Specialty Pharmacies and Delivery Models

The words "specialty pharmacy" can incite a range of emotions and opinions among healthcare practitioners. The specialty medications these pharmacies provide are expected to continue to be the biggest driver of branded drug spending. (This will also be true of biosimilars once they reach the U.S. market.) A recent report by the IMS Institute for Healthcare Informatics, titled *Medicine Use and Shifting Costs of Healthcare*, notes that specialty drugs represented 29 percent of spending on medicines in 2013 (up from 23 percent in 2008), averaged 10 percent growth in the last five years and grew by 9 percent in 2013. In addition, spending on biologics rose 9.6 percent in 2013, representing 28 percent of the total, which was up from 21 percent in 2008. Specialty therapies play a very important role in oncology, asthma, chronic obstructive pulmonary disease, cystic fibrosis, HIV, other viral diseases including hepatitis C, rheumatoid arthritis, and conditions treated with immunostimulants, immunosuppressants and interferons. Although these chronic conditions can sometimes be treated with oral or self-administered specialty medications, some of these products are injectable and need to be administered in infusion centers.

Shifting Benefit Design

Specialty medicines are currently paid for under Medicare Parts B and D.

Part B drugs are tied to physician services and fall under the medical benefit. They're usually injectables furnished incidental to a physician's service and not usually self-administered. Part D drugs generally are prescription drugs prescribed and dispensed for self-administration, but they also include biological products; insulin and medical supplies associated with insulin injection; and certain vaccines not covered under Medicare Parts A or B.

A growing trend is to move expensive specialty drugs out of the medical benefit and into the drug benefit. The next steps often are to move these into new payment tiers and place them under the control of specialty pharmacies.

What Is a Specialty Pharmacy?

A specialty pharmacy is a pharmacy service model that provides patient-focused care to optimize outcomes of specialty drugs for chronic and low-incidence medical conditions. It integrates medication management and clinical and fulfillment functions with disease management principles and practices. And, it provides a framework to manage medication necessity, efficacy, cost and the pipeline. Proponents say a specialty pharmacy is designed to help ensure appropriate medication use, help avoid unwarranted drug expenditure and optimize adherence to medication therapy.

Medicare Part D defines "specialty" as any drug with a negotiated monthly price of $600 or more, whereas the Academy of Managed Care Pharmacy defines it using a commercial payer's threshold of $1,200 per month or more. Typically, specialty biologic- or biotech-based formulations that may require additional supervision, monitoring and handling are those that are oral, injectable, infused or inhaled. These products can be administered at home, in a physician office, infusion center or outpatient hospital area.

In addition to the high cost of specialty pharmaceutical products, the delivery model — the way the drugs are handled, acquired and distributed — as well as the restrictions being placed on them by payers, often differs from the traditional model. The traditional model, which is the normal open-distribution model, allows product to be available from regular/routine drug wholesalers with wide distribution. The manufacturer bears the cost of increased inventory, outdated merchandise, frequent returns and special packaging, shipping or storage. But, with the restricted drug distribution system (RDDS) model by which specialty drugs are often delivered, the costs of inventory are reduced, and outdated merchandise and frequent returns are eliminated. In addition, specialty pharmacies provide special packaging, shipping and storage to preserve and deliver these delicate medicines in high-tech, cold-chain and just-in-time delivery systems.

The healthcare setting is a complex environment in which patients are being seen and treated in a multiplicity of outpatient clinics and treatment sites — all designed to keep the patient ambulatory and to avoid hospitalization unless absolutely necessary. That has spurred the growth of the specialty pharmacy industry, which is governed by the same regulations as distributors that follow the traditional delivery model. The specialty pharmacy industry has created an entirely new dimension in the procurement and distribution of specialty pharmaceuticals whose costs are staggering compared with traditional medications used at home. The RDDS model, with its potential for better therapy efficacy, safety and convenience of administration, justifies the extra distribution cost of specialty medicines that often present logistical and financial challenges to the healthcare facility or practice that struggles with issues of patient safety, institutional liability and reimbursement.

Making It Work

Moving to a new healthcare delivery model has accelerated the need for change, cooperation and coordination between sites of care. So, what are some options to help practitioners and pharmacists manage this change? White or brown bagging.

White bagging is the practice of having patient-specific medications or supplies delivered directly to the practice setting. That setting may be an outpatient infusion center, a physician's office or a hospital, but the common link is that the drug is intended for use by a specific patient and must be stored and used only for that patient. Discontinued medications are not returnable, cannot be used for another patient and must be destroyed at the expense of the site. As the medications may be prepaid or complimentary, no billing for these products/supplies transpires. However, billing for the clinic visit where the drugs are administered and for the drug administration itself still brings income to the facility or practice site. Brown bagging is essentially the same as white bagging with the exception of the delivery location. Medications are delivered to the patient's home, and the patient brings the medication with him or her to the appointment for administration.

For white bagging, the Centers for Medicare and Medicaid Services (CMS) has specific requirements for how this transpires. Thus, following the guidelines determined by the Medicare administrative contractor or fiscal intermediary is essential. Basically, the drug is billed at a zero charge to indicate that it was given; this, then, allows the drug administration fee to be processed. Maximum payments depend on the reimbursement team understanding the nuances of proper coding for these drugs. One key point to remember: Common procedural terminology (CPT) codes are used to describe and bill for services/tasks performed, while Healthcare Common Procedure Coding System codes are used to describe and bill for drugs and other items. There are no fewer than 40 CPT codes that are used to bill for drug administration. Some are specific to the type of drug administered, with more complex administrations receiving considerably higher reimbursement. Both private payers and Medicare reimburse for drug administration using these codes. Therefore, it's important to look at the CPT definition of drug administration, which includes the use of local anesthesia; starting the IV; access to IV, catheter or port; routine tubing, syringe and supplies; preparation of the drug; flushing catheters at completion; and hydration fluid.

In the case of brown bagging, CMS is not as clear. CMS acknowledges that medical societies are opposed to brown bagging and "continues to urge them to reinforce this message with their members."[1] Part D plan sponsors may contractually specify medications are only covered when administered in the home setting. Billing for administration of medications provided under brown bagging would follow the same approach as white bagging.

Changing Perceptions

Perhaps the most difficult part of implementing a white-bagging or brown-bagging program for specialty pharmaceuticals at a facility is to understand how well and easily this process works. A facility or practice can generate revenue by handling these drugs, and concerns about product integrity and storage can be allayed by understanding the process. White-bag medications are sent directly from the specialty pharmacy to the hospital or other practice site, and the drugs are sent in their original packaging with appropriate shipping, packaging and usually insurance due to their high cost. This is similar to patient-assistance drugs or routine wholesaler shipments; the drugs do not go to the patient. Brown-bag medications are delivered to the patient and may or may not be in their original packaging. Concerns about product storage are significantly different than with white bagging, but can be overcome by working with specialty pharmacies accredited by The Joint Commission, Accreditation Commission for Health Care, Community Health Accreditation Program or Utilization Review Accreditation, which require validation of delivery processes.

With today's evolving healthcare delivery models, healthcare providers should develop an organized, careful multidisciplinary approach that supports the use of pre-paid or complimentary specialty medications. To achieve success, they should comprehensively assess how these models work with their practice, and ensure staff understand the billing methodology. ❖

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Reference

1. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements – Appendix C Medicare Part B versus Part D Coverage Issues.

Ask Our Experts

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Editor's Note: The content of this column is intended to provide a general guide to the subject matter. Specialist advice should be sought about your specific circumstances.