

# Emerging Trends in the Specialty Drug Market



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As the specialty drug market continues to evolve and grow, it is important to understand the opportunities and challenges that lie ahead for your alternate site pharmacy. Having the right resources and infrastructure in place can help you demonstrate value to facilities and manufacturers, but more importantly, allow you to offer patients the life-changing medications that they need. In fact, current McKesson U.S. Pharma alternate site and health systems customers can access a host of specialty products and services through our regular U.S. wholesale channel and the Plasma and Biologics division. Email [mpb@mckesson.com](mailto:mpb@mckesson.com) to learn more.

## What is driving the growth in the specialty drug market?

According to IMS Health, the specialty drug market grew by nearly 27% in 2014.<sup>1</sup> Hepatitis C, cancer and multiple sclerosis classes of specialty drugs led with the highest total dollar of sales.<sup>1</sup> For the long-term care segment, this translated into a 289% increase in the use of drugs to treat hepatitis C. This was partly due to the introduction of Sovaldi®, Harvoni® and Olysio®. The 2015 MHA Independent Long Term Care Study also found that utilization of anti-tumor necrosis factor drugs to treat conditions like rheumatoid arthritis grew by 29%, while the use of drugs to treat multiple sclerosis including Copaxone®, Rebif® and Extavia® grew by 27%.<sup>2</sup> By 2018, specialty drugs are expected to make up 50% of overall drug costs.<sup>3</sup>

Below is an overview of some of the key factors and emerging trends that are fueling the growth of this niche market.

- **Personalized medicine** — Growing interest in personalized or “precision” medicine, which is tailored to a person’s genomic makeup to help predict, diagnose and treat diseases, is leading to new investments in this segment.<sup>4</sup>
- **More insured patients** — Health reform, including the expansion of Medicaid, has given more patients access to healthcare than ever before.

- **Prevalence of complex, chronic conditions** — Increasingly, patients are facing more than one chronic disease, requiring them to take multiple medications. For many, the latest treatments include specialty drugs.
- **Government incentives** — For decades, the FDA has offered incentives — such as fewer barriers to approval and extended patent protections for orphan drugs — to encourage pharmaceutical manufacturers to find treatments for rare genetic diseases. And recently, the FDA developed breakthrough therapy and fast-track designation programs to help speed up the development of drugs to treat what are considered serious or life-threatening conditions.<sup>5</sup>

## Specialty drugs must meet 4 out of 7 criteria and treat a chronic, complex condition:

1. Treatment initiated by a specialist
2. Generally not taken orally
3. Requires special handling
4. Limited distribution
5. Very expensive
6. Requires extensive patient counseling/follow-up
7. Patients may need reimbursement assistance

Source: IMS Health

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- **Price** — A lack of generic alternatives, along with the high cost to research and develop these breakthrough drugs, often plays into their \$6,000- to \$750,000-a-year price tag.<sup>6</sup> Special handling, clinical support, and risk evaluation and mitigation strategy (REMS) programs also impact the steep price for these drugs. Recently, however, payers and pharmacy benefit managers have started to push back on the prices. In the future, expansion of biosimilars may also help drive down prices.

#### **How can your pharmacy gain access to specialty drugs?**

To help your alternate site pharmacy gain or improve access to specialty drugs, your organization needs to be relevant to payers and specialty drug manufacturers. One way to accomplish this is by demonstrating the value that your organization can bring to preferred dispensing networks. Below are some other best practices to consider.

- **Think like a specialty pharmacy** — To help retain scripts and grow your business, consider implementing clinical support programs in niche specialty therapeutic areas. Not only will these and other similar services give your pharmacists an opportunity to expand their roles in patient management, but they will also help differentiate your business from the competition.
- **Facilitate financial assistance for patients** — High out-of-pocket costs for specialty drugs can deter patients from filling their prescriptions. By identifying patient assistance programs like co-pay foundations and drug coupon programs, you can help patients afford their treatments and improve adherence and compliance with medication regimens.<sup>7</sup>
- **Demonstrate therapeutic expertise and improved outcomes** — As we continue to move toward a performance-based reimbursement model, payers and manufacturers expect clinicians to help improve outcomes and contain costs. This involves active management of drug therapy including following up with patients to increase prescription adherence and monitoring for side effects. It also includes ensuring proper dosing and utilization to help curb waste.

#### **Other considerations for dispensing specialty drugs include:**

- Determine what disease states you will support by evaluating patient demographics in surrounding communities and your areas of expertise.
- How will you ensure a referral base? Consider the sales and marketing investment that may be necessary to build a steady patient stream.
- Research the requirements to dispense specialty products, as determined by manufacturers, PBMs and/or payers.
- Evaluate whether your current pharmacy software system will support specialty drugs and services.
- Determine what investments may be necessary to store, handle and ship specialty products to patients.
- Understand the steps and investment required to become properly credentialed and to establish a sterile pharmacy that meets all regulations.
- Consider joining a Group Purchasing Organization (GPO) that specializes in providing specialty contracts and support.

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*Email [mpb@mckesson.com](mailto:mpb@mckesson.com) to learn more about specialty drugs and access through your current U.S. Wholesale and Plasma and Biologics contract relationship. You can also email the McKesson Alternate Site Pharmacy<sup>SM</sup> team directly, at [alternatesite@mckesson.com](mailto:alternatesite@mckesson.com).*

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### Where to find additional information

Even though there is no single definition of specialty, one thing is clear: The future of specialty drugs to treat complex, chronic conditions like HIV, cancer and rheumatoid arthritis will continue to grow as patients seek targeted treatments for their diseases. To learn more about this ever-evolving industry, please visit the following resources:

- [American Society for Health-System Pharmacists](#)
- [National Association of Specialty Pharmacy](#)
- [Joint Commission on Accreditation of Healthcare Organizations](#)
- [Community Health Accreditation Partner](#)
- [URAC Accreditation Organization](#)

### Sources:

<sup>1</sup> [Medicine Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014](#), IMS Institute for Healthcare Informatics, April 2015

<sup>2</sup> [MHA Independent Long Term Care Member Study](#), Managed Healthcare Associates, 2015

<sup>3</sup> [Specialty Drugs Will Account for 50% of All Drug Costs by 2018](#), *Formulary Watch*, June 1, 2013

<sup>4</sup> [Overview of the Specialty Drug Trend: Succeeding in the Rapidly Expanding U.S. Specialty Market](#), IMS Health, 2014

<sup>5</sup> [Frequently Asked Questions: Breakthrough Therapies](#), Food and Drug Administration, Accessed May 1, 2015

<sup>6</sup> [Changing the Channel: Developments in the U.S. Specialty Pharmaceutical Distribution](#), IMS Health, 2009

<sup>7</sup> [Specialty Drugs Driving Pharmacy Benefit Costs](#), Society for Human Resource Management, April 4, 2011

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ASRX-09343-06-15

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