRICS BY CHANNEL FOR TOP RA PRODUCTS

9 http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Specialty%20Pharmaceuticals/Static%20Files/PC_Specialty.pdf

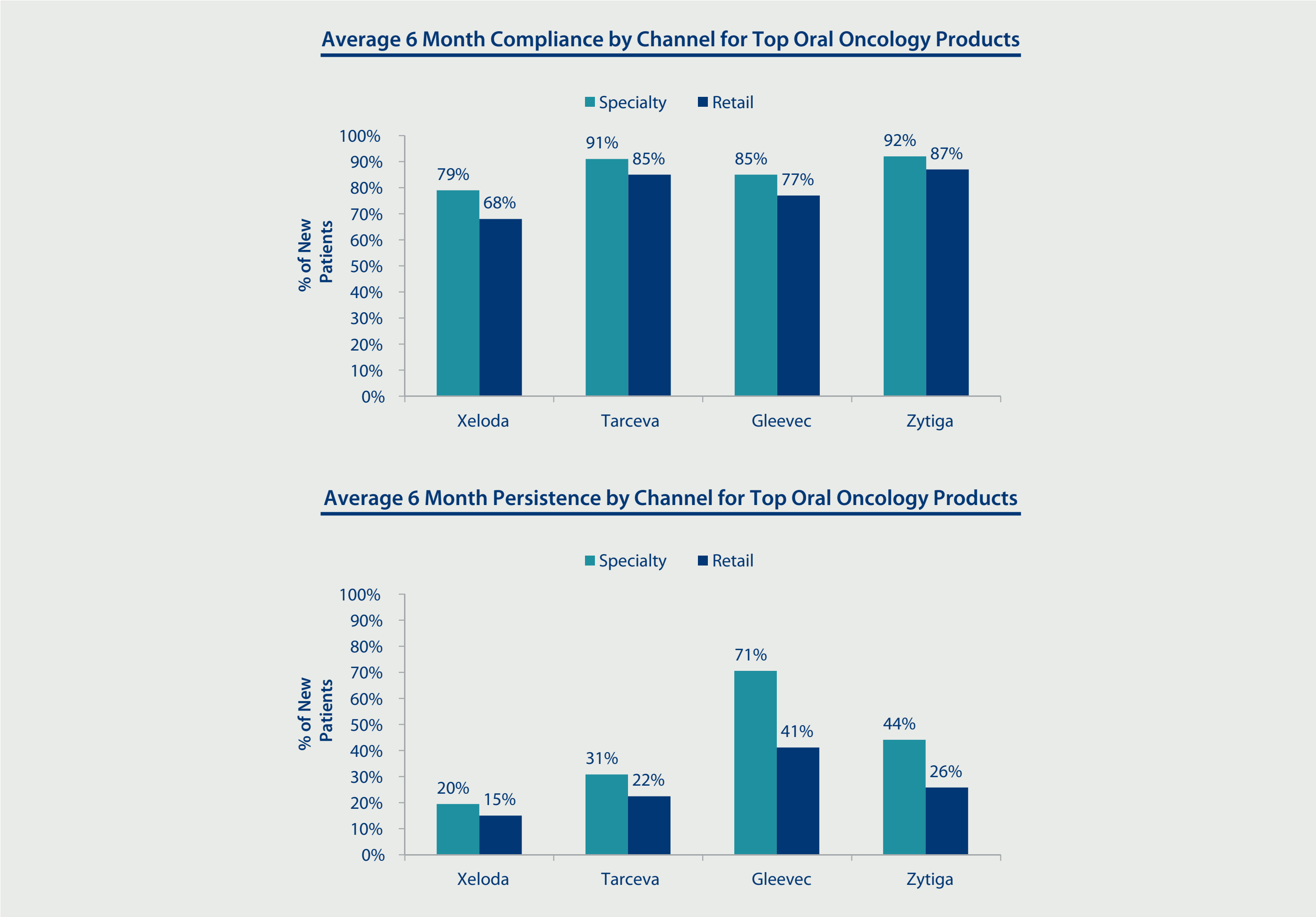


FIGURE 5: AVERAGE 6 MONTH ADHERENCE METRICS BY CHANNEL FOR TOP ORAL ONCOLOGY PRODUCTS

## Implications for Payers and PBMs

Payers and pharmacy benefit managers (PBMs) are actively looking to manage this class of drugs in order to deal with the increasing specialty drug trend. As a result, they are increasingly employing utilization management programs such as prior authorizations for high-cost, provider-administered injectables and are now starting to drive utilization toward preferred formulary agents through this process. PBMs such as Catamaran and Humana's PBM are involved in novel tactics to control spending. These include specialty pharmacy point-of-sale interventions such as dose optimization and management, patient assessments before refilling the drug, and programs aimed at improving patient adherence as a way to contain costs.

Health plans are also growing their involvement in the delivery of specialty pharmacy services as they strive to control rising costs. A majority of plans today rely on their specialty pharmacy provider to improve adherence through increased patient touchpoints. However, research suggests that the growing number of plans that actually utilize their internal staff to manage adherence find this strategy most effective. Currently, most of the smaller health plans are not staffed sufficiently to manage this process in-house and therefore are expected to continue delegating this responsibility to their specialty pharmacy provider or case/disease management vendors. In contrast, larger plans with strong ties in their local markets are expected to increasingly perform utilization management, disease management, and patient coaching and counseling services on their own[10], while still continuing to contract with specialty pharmacies for drug distribution.

The use of specialty pharmacy as a distribution channel offers another area for payer cost management. This channel is often cost effective for payers when compared to the higher reimbursement rates that are generally incurred through a hospital, outpatient or other provider channels. In many cases, health plans may establish a narrow pharmacy network where a patient is required to obtain specialty drugs from a limited network of specialty pharmacies. This strategy allows payers to gain economies of scale and concentrate purchasing power. These limited networks also may be able to improve the ability of health plans to implement care protocols, improve adherence, avoid product waste, and implement FDA-required use plans[11].

10 http://www.managedcaremag.com/archives/1205/1205.sp_trends.html
11 http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=103

However, these efforts to limit specialty drug distribution conflict with the interest of retail pharmacists and physician business models built in part on the revenue from administering specialty drugs. Some states do not permit health plans to mandate the use of narrow pharmacy networks. In these states the payer must allow all providers that are willing to accept the network rate and compliant with network performance requirements into their network. As a result, a recent study suggests that only 66% of commercial and Medicaid plans mandate the use of specialty pharmacy providers for self-administered specialty drugs. The study results also reveal that 30% of commercial plans do not mandate the use of specialty pharmacy providers but charge a higher cost share when members use a non-network provider[12]. These plans may also use incentives such as direct billing and lower prices to drive patients to their preferred specialty pharmacy. For physician-infused drugs that are covered under the medical benefit the mandatory use of specialty pharmacy providers is much less common. However, payers and PBMs are also exploring ways to move specialty products from the medical benefit where drug costs may be bundled in with other services to the relatively transparent pharmacy benefit where they can more directly influence pricing and gain information on use and outcomes.

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