

What is a Specialty Drug?

pecialty drugs are used to treat complex and chronic conditions. Though there is no standard definition, there are two main considerations for determining whether a product is a specialty medication: **complexity** and **cost**.

- **Complexity** may be specific to the handling or administration of the product itself, such as an injectable for the management of psoriasis; it may also be due to the complexities of managing the disease state, such as an oral oncolytic with specific monitoring parameters.
- High cost of most specialty products is in part due to the complexities of manufacturing the
 product. For instance, some specialty products are biologics which are manufactured or
 synthesized from a biological source. These specialty products may require cold chain
 management and subcutaneous administration. As a result, patients who are utilizing specialty
 medications also require a higher level of clinical management and specific drug and disease
 support services.

What is a Specialty Pharmacy?

Just as there is no widely accepted definition of a specialty drug, there is also no universal definition of specialty pharmacy. Any pharmacy can be considered a "specialty pharmacy" if they focus on dispensing specialty products and are covered under a patient's pharmacy benefit plan.

In 2016, the National Association of Specialty Pharmacy (NASP), a major association representing Independent Specialty Pharmacies, defined a specialty pharmacy as the following:

"A specialty pharmacy is a state licensed pharmacy that solely or largely provides only medications for people with serious health conditions requiring complex therapies. These include conditions such as cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, and hemophilia and other bleeding disorders. In addition to being state-licensed and regulated, specialty pharmacies should be accredited by independent third parties such as Utilization Review Accreditation Commission (URAC), the Accreditation Commission for health Care (ACHC), the Center for Pharmacy Proactive Accreditation (CPPA) or the Joint Commission, in order to ensure consistent quality of care."

What Types of Specialty Pharmacies Exist?

Numerous types of specialty pharmacies exist in the market today, including: Pharmacy Benefit Manager (PBM) owned, independent, wholesaler owned, retail chain, physician practice, and hospital system specialty pharmacies.

- PBM-owned are the largest group of specialty pharmacies and dominate the market due to their ability to manage their network strategy by requiring patients to utilize their in-house specialty pharmacies.
- Independent pharmacies do not have one specific payer funneling prescriptions to them. They must sell their services by proactively messaging to physicians. Many independent pharmacies will advocate that they will do everything in their power, including transferring a prescription to a competing pharmacy if mandated by the insurance, to ensure that patients receive the prescribed product.

What Differentiates One Specialty Pharmacy from Another?

As physicians receive multiple messages from different specialty pharmacies, it is important for specialty pharmacies to differentiate themselves in order to increase business with a physician or a manufacturer. One way they do this is through **enhanced services**.

Many of the enhanced services that a specialty pharmacy can provide to patients are based on a fee for service contract with a manufacturer; in these types of agreements, a specialty pharmacy will

perform a service, on behalf of the manufacturer, that goes above and beyond what they normally would perform.

- For example, if a product requires therapeutic drug monitoring during treatment, the specialty pharmacy could proactively reach out to the patient to remind or confirm if a lab test has been scheduled. The manufacturer will compensate a specialty pharmacy for performing this added service that ultimately enhances the care of patients who are taking their product.
- With the number of specialty pharmacies competing to fill specialty products continually increasing, these types of customized fee for service programs continue to grow and act as a main differentiator for specialty pharmacies.

What Does the Future Look Like?

As products become more complex and specialized, manufacturers feel continued pressure to provide patients with the most innovative patient-centric care. Specialty pharmacies have proven that they may be the most efficient conduit to provide specialized care to patients. With innovation being the main differentiator between specialty pharmacies, there may be one company who has tapped into the market at the perfect time: Amazon.com.

In June 2018, Amazon set the stage by acquiring PillPack, a small mail-order pharmacy. With Amazon already a leader in advanced technology, consumer-centric platforms, and digital distributions, could this be their entrance into specialty pharmacy?

This is already a crowded marketplace, which gives Amazon many barriers to overcome. Amazon Alexa, their virtual assistant capable of voice interaction, music playback, and reporting other real-time information, has the capability to disrupt this marketplace. Through Alexa, Amazon can leverage their access to patients at the patients' most convenient time and place, allowing them to deliver disease management services unlike current specialty pharmacies. With access to patient's Amazon accounts and purchase history, Amazon will also be able to capture infinite amounts of data to track patients' overall activity and health trends.

If Amazon decides that they want to compete in this space, the biggest hurdle they will have to overcome (in my opinion) is payer contracting. Even though Amazon may have access to patients, the specialty channel is more complex than simply ensuring distribution. Amazon will have to fight to be part of payers' preferred networks unless they decide that their next purchase is a PBM.

With disease management continuing to grow more complex, and with new entrants coming into the market, specialty pharmacies will be expected to adapt and take more of a role in patient management and care coordination, through continued innovation.

References available upon request.