



SPECIALTY PHARMACIES

Offering Patients Safety, Expertise, and Access

High priced drugs account for majority of growth in total drug expenditures in the U.S. and have disproportionately increased out of pocket costs for a relatively small group of very sick patients. These high-cost medications are typically specialty drugs and the pace of new specialty drugs becoming available is placing strain on the budgets of families, employers and government programs like Medicaid and Medicare.

What is a specialty drug?

Specialty drugs are costly medications that require special storage and handling and high-touch patient management to ensure effectiveness. Specialty medications represent 3% of all prescriptions in the U.S., but they account for nearly 40% of total pharmacy costs. Many specialty drugs have a narrow therapeutic index (NTI) which, **according to the FDA**, means that a mistake in dosage could result in permanent disability or even be life threatening.

High Risk and High Reward

Specialty drugs come with great potential but also carry great risk to patients. Consider the specialty drug Kalydeco®. Kalydeco is used to treat cystic fibrosis – a chronic genetic disease that impairs lung function and typically presents itself at birth. A child born with cystic fibrosis has a life expectancy of 37 years.

Kalydeco is the first therapy to treat the underlying cause of cystic fibrosis rather than the symptoms, dramatically improving lung function for children with this disease. As such, this innovative therapy has a list price of over \$300,000 per year.

While Kalydeco has the ability to greatly improve a patient's quality of life, it has a number of risks as it only works for a specific genotype. The exact prescribed dose of Kalydeco is unique to each individual patient. Patients prescribed Kalydeco must have a blood test prior to treatment and be continuously monitored for the presence of enzymes that may harm the liver.

When Kalydeco interacts with certain drugs or certain types of food, such as Seville oranges, a patient's body does not appropriately process the drug into the bloodstream, risking long-term liver damage. Pharmacists must be diligent in their review of other drugs taken by a patient prescribed Kalydeco as certain drugs can affect how Kalydeco is absorbed in the bloodstream potentially increasing its toxicity to dangerous levels.

Given the risk to patients and the need that each dosage of Kalydeco be uniquely tailored to an individual patient, pharmacists need a specialized set of skills to actively monitor for side effects and provide the type of care required to minimize the risk of harm to the patient and maximize the drug's effectiveness.

The Role of Specialty Pharmacy

In order to protect patients, the dispensing of specialty drugs like Kalydeco is limited to a specialty pharmacy by pharmaceutical manufacturers, health plans and their pharmacy benefit managers.

A specialty pharmacy is a licensed pharmacy and provides more advanced services than those available at a traditional pharmacy. Staff at a specialty pharmacy are uniquely trained to handle, dispense, and manage patients prescribed specialty drugs. Specialty pharmacies also have operations uniquely designed to meet the special requirements of these drugs and track the outcomes of their patients.

Access to high-cost specialty drugs via unprepared pharmacies can place patients in harm's way. Specialty pharmacies are leading efforts in their communities across the country to increase patient access to specialty drugs in high-quality, safe environments.

URAC is the nation's leading accreditor of specialty pharmacies. To learn more, please visit: https://hubs.ly/H0hS4_g0

About URAC®

Founded in 1990, URAC is the independent leader in promoting healthcare quality through leadership, accreditation, measurement and innovation. URAC is a nonprofit organization using evidence-based measures and developing standards through inclusive engagement with a range of stakeholders committed to improving the quality of healthcare.

Our portfolio of accreditation and certification programs span the healthcare industry, addressing healthcare management, healthcare operations, health plans, pharmacies, telehealth providers, physician practices, and more. URAC accreditation is a symbol of excellence for organizations to showcase their validated commitment to quality and accountability. Learn about URAC accreditation at urac.org.