ADVANCES IN DRUG DEVELOPMENT

Current Developments in Oncology Drug Research

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Novel Approaches to Delivering Value in Oncology Drugs

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H&O What are some of the problems related to reimbursement for cancer drugs in this country?

SM Thanks to highly productive pharmaceutical and biotechnology industries that have developed a tremendous number of new products, we are now able to treat patients with cancer for whom effective treatments previously were not available. The trouble is that the prices of these products, especially when they first come to the marketplace, often are extraordinarily high. This is extremely problematic for payers and patients in the United States. And instead of decreasing over time, prices that are high when the products first come out usually continue to increase year after year. For example, a drug that 10 years ago cost $30,000 can cost more than $100,000 today.

Cancer is one of the fastest-growing areas of pharmacy spending in the United States, and it is also the area with the largest drug pipeline. As the largest pharmacy benefit management (PBM) organization in the United States, Express Scripts has seen its clients' cost of cancer care go up dramatically each year. Cancer drugs are the No. 1 area of concern for plans when it comes to drug coverage.

H&O How are drug prices set?

SM In most cases, the price is based on what the market will bear, with the prices of newer drugs pegged to those of existing products. If a new product is similar to one that is already available, the company will make the price roughly the same. If the product works better than what is available, the company will charge a premium price. The price has very little to do with the costs of research and development (R&D), manufacturing, or marketing.

H&O Without any changes in the way things are done, what do you see the future looking like for oncology drug access?

SM A number of smaller employers might decide to stop providing their employees with health coverage, which will push the employees out to the exchanges. That is not a desirable outcome because most employers like to use good health care benefits to attract the best employees. If employers stop providing health care coverage because of the expense, they have one less tool for recruiting employees. Furthermore, the employees are usually left with a health care plan that is less desirable. We would go from having high levels of adequately covered patients to having more and more underinsured patients, meaning patients with high-deductible plans whose copays are higher than the patients can afford. Even the larger companies that must continue to provide health care coverage would change to plans with higher deductibles and copays, which has already started to happen.

H&O Are high prices needed to support the development of new oncology drugs?

SM We want patients with cancer to have the best clinical outcomes, and we want pharmaceutical manufacturers to continue to do their valuable research. So the model needs to be sustainable, and we need to make sure that access and affordability are there for our patients.

The dynamic between innovation and affordability shifts over time, and right now that dynamic has shifted too much in favor of the pharmaceutical manufacturers. The pharmaceutical and biotechnology companies have

Table. Drugs Whose Cost Could Be Reduced With Biosimilars[a]

bevacizumab (Avastin)
epoetin alfa (Epogen, Procrit)
filgrastim (Neupogen)[b]
infliximab (Remicade)
interferon alfa-2b (Intron A)
pegfilgrastim (Neulasta)
peginterferon alfa-2b (PegIntron)
rituximab (Rituxan)
trastuzumab (Herceptin)

[a] Express Scripts estimates that $250 billion could be saved over the next 10 years if biosimilars for the drugs listed in the table were approved.

[b] The biosimilar filgrastim-sndz (Zarxio) was approved in 2015, which will save an estimated $5.7 billion over 10 years.

Source: Infographic: two biosimilars to save $22.7 billion. Express Scripts. http://lab.express-scripts.com/lab/insights/drug-options/infographic-two-biosimilars-to-save-227-billion. Updated December 4, 2014. Accessed March 11, 2016.

7000 drugs in the pipeline today, but they are also making record profits. We believe that the dynamic has to move back toward affordability, which will lead to greater access.

H&O What are some of the steps your company has taken to promote value in oncology drugs?

SM This year, we came out with our Oncology Care Value Program, which has several components that we think our plan sponsors and patients will appreciate. First, it allows us to move patients effectively from brand name to generic oncology drugs when they are available. Second, we are taking steps to help patients get appropriate biosimilars as they become available. Third, we have added an indication-based reimbursement program.

H&O What does the indication-based reimbursement program entail?

SM This program reimburses for oncology drugs based on value. We have started this as a relatively small program in the first year but will expand it over time. The first 3 cancers to be included are non–small cell lung cancer, renal cancer, and prostate cancer.

What we do is look at the indications for which a drug has been approved and devise a premium for its best indication. We then look at the alternative indications for the drug, for which it may be less beneficial, so that a lower premium is warranted. A mathematical model is used to determine the blended rate: a single premium that incorporates a variety of different values. If the overall value of the drug is relatively low, we request a discounted drug price from the manufacturer before we add it to our formulary. For example, reimbursement for a drug that works very well in lung cancer and only moderately well in pancreatic cancer should be at a weighted rate that reflects both the high-value and lower-value uses and the percentage of patients in each category.

This program is still being rolled out. The historical way to adjudicate claims has been based on the drug, and we have had to change our system to adjudicate claims at the level of the indication. We are currently developing reporting capabilities to show plan sponsors exactly how many patients they have had in each category and what the reimbursement should be. We have the same types of reports for the pharmaceutical manufacturers, so that they can be confident that they are being treated fairly.

If the program works well in 2016, we can expand it to include many more forms of cancer and other conditions as well.

H&O What additional steps are planned for the future?

SM We think that indication-based pricing will be the most effective way to conduct value-based contracting in oncology because it allows patients to have access to the drugs they need, oncologists to have a lot of flexibility, and manufacturers to bring some value-based discounting to the marketplace. We also are very interested in pathways and are working with different plans on their pathways.

In addition, we have been working for years on the problem of medication waste, such as the waste associated with not using an optimal vial size. PBMs historically have processed claims based on National Drug Codes (NDCs), which describe both the type of drug and the amount—so we have always reimbursed based on the correct vial size. The doctor is reimbursed fairly, but there is no profiteering based on the use of inappropriate vial sizes.

The medical insurers, however, have always used Current Procedural Terminology (CPT) J or U codes, which do not include information about vial size, so that creates a lot of waste. As a result, our clients want to incorporate more of the utilization management tools we are using on the PBM side into the medical side, where most oncology spending takes place. In fact, some of our clients are having us take over the prior authorization process from the medical side.

H&O What about cases in which not enough appropriate vial sizes are made?

SM We identified this problem many years ago with the red cell stimulator erythropoietin, and it is becoming an even bigger problem with oncology drugs. We have worked with the US Food and Drug Administration (FDA) and

other regulators for years to encourage the manufacture of more appropriate vial sizes. We think there is a great opportunity to drive out waste there. We are adamant that patients continue to have access to the right therapies, so by going after waste we can afford to treat more patients at a lower cost.

H&O What has been the response from industry to the steps your company has taken?

SM As you can imagine, there is a spectrum of responses across the manufacturers. Some of them love the way the market has been and do not want to see it change. Others have embraced our changes and are fully cooperative. The same is true of different groups of doctors; some are happy with the status quo and others, such as Dr Peter Bach and Dr Leonard Saltz, have been very outspoken critics of the way pricing is done.

H&O What are some of the changes your company has discussed with the FDA?

SM We have been potent advocates of biosimilars in discussions with the FDA because they could make very expensive cancer agents more affordable (Table). We also have been strong advocates for better funding of the FDA so that all drugs can receive the same fast track approval status, which supports healthy competition in the marketplace. Competition is important for driving down prices.

H&O What other steps should be taken to promote value in oncology drugs, apart from what your company has done?

SM Another step that would lead to further advances in oncology is getting more patients to participate in trials. The more knowledge we have about the use of these drugs in various patient populations, the better off everyone will be in the future.

Disclosures

Dr Miller is the senior vice president and chief medical officer of Express Scripts.

Suggested Readings

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