Kudos to our colleagues at EMD Serono for the publication of the 9th edition of the EMD Serono Specialty Digest.1 If you are not familiar with this annual survey, you ought to be, as it highlights managed care strategies for specialty pharmaceuticals and is an outstanding source of data. Let me highlight some of the recent findings from the 2013 edition of the report.

First of all, EMD Serono does it right. Their team has assembled a diverse external advisory board that comprises pharmacists, physicians, and other specialty pharmacy experts, and they use a well-known external survey company for the data collection. Drawing on results from more than 100 health plans across the country representing more than 100 million covered lives, I am confident that the results are not only valid but also broadly applicable.

What do we actually mean by a “specialty pharmaceutical”? Once again, EMD Serono embraces the Academy of Managed Care Pharmacy format for formulary submissions, Version 3.1, whereby a product can be classified as a specialty pharmaceutical “if it includes either of these two requirements: difficult or unusual process or delivery or requires patient management.”1

Although specialty drugs have become the standard of care for many complex diseases, they may be administered by various routes, including oral, injection, and infusion. Sometimes, the administration of the medication requires the expertise of a healthcare provider.

Unlike traditional oral agents, however, these specialty drugs may be covered under the pharmacy benefit or under the medical benefit, and they may be distributed or administered to the patient from various sites, including a retail pharmacy, a specialty pharmacy, a physician’s office, an outpatient hospital facility, or a home infusion company.

One take-home message from this 2013 survey is that more than 50% of the commercial plans participating in this survey now have unique cost-sharing tiers for specialty drugs, unlike non-specialty drugs. Among plans that utilize a unique specialty drug cost-sharing, 67% use a single tier, which represents 55% of all covered lives in the United States. Multitier cost-sharing is used by 33% of health plans, representing 45% of the covered lives.1

Not surprisingly, more than 90% of the plans surveyed require prior authorization for specialty pharmaceuticals. Nearly 15% of the plans, for example, provide oncologists with an electronic prior authorization system through a specially designed secure web portal.1

I have also learned by reading this report that provider reimbursement for specialty pharmaceuticals continues to evolve. Because specialty drugs are distributed through a number of different care providers, depending on the specific drug, there are multiple programs, almost on a specialty-specific basis. For example, the actual reimbursement rate to each provider is determined by the health plan itself and can be based on the average wholesale price (AWP) plus or minus a discount, the average sales price plus a percentage, or the wholesale acquisition cost plus or minus a percentage. The reimbursement methodology is also influenced by the type of provider and the site of care. This is especially true when comparing oncologists with other clinical care providers. According to the report, specialty pharmacies receive the lowest AWP-based reimbursement, and oncologists receive the highest AWP-based reimbursement.1

More than 60% of the plans noted that they, currently or in the near future, intend to implement a preferred infusion network. What is evolving here is the further stratification among provider groups that can confer high value to this system. If your infusion center does a good job, makes very few errors, and has high patient satisfaction scores, you will no doubt get a bonus payment from these manufacturers. Under health reform, we will likely see an explosion in these types of targeted and customized reimbursement schemes.

I was fascinated to learn that half of all surveyed health plans restrict the use of drugs based on certain companion diagnostic test results. “Recently, several oncology drugs have been approved with a label stating that an FDA-approved test must be used to detect the related genetic mutation. Survey results indicate that 40% of plans currently allow use of the CLIA [Clinical Laboratory Improvement Amendments] lab developed test, while 26% of plans require a use of the specific test as indicated in the FDA label for a drug.”1

**Specialty Pharmaceuticals Update**

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One aspect of this survey that continues to perplex me is the creation of specialty pharmacy provider networks. Apparently it works this way: “For specialty drugs covered under the medical benefit, health plans may allow medical benefit providers to maintain their own drug inventory and bill the health plan at their contracted rate (commonly referred to as ‘buy and bill’) or, they may require the providers to order the drug from a specialty pharmacy and bill the health plan for their administration and procedural related costs only. In this case the specialty pharmacy bills the health plan and collects any applicable cost share from the patient.”1 This suggests further complexity, opportunity for error, and, of course, an increase in overall costs. Can’t we make this process any simpler?

Because these drugs are uniformly expensive, getting patients to adhere to their drug regimens is more important than ever. “Patients may be faced with a higher financial burden and challenged with the complexity of the disease, alternate weeks of delivery and administration and treatment side effects. Payers cite improving adherence to specialty drugs as a top priority.”1 Yet, according to this recent survey, 70% of health plans say they rely on their specialty pharmacy providers to improve medication adherence. I am confident that this is going to be a battleground for the future. Given how expensive these specialty pharmaceuticals are, how can we better engage with patients across the spectrum of diseases and specialists to improve overall medication adherence?

I hope our readers will carefully study this illuminating survey-based document. It is safe to assume that specialty pharmaceuticals will play an increasingly important role as new discoveries make their way from the bench to the bedside. You can download a copy of this year’s report from www.specialtydigest.emdserono.com (registration required).

As always, I would be interested in your views about this new and important survey. You can reach me at david.nash@jefferson.edu.

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