

## The Path to “Economic Value” in Specialty-Patient Care

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### Specialty Products: New World Order

Drug approvals over the past decade have shifted from the treatment of common health issues—such as diabetes, hypertension, and lipid management—toward more rare disease states with smaller patient populations. A key driver of this shift has been the successful challenge, or expiration, of patents, which has facilitated the availability of quality generics to treat most common health issues.

Markets and managed care organizations have played a very strong role in shifting utilization from branded products to generics, where those alternatives are available to community pharmacies that are dispensing more than 90% of their prescriptions using multisource products. A manufacturer can spend hundreds of millions of dollars to launch a new product, only to find that the market may not support it—for example, the recent approvals of PCSK9 inhibitors.

Purposeful hurdles have been established by payers to ensure appropriate utilization after more traditional therapies and measures have failed to reach the desired end points. Because of this shift, the research and development efforts of manufacturers have, by and large, focused on what the market refers to as specialty products.

In 2016, the FDA approved 22 new molecular entities, all of which clearly fit the definition of specialty products: they are distributed through limited access; require special handling, distribution, and/or administration; are included in the FDA-mandated Risk Evaluation Mitigation Strategy program; are high in cost; and have complicated regimens with critical and proactive adverse effect management.

As we move closer to the end of 2017, these trends continue to play out. President Donald Trump has made it very clear to the FDA that the previous administration overregulated the approval process, and the need for new specialized therapies is essential. As such, we

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anticipate a significant expansion of specialty products that will require the oversight and a partnership between specialty pharmacy and managed care to truly balance the scale between cost and improved patient outcomes.

### Pharmacy Economics 101

The economics of pharmacy have always been tied to providing a commodity to a patient at a price dictated by the cost of the product established by the manufacturer. Because most products are dispensed in the retail setting, any professional services provided by the community pharmacy were integrated into the price paid, either by the payer or the patient with co-pays, or both. Community pharmacy has been working hard as of late to establish provider status for pharmacists to help separate the distribution and dispensing elements from the service elements. That is the hope.

Clearly, over the past several decades, pharmacy education has evolved and pharmacists have received a predominance of clinical education to the point where they currently play a key role on the healthcare team, with a focus on product selection, optimization, and patient outcomes. This certainly has become true in the specialty pharmacy space. However, this evolution has not been followed by the economics.

The convergence of higher-cost products, changes in our healthcare system under the Affordable Care Act, and better coordination of care have not necessarily resulted in specialty pharmacy services getting compensated for their value. There are only so many dollars to go around, including the patient shouldering more of a cost burden. Specialty is making progress, however, but it will still take hard evidence to demonstrate the incremental value that is being provided by enhanced services in the business and profession.

Even with specialty pharmacy, the bulk of the bottom line is driven by reimbursement focused on the average wholesale price or wholesale acquisition price. There are exceptions, driven primarily by specialty pharmacies that have agreements with payers or pharmacies owned by payers and/or manufacturers. In exchange for providing focused professional services, supply chain management, and data, some specialty pharmacies can supplement their revenues. Most pharmacies that may dispense a specialty product do not have service or direct distribution agreements in place with manufacturers. Arm yourself with the information our authors have diligently provided you.

### “Show Me the Money”

There are a good number of tactics being implemented in the market place, including value-based contracting (VBC). VBC involves payment, or reimbursement, based on indicators of value, such as patient health outcomes, efficiency, and quality. This is distinct from volume- or fee-for-service–based contracting, which involves payment for every unit of service delivered, often without terms related to outcomes, quality, or cost performance. Specialty must, therefore, objectively demonstrate what incremental value it brings toward optimizing patient outcomes.

Each therapeutic class or disease state presents itself with potential measures. Those measures can be based on multiple factors, including quality, cure, outcomes, adherence, cost, and potentially so many more. Often, the measures can be subjective based on how the patient feels. Objective measures, however, are best when designing a VBC initiative. Specialty pharmacy can be the focal point of data convergence and in the case of specialty products,

interpretation and action taken in the care and management of pharmaceutical care with multiple payers.

### AJPB®: Supplying Specialty With Tools

In this month’s edition of *The American Journal of Pharmacy Benefits*® (AJPB®), our authors have included several studies, the results of which demonstrate the hard costs and value that specialty pharmacy brings to the market around many therapeutic categories. Machaon Bonafede, PhD, MPH, and his team have researched the compliance and cost of biologic therapies for rheumatoid arthritis (RA) and clearly demonstrated the economic value provided through patient and provider education. The value of these services has been quantified and is remarkable, especially considering the cost, not only of products that treat RA, but also in treating these patients in general. Adherence to therapy is a key cornerstone provided by specialty and a basis of demonstrable value.

The results of this study show that across all index medication cohorts, compliant patients had consistently lower all-cause nonbiologic healthcare costs compared with noncompliant patients. Medication cost represents a large component of healthcare cost among patients with RA. Intuitively, although increasing compliance would increase their medication costs, understanding whether there may be a reduction in other healthcare costs due to improved outcomes is important to the overall care of the patient. Showing that improved compliance with biologics for RA reduces other healthcare costs can help a health plan justify new programs to boost compliance and patient outcomes.

We invite our readers to closely review the methodologies used in studies, such as those contained in our current and past editions of AJPB®. They are resources that may be deployed in your efforts to demonstrate value across the spectrum of stakeholders. VBC will be more than a passing fad, as more products, more patients, previously untreatable diseases, and few dollars will demand that value be provided. The trends will continue around separating the cost of the product for specialty services to demonstrating the value of those services.

### AJPB® Is Evolving and We Invite You to Participate: Call for Papers

As we continue to refine AJPB®, we would like to reach out to our readers and request your contribution to sharing your experiences in our publication, your publication. We will continue to provide you with peer-reviewed articles, but in addition, we are expanding our focus to include the application of strategies and tactics in the areas of product access, reimbursement, services involving specialty »

products, specialty pharmacy, providers, and pharma. We are seeking a balanced approach to our publication and contributions from professionals from the payer and managed markets sector. Below are some suggested topics. If you are interested, please reach out to us:

- ◆ Payer perspective: new products, innovation, or market share?
- ◆ Formularies for specialty and the expansion of therapy choices
- ◆ Payer perspective: gain clarity on the current state and direction of the healthcare landscape
- ◆ Health plan dynamics and utilization management strategies
- ◆ VBC
- ◆ Coverage decision making in a value-based landscape
- ◆ Techniques in gaining reimbursement, a payer's perspective

*AJPB*<sup>®</sup> is committed to providing you both peer-written and -reviewed articles focused on the “real world” of managed markets and specialty pharmacy practice. We invite you to enjoy this issue and pass it on! We welcome

your feedback on this topic and on any topics you would like us to cover in future editions of *AJPB*<sup>®</sup>. Please reach out to us at [dsteiber@specialtypharmacytimes.com](mailto:dsteiber@specialtypharmacytimes.com) or [djames@specialtypharmacytimes.com](mailto:djames@specialtypharmacytimes.com), and we also encourage you and your colleagues to subscribe to this unique journal by logging on to [www.ajpb.com](http://www.ajpb.com). 

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